



Office for
Nuclear Regulation

New nuclear reactors: Generic Design Assessment Guidance to Requesting Parties

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Section 1: Introduction

The purpose of this guidance

- 1 This document provides guidance on the Office for Nuclear Regulation's (ONR) Generic Design Assessment (GDA) process for the safety and security assessment of nuclear power stations intended for construction and operation in Great Britain. This process will be applied where ONR is asked to assess a reactor design in advance of an application for a nuclear site licence being made. This document is primarily intended to inform those parties who request such an assessment (the 'Requesting Parties' (RP)). As discussed below, an intending RP must have the endorsement of the UK Government before ONR will consider a request to carry out GDA.
- 2 The objective of this guidance document is to provide RPs with:
 - a description of the safety and security documentation that they should submit to ONR;
 - a clear explanation of what ONR will deliver;
 - indicative timescales for those deliverables; and
 - information on the principles that ONR will apply when judging the adequacy of the safety and security submissions.
- 3 The environmental aspects of the generic design are assessed by the Environment Agency with which ONR works closely in GDA. There is a separate 'top-tier' guide (Ref. 1) which provides an overview of the processes followed by both regulators and how those processes are integrated. The Environment Agency has also published separate guidance to RPs on its GDA process (Ref. 2).

Background

- 4 ONR is the independent regulator of safety and security at nuclear licensed sites in Great Britain. It also regulates radioactive materials transport and ensures that nuclear safeguards obligations for the UK are met. ONR's duty is to ensure that the nuclear industry controls its hazards effectively, has a culture of continuous improvement and maintains high standards.
- 5 In a report to the Government's 2006 Energy Review, ONR concluded that important lessons had been learnt from previous experience with new nuclear power stations. In particular the use of a standardised design, where the design and safety case are well developed much earlier in the project, would facilitate a reduction in both the time for regulatory assessment as well as the regulatory uncertainty for a site licensee wishing to build such a design. Subsequently, at the request of the Government, ONR and the Environment Agency, working together, went on to develop a 'pre-licensing' assessment process which came to be known as GDA.
- 6 The first round of GDA started in 2007 when ONR and the Environment Agency began assessment of four reactor designs. Two of the first round designs were withdrawn by the RPs part way through assessment. The EDF and AREVA UK EPR™ design was taken through to the end of GDA, and in December 2012 ONR issued a Design Acceptance Confirmation (DAC) and the Environment Agency granted a Statement of Design Acceptability (SoDA). The Westinghouse AP1000® assessment was paused at Westinghouse's request after ONR issued an Interim Design Acceptance Confirmation (iDAC) in December 2011; Westinghouse re-entered GDA in 2014 and are currently working towards a DAC. Also, in 2013 ONR and the Environment Agency began GDA of Hitachi-GE's UK-ABWR and that work continues.

- 7 This guidance was first published in 2007 and has been updated and supplemented a number of times. This update draws on the experience gained by ONR with all the designs that have been or are being taken through GDA.

Objectives of the Generic Design Assessment process

- 8 Compared with the previous regulatory approach to proposals for new reactors, GDA is designed to have a number of advantages. For example, it:
- allows ONR to get involved with designers at an early stage, where it can have maximum influence. Design changes required to address regulatory expectations are more easily implemented while the plant is still at the proposals stage rather than when construction has begun, or expensive plant items have been manufactured;
 - is a step-wise process, with the assessment getting increasingly detailed at each step. This allows ONR to identify key design issues early in the process thereby reducing the financial and regulatory risks for developers intending to construct a power station based on the design; and
 - is open and transparent. The public can view design information on the Internet and comment on it. ONR also gives regular feedback on how its assessments are progressing and publishes reports at the end of each step.
- 9 GDA also allows the separation of design issues from specific site related issues, which is likely to be beneficial where the generic design is intended for construction on a number of different sites.
- 10 Other key features of the GDA process are that it:
- gives RPs the opportunity to demonstrate at an early stage that the design is capable of meeting the legal requirements of Great Britain;
 - facilitates a rigorous ONR assessment;
 - will, where possible, be completed within reasonable and predictable timescales;
 - facilitates joint working between ONR and the Environment Agency;
 - gives clarity to ONR's requirements, processes and timescales;
 - has clear outcomes; and
 - leads to generic Pre-Construction Safety and Security Reports and (if the design is considered acceptable) to a DAC, which can both be used in subsequent nuclear site licence applications.

Requesting Party

- 11 A request for ONR and the Environment Agency to undertake a GDA must initially be made to the Department of Energy and Climate Change (DECC) as this department oversees UK Government policy on nuclear power. Such a request will normally originate from a reactor vendor, although this may also come from a vendor / operator partnership. The term Requesting Party (RP) is used throughout this document to identify the organisation(s) seeking the DAC. If satisfied that the request is consistent with UK Government policies, a DECC Minister will write to both regulators asking them formally to undertake a GDA of the design proposed by the RP.

Overall process and timescales

- 12 Although GDA is not a mandatory process, because of its advantages for both reactor vendors and potential licensees, it is expected that it will usually be requested for new nuclear power stations intended for construction in Great Britain.
- 13 From its inception GDA was designed to progress in steps. This would allow for a gradual development of the RP's safety and security case with ONR reporting progress at completion of each step. The successful completion of one step and progress to the next allows for a step-wise reduction in the uncertainties associated with the regulatory process. This provides greater certainty for intending operators and their investors before major financial commitments to a site-specific project are made.
- 14 ONR's decision to divide GDA into 4 steps (one preparatory and three assessment steps) was a pragmatic one given that the totality of the assessment work to be undertaken was anticipated to take typically around 4 years: too many steps would carry too great an overhead in terms of reporting, and the associated interruptions could potentially lengthen the overall process.
- 15 When one assessment step should end and another begin is, to some extent, arbitrary. However, ONR has a great deal of experience in assessing a variety of nuclear safety (and security) cases, and that experience has led to the approach adopted in GDA to date. ONR's guidance to its assessors (Ref. 3) sets out its expectations for safety cases but makes clear that, consistent with its goal-setting approach, ONR would not be prescriptive about the form or structure of the safety case provided for regulatory assessment. Nevertheless, the guide emphasises the need for the safety case to be intelligible, with a clear trail from claims, through the arguments, to the evidence that fully supports the conclusions.
- 16 This claims-arguments-evidence (CAE) approach is commonly used in structuring safety cases in the nuclear industry and elsewhere. ONR sees advantages in this structured approach being employed by Requesting Parties – particularly where the RP is proposing a design produced in another country under a regulatory regime which has different expectations, rules or traditions for safety case production than are usually applied in Great Britain. Consequently the CAE approach is the one on which the GDA assessment steps described in this document are based. Further details of the CAE approach are given in Section 5.
- 17 The GDA process is presented in Table 1 with indicative timescales. The process is divided into four steps, which are described in detail in this document, and shown schematically in Appendix 1. Specific assessment timetables will be drawn up and agreed by ONR and the RP during Step 1. Step 1 will be preceded by preliminary administrative work necessary to prepare an agreement allowing ONR to recover its costs from the RP, and for the RP to provide ONR with assurances regarding the viability of the GDA process for the proposed reactor design.

Table 1: The GDA process

Step	Process	Approximate timescale
1	Preparation of the design, safety and security case submissions	RP is responsible
2	Fundamental design, safety and security case claims overview	~6-8 months
3	Overall design, safety and security case arguments review	~12 months
4	Detailed design, safety and security case assessment	~28 months

Note: the RP and the regulators may agree to extend an individual GDA step by a limited period, while aiming to keep to the overall GDA timescale broadly unchanged.

- 18 The timescales in Table 1 are indicative. The actual timescales will depend on factors such as: the content, quality and timeliness of the RP's submissions;
- the completeness of the generic design;
 - the significance of any issues arising during ONR's assessment;
 - the responsiveness of the RP to ONR challenges and questions;
 - the availability of sufficient RP resources;
 - the availability of sufficient ONR resources;
 - ONR's ability to draw on relevant experience of overseas nuclear regulators; and
 - ONR's experience with similar reactor designs.
- 19 A crucial factor in achieving these indicative timescales is that suitable and sufficient documents are available at the start of each GDA step, and that the agreed schedule for further submissions is met by the RP. If submissions are late, incomplete or of poor quality then this may cause delays to the completion of that step.
- 20 It should be noted that:
- GDA and nuclear site licensing are separate assessment processes;
 - there is no guarantee that completion of GDA will lead to a DAC - this will depend on whether the design, safety case and security submissions meet ONR requirements;
 - similarly, a DAC does not guarantee that a subsequent site licensing application will be successful, as the latter phase covers wider issues; and
 - the nuclear safety and security of plants is the responsibility of the licensee, and the issue of a DAC or a nuclear site licence does not transfer any of this responsibility to ONR.
- 21 It should also be noted that the issue of a DAC and the granting of a nuclear site licence do not provide regulatory permission for the start of construction. Under the conditions attached by ONR to a nuclear site licence, the licensee will require ONR's specific regulatory permission before nuclear safety related construction can commence.

Security

- 22 In GDA, ONR will conduct a security assessment alongside the safety assessment. The key focus of this will be to understand which areas of the plant require protection and the measures that will be designed into the plant to form an integral part of the overall security infrastructure to prevent sabotage or theft of Nuclear or Other Radioactive Material and ensure the security of equipment and software in relation to Nuclear Material. A robust process for identification of potential 'vital areas' including Computer Based Systems and plant control systems underpins this approach.
- 23 The overall aim will be for the RP to develop an acceptable nuclear security case for the design in question. If this design of reactor is subsequently constructed, ONR will require these arrangements to be incorporated into the licensee's approved nuclear site security plan, required for all licensed civil nuclear premises. This plan will need to identify the security arrangements that will be in place as the project moves through different stages (for example when nuclear fuel is first brought into the site).
- 24 ONR CNS has responsibility for coordinating the production of the UK Design Basis Threat, the Nuclear Industry Malicious Capabilities Planning Assumptions (NIMCA), which is produced under the control of the NIMCA Panel Board, chaired by the DCI CNS in his capacity as the head of the Competent Security Authority. It defines a range of threats that could be faced by civil nuclear facilities and is ratified by UK Government departments, Police and Intelligence agencies. The RP will need to make suitable arrangements to demonstrate how the plant is designed and operated and what security measures are in place to mitigate the defined threats.
- 25 A cyber risk assessment should be conducted against a wide range of threat actors, to provide evidence of where the design is mitigating against the threats or where mitigation is expected to be developed by the licensee.
- 26 Some security related information may be "sensitive nuclear information" which is required to be protected in accordance with the Nuclear Industries Security Regulations 2003. Any person who holds sensitive nuclear information in Great Britain is subject to these Regulations (see ONR guidance in Ref 4).
- 27 Where sensitive nuclear information has to be shared across international borders the RP will need to provide ONR with assurance that they meet UK Government policy.
- 28 Some information, such as the UK DBT, has a higher protective marking and national "UK Eyes Only" caveats. The RP must make arrangements for those areas of work requiring such material to be undertaken in the UK by UK nationals.
- 29 Information relating to the UK specific design must be clearly identified and labelled with a security classification in accordance with the ONR Classification Policy for the Civil Nuclear Industry.

Section 2 - The Generic Design Assessment process

- 30 The description of the steps set out in this section is based on the claims-arguments-evidence (CAE) approach to presenting a safety case. This is ONR's preferred approach and is mapped onto the assessment steps described below.
- 31 ONR recognises that CAE is not the only approach to presenting a safety case, and it is open to the RP to propose an alternative. However the need for ONR and the RP to agree to an alternative set of regulatory expectations and outputs for each of the assessment steps may extend the time taken to complete step 1.

Preliminaries

- 32 Embarking on a Generic Design Assessment is a significant undertaking for both the RP and ONR; for the RP the costs may run into tens of millions of pounds, while for ONR it entails the commitment of a team of specialists for a period of several years. Subject to satisfactory progress through all of the GDA steps, it is ONR's intention that once step 1 begins the process will run through uninterrupted to the end of step 4. It is appropriate, therefore, for ONR to seek certain information and assurances from the RP prior to the start of Step 1 to ensure the project appears viable from the outset, and that the risks of nugatory effort are minimised.
- 33 A key requirement for ONR is that prior to the start of GDA it has entered into a cost-recovery agreement with the intending RP. This will ensure that ONR can recover from the RP all of the costs incurred in GDA from the start of step 1 through to the end of step 4.
- 34 The precise nature of the information and assurances that ONR will seek from the RP will depend on the organisational nature of the RP (for instance whether it is a single body or a joint enterprise of two or more bodies), as well as on the development status and ownership of the proposed design; this will be elaborated by ONR during preliminary discussions.
- 35 The list below is indicative of the types of questions that ONR will wish to raise with the intending RP and are based on the assumption that the RP is a joint enterprise; for an RP consisting of a single company several of these may not apply.
- 36 Typical matters for discussion with the RP prior to Step 1:
- Ownership structure of the RP;
 - RP organisational structure;
 - RP decision making authority including budgetary control;
 - RP resourcing strategy for duration of GDA;
 - Clarity on the design being proposed and its ownership;
 - Assurance on the timely availability to ONR of all necessary design and safety case related information, including proprietary information owned by third parties;
 - RP plans and proposals for a UK regulatory interface office;
 - The "Duty holder" in relation to NISR Reg 22 for protection of SNI.
 - Acknowledgement that the RP understands and will comply with the expectations set out in this guidance including legal obligations under UK nuclear security regulations.
- 37 Preparation of the cost-recovery agreement should be able to commence when ONR is satisfied regarding such preliminary enquiries.

GDA Steps

Step 1: Preparation of the design, safety case and security submissions

Step 1: Description and aims

Step 1 is the preparatory part of the design assessment process. Mostly this will involve the RP setting up its project management and technical teams and arrangements for GDA, and writing and preparing submissions for Step 2, including the Preliminary Safety and Security Reports. It also involves discussions between the RP and ONR to ensure a full understanding of the requirements and processes that will be applied.

Step 1: The RP is required to:

- 1.1 Discuss with ONR the overall GDA timescales and the proposed schedule and format for the submission of documentation including the Safety and Security Reports.
- 1.2 Enter into agreements with ONR as appropriate, covering:
 - (a) the scope of ONR assessment;
 - (b) project management arrangements and quality management system;
 - (c) the design change control process to be applied during GDA;
 - (d) timescales for responses to ONR assessment questions / issues etc;
 - (e) arrangements for the public input process;
 - (f) arrangements for ensuring that the designers, and safety and security case producers are suitably qualified and experienced persons;
 - (g) the safety and security case developer's quality control, including peer review arrangements;
 - (h) a work programme and bespoke timetable for assessments (which will be kept under review).
- 1.3 Ensure that ONR will have full access to any commercially confidential information necessary for it to complete its assessments at each step; this must also include relevant commercial information which is the property of third parties. ONR expects this information to be made available for inspection in ONR's offices. [Note that failure to ensure timely access to all necessary information may jeopardise or significantly delay the completion of GDA].
- 1.4 Prepare sufficient safety and security documentation to enable ONR to undertake at least the Step 2 assessment.
- 1.5 Prepare the template for the Master Document Submission List and any required arrangements for handling it.
- 1.6 Identify and suitably mark those elements of the documentation that are commercially sensitive.
- 1.7 Undertake discussions with ONR and classify the documentation in accordance with security requirements, identifying sensitive nuclear information against ONR guidance.
- 1.8 Publish the Preliminary Safety Report on its website (removing commercial and security sensitive information) to allow comments to be made by the public during

GDA.

- 1.9 Update the public version of its Safety Report when a significant update is made to the information submitted to ONR.
- 1.10 Undertake a review of its readiness to begin Step 2 and report on the outcome of this review to ONR.
- 1.11 Have appropriate security arrangements in place for the identification and protection of SNI including appropriate security cleared personnel

Step 1: ONR will:

- 1.11 Agree with the RP the proposed schedule for submission of documentation and its format, and inform the RP of the implications of this for ONR's assessment programme.
- 1.12 Review the scope of the safety and security submissions for the Step 2 assessment and inform the RP:
 - whether this is sufficient for ONR to begin Step 2 assessment;
 - of any shortfalls in the documentation and the potential for delay in the completion Step 2.
- 1.13 Undertake a review of its readiness to begin Step 2.
- 1.14 Confirm whether the administrative security arrangements are adequate for the protection of SNI throughout the process.

Step 1: ONR output

ONR will publish statements to announce:

- *[at the beginning of the step]* that it has received a request from the Government to undertake the GDA and is beginning Step 1; and
- *[at the end of the step]* that the information submitted by the RP is sufficient to allow the start of Step 2.

Step 2: Fundamental design, safety case and security claims overview

Description and aims

Step 2 is primarily an overview of the acceptability, in accordance with the regulatory regime of Great Britain, of the design fundamentals, including review of key safety and security claims (or 'assertions').

The aim of this step is to assess the key claims and identify any fundamental safety or security shortfalls that could prevent ONR permitting the construction of a power station based on the design.

A related aim is that the RP will come to fully understand the regulatory approach used in Great Britain and thus ensure that adequate safety and security documentation will be developed for Steps 3 and 4.

It will also introduce ONR inspectors to the fundamentals of the design and provide a basis for planning subsequent, more detailed, assessment.

This step may take around 6 to 8 months, assuming the RP is able to provide quality and timely submissions and responses to regulatory concerns.

Exceptionally, in the event that the RP is not able to provide the information necessary for ONR to complete the step in the indicative time period, there is scope for the step to be extended for an agreed, limited period to allow the requisite documentation to be developed, submitted and assessed. Agreement to such an extension would be dependent on the availability of ONR's specialist resources during the proposed extension period. ONR will still aim to achieve the original planned overall timescale for completing GDA, for instance by seeking to shorten the next step.

The RP is required to:

Provide documentation in the form of a Preliminary Safety Report (PSR) and Preliminary Security Report, that includes sufficient information for ONR's Step 2 assessment, in particular:

- 2.1 A statement of the design philosophy and a description of the design sufficient to allow identification of the main nuclear safety claims including identification of hazards, control measures and protection systems.
- 2.2 A description of the process being adopted by the RP to demonstrate compliance with the legal duty in Great Britain to ensure that the risks to human health arising from the operation of a power station based on the proposed design are reduced 'So Far As Is Reasonably Practicable' (SFAIRP). For ONR's assessment purposes the terms ALARP (As Low As Reasonably Practicable) and SFAIRP are interchangeable and require the same tests to be applied (refer to Section 5 below for further information).
- 2.3 Details of the safety principles and criteria that have been applied in the RP's own assessment processes, including the control of risks to workers and the public.
- 2.4 A broad demonstration that the RP's safety principles and criteria are likely to be achieved by the design.
- 2.5 An overview of the approach, scope, criteria and output of the deterministic safety analyses.
- 2.6 An overview of the approach, scope, criteria and output of the probabilistic safety analyses.
- 2.7 Specification of the site characteristics to be used as the basis for the safety analysis (the 'generic site envelope').
- 2.8 Explicit references to standards and design codes used, justification of their

- applicability, and that they represent relevant good practice, and a broad demonstration that they have been met (or exceptions justified).
- 2.9 Information on the quality management arrangements for the design, including design controls, control of standards, verification and validation, and the interface between design and safety.
 - 2.10 Details of the safety case development process, including peer review arrangements, and how this gives assurance that nuclear risks are identified and managed.
 - 2.11 Information on the quality management system for the safety case production.
 - 2.12 Identification and explanation of any novel or complex features, including their importance to safety.
 - 2.13 Identification and explanation of any deviations from modern, international good practices.
 - 2.14 Sufficient detail for ONR to satisfy itself that relevant Safety Assessment Principles (SAP) are likely to be satisfied.
 - 2.15 Bring to ONR's attention any relevant information about assessments undertaken by regulators outside Great Britain.
 - 2.16 Identification of outstanding information that remains to be developed and its significance.
 - 2.17 Information on radioactive waste and spent fuel management, and on decommissioning.
 - 2.18 Information about the Reference Design (or designs) on which the PSR is based, and when the RP intends to 'freeze' the generic safety and security submissions.
 - 2.19 Security related information covering the reactor technology concept,
 - 2.20 A methodology to be adopted for the identification of Vital Areas
 - 2.21 Sufficient detail for ONR to satisfy that "defence in depth" principles have been applied to the design to prevent both internal "insider" and external threats from carrying out acts of sabotage or theft ie: Concept of Security Operations
 - 2.22 Suitable cyber risk methodology has been adopted
 - 2.23 At the end of Step 2, undertake a review of its readiness to move to Step 3 and report on the outcome of this review to ONR.
- The RP will also be required to provide the first Master Document Submission List.
In addition, the RP will be required to respond to matters raised by ONR during its assessment, and to issues arising from public comments.

ONR will:

Undertake an assessment directed at reviewing design concepts and claims. This will include:

- 2.21 The design safety philosophy, standards and criteria used.
- 2.22 The approach to ALARP.
- 2.23 The fault study approach including Design Basis Analysis (DBA) and Severe Accident management.
- 2.24 The probabilistic safety analysis (PSA) approach.
- 2.25 The overall safety case scope and extent.
- 2.26 An overview of the claims in safety analysis and engineering design across a wide range of technical areas.
- 2.27 The generic site envelope and its relevance to the safety case.

- 2.28 The proposals for nuclear security including the general concept of security operations.
- 2.29 The proposals for the Design Reference and safety submission freeze, including proposals for management of design changes during GDA.
- 2.30 Identification of any matters that might be in conflict with Government policy.
- 2.31 Identification of any significant issues that may prevent ONR from issuing a DAC.
- 2.32 Consideration of relevant issues identified through the public involvement process.
- 2.33 Undertaking a review of its readiness to move to Step 3.
- 2.34 Assessing the VA Identification methodology
- 2.35 Assessing the Cyber Risk Assessment

Where necessary, the RP should update the safety documentation on their website (removing commercial information, and security sensitive information) to reflect additional details provided during the step.

Step 2: ONR output

- 2.34 Publication of:
 - a statement on whether any fundamental safety or security issues have been identified that might prevent the issue of a DAC or which would need to be addressed in order to acquire one.
 - a summary report to support this statement, plus the ONR assessment reports, along with any other reports relevant to Step 2.
 - a statement on whether the design assessment can progress to Step 3.

Step 3: Overall design, safety case and security arguments review

Description and aims

Step 3 is primarily a review by ONR of the arguments (or 'reasoning') supporting the RP's claims regarding the safety and related security aspects of the proposed design.

The intention in this Step is to move from the fundamentals of the previous step to an analysis of the design, primarily at the system level, and by analysis of the RP's arguments that support the safety and security claims.

The specific aims of this step are to:

- improve ONR knowledge of the design;
- assesses the safety and security arguments;
- progress the resolution of issues identified during Step 2;
- identify whether any significant design or safety case changes may be needed;
- identify major issues that may prevent ONR issuing a DAC and attempt to resolve them; and thereby
- achieve a significant reduction in regulatory uncertainty.

The exact scope and focus of step 3 will depend on the design and on the outcome of Step 2.

This step may take around 12 months, assuming that the RP is able to provide quality and timely submissions and responses to regulatory concerns.

Exceptionally, in the event that the RP is not able to provide the information necessary for ONR to complete the step in the indicative time period, there is scope for the step to be extended for an agreed, limited period to allow the requisite documentation to be submitted and assessed. Agreement to such an extension would be dependent on the confirmed availability of ONR's specialist resources during the proposed extension period. ONR will still aim to achieve the original planned overall timescale for completing GDA, for instance by seeking to shorten the next step.

The RP is required to:

Provide, at the start of Step 3, sufficient safety and security documentation to allow ONR to proceed with assessment across all technical areas. Where full documentation cannot be provided at the start of the step, ONR and the RP will need to agree a schedule of submissions. The documentation should include the following:

- 3.1 Responses to any matters outstanding from Step 2.
- 3.2 Explanation of how the decisions regarding the achievement of safety functions ensure that the overall risk to workers and public will be ALARP.
- 3.3 Sufficient information to substantiate the claims made in the Safety and Security Reports.
- 3.4 Sufficient information to enable ONR to assess the design against all relevant SAPs.
- 3.5 A demonstration that the detailed design will meet the safety and security objectives before construction or installation commences, and that sufficient analysis and engineering substantiation has been performed to prove that the operational plant will be adequately safe and secure.
- 3.6 Detailed descriptions of system architectures, their safety or security functions, and reliability and availability requirements.
- 3.7 Confirmation and justification of the design codes and standards that have been used and where they have been applied, non-compliances and their justification.
- 3.8 Fault analyses including DBA, Severe Accident Analysis and PSA.

- 3.9 Safety function categorisation and the safety classification of structures, systems and components (SSC) - with a demonstration of how this is reflected in the design.
- 3.10 Justification of the safety and security of the design throughout the plant's life cycle, from construction through operation to decommissioning and including on-site spent fuel and radioactive waste management features.
- 3.11 Identification of potentially significant safety and security issues that have been raised in assessments of the design by overseas regulators, and explanations of how they have been (or will be) resolved.
- 3.12 Identification of the safe operating envelope and the operating regime that maintains the integrity of that envelope.
- 3.13 Definition of the technical and documentary scope of GDA, including definition of the safety and security submission, definition of a Design Reference, and Design Reference Point, and implementation of GDA submission configuration control arrangements. This should also include confirmation of:
 - those aspects of the design, safety case and supporting documentation that are complete and are intended to be covered by the DAC;
 - any aspects that are still under development; and
 - identification of outstanding confirmatory work that will be addressed during Step 4.
- 3.14 Confirmation of the proposals for:
 - updating the Master Document Submission List;
 - the Design Reference;
 - the management of design changes during GDA; and
 - the safety submission freeze.
- 3.15 Towards the end of Step 3, undertake a review of its readiness to move to Step 4 and report on the outcome of this review to ONR
- 3.16 Provide a list of Vital Areas and provide an example(s) of how the VAI methodology has been applied.

The above documentation may be in the form of a draft Pre-Construction Safety Report (PCSR) or Generic Security Report (GSR). Where necessary, the RP should update the safety documentation on their website (removing commercial information, and security sensitive information) to reflect additional details provided during step 3.

The RP will also be required to respond to questions and points of clarification raised by ONR during its assessment, and to relevant issues arising from public comments.

ONR will:

Undertake an assessment of the RP's submission, on a sampling basis, primarily directed at the system level, focussing on the RP's supporting arguments. The scope of ONR's assessment will be partly defined by experience in step 2 and the issues arising in that step, and also by experience in previous GDAs.

This will include:

- 3.16 Considering whether the design is likely to meet the RP's design safety criteria and that these ensure risks will be ALARP.
- 3.17 Undertaking an initial assessment of the scope and extent of the arguments in each of the technical areas, including the generic site envelope.
- 3.18 Assessing the safety case development process scope and extent.
- 3.19 Reviewing what overseas regulators have done and how ONR can make use of it.
- 3.20 Deciding on scope of, and plan for, further assessment.

- 3.21 Assessing the quality assurance (QA) arrangements, including safety case and design change control arrangements.
- 3.22 Assessing the RP's independent verification process.
- 3.23 Identifying the need for additional regulatory verification / analysis.
- 3.24 Judging whether the design is balanced in terms of the different contributors to the overall risk from the plant.
- 3.25 Reviewing the RP proposals for spent fuel management, radioactive waste management and decommissioning.
- 3.26 Identifying any research needs and setting up of longer-term research or contract support to complement Step 4.
- 3.27 Considering security proposals and undertaking a detailed review of the security architecture of the plant including assessment of how those areas requiring protection have been identified and categorised.
- 3.28 Considering issues identified through the public involvement process.
- 3.29 Undertaking a review of ONR's own readiness to move to Step 4.

Step 3: ONR output

- 3.30 ONR will publish:
 - a statement on the progress of ONR's assessment of the design, safety case and security arguments;
 - a summary report describing any outstanding safety or security issues which have the potential to require significant design or safety case changes, or which may prevent ONR issuing a DAC;
 - a statement on whether the design assessment can move to Step 4.

Step 4: Detailed design, safety case and security evidence assessment

Description and aims

Step 4 is an in-depth assessment of the safety case evidence, security case evidence and the generic site envelope

The general intention of this step is to move from the safety and security arguments and system level assessment of step 3 to a fully detailed examination of the available evidence, on a sampling basis, provided in the safety and security submissions.

The aim of this step is to:

- confirm that the higher-level claims and arguments are properly justified;
- progress the resolution of issues identified during Step 3;
- complete sufficient detailed assessment to allow ONR to come to a judgment of whether a DAC can be issued.

The exact scope and focus of the step will depend on the design and the outcome of Step 3. This step may take about two years, assuming the ONR GDA assessment team is fully resourced.

Subject to negotiation with ONR the step may be extended at the request of the RP. This may be necessary if the all the evidence needed from the RP to address outstanding regulatory concerns cannot be provided by the planned GDA end date.

The RP is required to:

Provide, at the start of step 4, any outstanding information, safety case material and research results that provide evidence to support the PCSR and the Generic Security Report

In addition, the RP is required to submit:

- 4.1 A demonstration that construction, manufacture and installation activities will result in a plant of appropriate quality.
- 4.2 A demonstration that the constructed plant will be capable of being operated within safe limits and is able to mitigate Design Basis Threats
- 4.3 Arrangements for moving the safety case to an operating regime; i.e. the arrangements to ensure that the requirements of, and assumptions in, the safety case have been clearly identified and can readily be captured in:
 - (a) technical specifications;
 - (b) maintenance schedule;
 - (c) procedures (normal operation, emergency, accident management);
 - (d) training programmes;
 - (e) emergency preparedness;
 - (f) operating limits;
 - (g) radiation protection arrangements for operators;
 - (h) lifetime records;
 - (i) commissioning requirements, etc.
- 4.4 The RP should also be able to submit arrangements for developing the GSR into a Nuclear Site Security Plan for the operating site, which clearly demonstrates that Security Assessment Principles can be achieved.
- 4.4 Confirmation of the Design Reference and safety submission definition and provision of updates to the Master Document Submission List.

- 4.5 Arrangements for supporting future licensees to put in place a Design Authority.
- 4.6 Arrangements to support future licensees in managing site-specific design changes from the generic design, within an agreed change control process.
- 4.7 Responses to any issues outstanding from Step 3.
- 4.8 A PCSR updated to reflect changes agreed during GDA.
- 4.9 A GSR updated to reflect changes agreed during GDA.

The RP will also be required to respond to questions and points of clarification raised by ONR during its assessment, and to respond to relevant issues arising from public comments.

ONR will:

Undertake a detailed assessment on a sampling basis of the safety and security case evidence. This will include:

- 4.9 Consideration of issues identified in Step 3.
- 4.10 Judging the design against the SAPs and whether the proposed design ensures risks are ALARP.
- 4.11 Inspecting the RP's procedures and records.
- 4.12 Independent verification analyses.
- 4.13 Reviewing details of the RP's design controls, procurement and quality control arrangements to secure compliance with the design intent.
- 4.14 Establishing whether the system performance, safety classification, and reliability requirements are substantiated by the detailed engineering design.
- 4.15 Assessing arrangements for moving the safety case to an operating regime.
- 4.16 Assessing arrangements for ensuring and assuring that safety claims and assumptions are realised in the final as-built design.
- 4.17 Judging whether significant site parameters are appropriately defined in the generic site envelope.
- 4.18 Reviewing the GSR.
- 4.19 Reviewing progress with and issues arising from overseas regulators' assessment of similar designs.
- 4.20 Considering relevant unresolved issues arising from the public involvement process.
- 4.21 Resolution of identified nuclear safety and security issues, or identifying paths for resolution.

Step 4: ONR output

ONR will publish:

- a statement of the conclusions of ONR's planned assessment;
- a report to support this statement;
- the associated internal ONR assessment reports, along with any other reports relevant to Step 4;
- ONR's decision on whether or not to grant a DAC or, if appropriate, an interim DAC (iDAC).

GDA Conclusions and close-out

- 38 There could be three potential outcomes at the end of Step 4:
- (i) Provision of a DAC, marking the end of GDA for that generic design.
 - (ii) Provision of an iDAC identifying outstanding GDA Issues.
 - (iii) No DAC being provided.

These three potential outcomes are discussed below.

(i) Design Acceptance Confirmation

- 39 If ONR are fully content with the generic safety and security aspects then it would provide the RP with a DAC which would mark the end of GDA for that generic design.
- 40 Provision of a DAC means that in ONR's opinion, on a site bounded by the generic site envelope, the generic reactor design could be built and operated in Great Britain, in a way that is acceptably safe and secure (subject to site specific assessment and licensing).

(ii) Interim DAC and GDA Issue close-out

- 41 It is ONR's expectation that the RP will wish to continue GDA until ONR judges that it has presented sufficient evidence for it to be provided with a DAC. Step 4 could be extended if necessary to allow for the provision of sufficient evidence if this cannot be done within the target timescale for Step 4. However, if the RP does not wish to extend Step 4, and if ONR is largely content with the generic safety and security aspects then it would consider the provision of an iDAC.
- 42 Provision of an iDAC means that step 4 has been completed, ONR has completed its planned assessment and is largely content that the design is capable of being built and operated in Great Britain, but that there are some GDA Issues remaining (see Section 4 below).
- 43 The provision of an iDAC would only be considered when the RP is able to provide credible resolution plans that identify how it will address each of the GDA Issues.
- 44 All the GDA Issues would need to be addressed to ONR's satisfaction before a final DAC could be provided or before ONR could consider granting permission for the start of nuclear island safety-related construction of a power station based on that design.
- 45 The GDA Issue 'close-out' process will involve an in-depth ONR assessment of the additional design and safety or security case evidence submitted in response to the GDA Issues.
- 46 Scope and timescales for this stage will depend on the programmes identified in the resolution plans provided by the RP.
- 47 The RP will have to submit evidence in accordance with the programmes identified in the resolution plans. The final submissions will need to include updates to the:
- Generic PCSR;
 - GDA Design Reference;
 - Generic Security Report; and
 - Master Document Submission List.
- 48 The RP will also be required to respond to matters raised by ONR during its assessment, and to respond to relevant issues arising from public comments.
- 49 ONR will complete sufficient assessment to be able to judge whether the additional information submitted by the RP is adequate to address all the GDA Issues. ONR will then publish:

- a statement providing the conclusions of the GDA Issue close-out assessment;
- a report to support this statement;
- the associated internal ONR assessment reports;
- a DAC if the design, safety case and security submissions are judged to be acceptable.

50 It is likely that the generic reactor design will be subject to development during a lengthy pause between gaining an iDAC and beginning the GDA Issue close-out stage, leading to a number of design changes being proposed by the RP when GDA restarts. If such design changes have consequences for the generic safety case or GSR that was the basis for the iDAC then this may necessitate additional assessment by ONR. Similarly, during a significant pause, there may have been changes to standards and codes and the advancement of relevant good practice, all of which can complicate, and potentially extend, the close-out process.

(iii) No Design Acceptance Confirmation

51 If, at the end of GDA, ONR is not content with the generic safety and security aspects then a DAC would not be issued. This would be the case where ONR judged that there is a significant, unacceptable shortfall in the design, safety or security submissions. ONR will publish a statement providing the conclusions of its assessment.

52 It would be a matter for the RP to decide whether to propose additional work to address the identified shortfalls, which may allow a DAC (or iDAC) to be provided at some future date.

Section 3 - Requesting Party GDA safety and security cases

Scope of GDA

- 53 Although ONR requires a certain minimum level of detail to complete GDA, it recognises that full engineering details of the design will not be available at the GDA stage, as it is normal to finalise some of these during the site-specific procurement and construction programme.
- 54 The scope of what is included within GDA is dependent on the information supplied by the RP. However, that information needs to be sufficient in scope and detail to allow ONR to undertake a meaningful assessment of the generic safety and security case for the design (see Section 5 for ONR's views on what constitutes a 'meaningful GDA'). If ONR considers the RP's proposed scope for the GDA, is too narrow or excludes essential information, it will require the scope of the GDA submissions to be expanded to address such shortfalls.
- 55 To ensure that ONR can develop adequate work plans covering the whole of step 4, the final GDA scope should be agreed well before the end of step 3.

GDA submissions, RP readiness review and internal challenge

- 56 Before each of the assessment steps, ONR requires the RP to conduct a readiness review to confirm that it can fulfil all the requirements for that step (as defined in the tables above). This should include an internal challenge process within the RP organisation. The results of the readiness review should be provided to ONR to support the RP's request to start the assessment step.
- 57 The process of preparing documents for submission to ONR should also include internal challenge within the RP organisation. This should be applied, on a graded approach commensurate with safety or security significance, both to the submissions and to responses to ONR questions etc., throughout GDA (see also 'Processes for development of the safety case' below).

GDA safety and security document submissions

- 58 In order to define the basis of what has been included within the scope of GDA, the DAC will list a number of key references. These include the:
- Generic PCSR;
 - Generic Security Report;
 - GDA Design Reference; and
 - Supporting references as identified in a Master Document Submission List.

These documents and their control arrangements are described below.

Generic Pre Construction Safety and Security Reports

- 59 The RP is required to develop and submit a comprehensive, generic PCSR and a GSR plus relevant supporting reference documents.
- 60 The SAPs include a section on the regulatory assessment of safety cases. This is supported by the ONR Technical Assessment Guide (TAG) on the purpose, scope and content of nuclear safety cases (Ref. 3) which identifies the principal safety reports associated with key stages in a nuclear facility's life cycle. Table 2 below shows how these relate to the GDA process.

- 61 As discussed in Sections 1 and 2 above, ONR’s preferred approach to the development of safety case documentation for submission through steps 2 to 4, is for the RP to adopt the claims-arguments-evidence (CAE) chain of reasoning. This means that the safety case should set out the technical **claims** (or ‘assertions’) that show that the risk is ALARP, supported by sound **arguments** (or ‘reasoning’) for which experimental or other detailed **evidence** is presented. It is important that the information provided in the safety case is suitable and sufficient to demonstrate, in the opinion of ONR, that risks have been reduced so far as is reasonably practicable (SFAIRP).
- 62 The GSR should demonstrate that the designed Physical Protection System is able to achieve the required outcome and effect.
- 63 The CAE approach is not compulsory and the RP is free to employ alternative methodologies for safety case composition. ONR recognises that the CAE approach may be more appropriate to some parts of the safety case (for example engineered systems) than others where the RP may choose to use alternative approaches. It is important, however, that the RP shares its strategy for safety case development with ONR as early as possible so that ONR has a clear understanding of what is proposed and can provide appropriate feedback.
- 64 Appendix 4 illustrates the CAE chain of reasoning for an engineered nuclear safety-related system.
- 65 For a generic PCSR ONR accepts that much of the evidence and associated confirmatory analysis cannot be gathered until the SSCs have undergone final detailed design by a manufacturer / supplier or have been manufactured and are in the process of being tested. Since the choice of supplier and the construction and commissioning are matters for the site operator, this level of information is generally not included within GDA. However, for GDA, ONR expects the RP to provide its arrangements for ensuring that the safety claims and assumptions can be realised in the as-built design (see Step 4 table in Section 2).

Table 2: Safety reports identified in T/AST/051 (Ref. 3)

Report	Input to
PSR	Assessment in Step 2
Generic PCSR	Assessment in Steps 3 and 4
Updated Generic PCSR	Assessment of GDA Issue responses (if required)
Site-specific PCSR	Site specific and Licensing assessment
Pre-Commissioning Safety Report	Prior to (inactive and active) commissioning
Pre-Operational Safety Report	Prior to reactor operation

- 66 The generic PCSR should include information that defines the characteristics assumed for the generic site envelope.
- 67 The security report will comprise the GSR and supporting references. Guidance on the content of this is provided in Ref. 5.
- 68 ONR requires the RP to make the safety reports and key supporting references available for public comment on the Internet (with the exception of any commercially confidential and security sensitive information).

GDA Design Reference and Design Reference Point

- 69 The RP is required to submit a Design Reference which lists all the documents that describe the design of the reactor and associated plant that the GDA submissions refer to. ONR will expect this to be 'frozen' at a specific date known as the Design Reference Point. ONR will agree the Design Reference and Design Reference Point with the RP.
- 70 To avoid uncertainty, inefficiency and possible delays to completion of its Step 3 and 4 assessments, ONR requires clarity on the design definition. Ideally, therefore, the Design Reference should be in place at the start of Step 3.
- 71 The PCSR and GSR must align exactly with the plant described in the Design Reference.

Design Reference change control

- 72 As part of its normal design development process, the RP may wish to make changes to the generic design after the Design Reference Point has been agreed. Changes to the design may also be necessary to respond to Regulatory Observations or Regulatory Issues (see Section 5 below). It is therefore important that a GDA design change process is implemented by the RP.
- 73 The details of the change control system are for the RP to propose and ONR to agree. However, ONR will expect this to be a robust system such similar to those implemented by licensees to satisfy nuclear site Licence Condition 20 (modification to design of plant under construction). ONR will inspect these arrangements as part of GDA.
- 74 Features that ONR will expect to see include:
- a categorisation system reflecting the potential safety and security impact of the change;
 - change control committees to oversee the categorisation of the proposed changes and the overall running of the process; and
 - a route for alerting ONR to the more significant changes to the safety or security case.
- 75 If design changes are accepted into GDA by ONR the RP should consolidate them into the Design Reference and propose an updated Design Reference Point for agreement by ONR.
- 76 Significant design changes proposed at an advanced stage in GDA may pose a threat to the delivery of a timely and meaningful ONR assessment. ONR will therefore take a view on whether such design change proposals can be accepted within the scope of GDA.

Master Document Submission List

- 77 As GDA progresses ONR will request submission of a selection of the PCSR supporting references so that more detailed information can be examined. There will also be developments in the safety case, design modifications, and responses to ONR questions that all need to be included within the totality of GDA submissions. The information submitted by the RP can therefore become a complex mix of documents.
- 78 Consequently, the RP will be required to put in place management arrangements to keep track of the documents submitted, of subsequent changes to these documents, and of documents withdrawn, etc. Key to these arrangements is a Master Document Submission List, which is a 'live' document that allows ONR to understand and reference precisely what constitutes the latest versions of the GDA submissions.

GDA submission Quality Assurance arrangements

- 79 As well as ensuring that an RP's safety and security case submissions is well defined, ONR requires that it is produced under robust QA arrangements. The RP's arrangements will be required to ensure that this is achieved, and examination of these arrangements forms part of ONR's assessment during GDA.

GDA cut-off dates and submission consolidation

- 80 It is important that ONR's assessment is based on an agreed set of documentation during each GDA step. To be able to assess new information and include this within ONR's reports at the end of a step, there needs to be an agreed cut-off date for submission of new information into that step. Each cut-off date will be agreed between ONR and the RP.
- 81 In addition, towards the end of GDA, there will be a need for the RP to re-consolidate the Design Reference and generic Pre Construction Safety and Security Reports and supporting documentation to take into account:
- all the additional information that has been provided in response to ONR technical questions; and
 - design (and safety case) changes that ONR has agreed can be included in the GDA scope.

It is the information contained within this final consolidated GDA submission that ONR will refer to in its concluding reports on GDA.

Generic site characteristics

- 82 The RP may specify generic site characteristics, such as the density and distribution of the assumed local population, seismic hazard, extreme weather events and other external hazards, which are typical for a range of sites in Great Britain. These characteristics should, as far as possible, envelop or bound the characteristics of known potential sites in Great Britain so that reactors of the proposed type could potentially be built at a number of suitable locations. Guidance on ONR's expectations on generic site characterisation is contained in Appendix 3.
- 83 To ensure that the assessment undertaken in GDA can be fully taken into account during ONR's nuclear site licensing assessment, a licence applicant would need to demonstrate that its chosen site fell within the site envelope used in GDA.
- 84 If a site for construction of a plant based on the generic design has been selected by a developer before the start of GDA, then the RP may choose the selected site to represent a 'generic site'. Any DAC issued at the end of GDA may thus be of limited applicability to a developer who wishes to construct the design on a different site. In such a case ONR would need to undertake an assessment of the applicability of the DAC to the different site, with a potential increase in regulatory uncertainty for that project.

Use of documentation not specific to Great Britain

- 85 ONR recognises that the RP may choose to make use of existing design and safety documents that were written to address the regulatory requirements of countries other than Great Britain. However, because the regulatory basis in Great Britain is goal-setting, rather than prescriptive, and is based on the ALARP principle, it is unlikely that such documents will be sufficient, on their own, for the purposes of GDA. ONR needs to receive additional and specific submissions that demonstrate how the regulatory requirements of Great Britain have been, or will be, met.

- 86 ONR requires that plants are designed and will be built and operated using SI (International System) Units and that documents submitted are written in English.

Protective markings

- 87 As far as possible safety case information provided to ONR should be made available on the RP's public website. However, if the RP considers that certain information should be protected because it is sensitive nuclear information or commercially confidential, it should clearly mark it accordingly. The RP should also give its reasons for designating the information in this manner.
- 88 The RP should use a protective marking scheme consistent with the UK Government's Security Classifications and ONR Classification Policy.
- 89 The RP should be aware that over-protecting information (i.e. marking documents with protective markings more restrictive than those required by the nature of the information contained) can complicate the process for handling the documentation and may cause delays.

Fault Analysis and PSA

- 90 Fault analysis should be carried out comprising DBA, PSA, and Severe Accident analysis.
- 91 ONR expects that the GDA submissions will include a full scope Level 1 and Level 2 PSA. The PSA should be used to help show that the design satisfies the ALARP requirement. A Level 3 PSA relevant to the generic site will also be expected.
- 92 The regulatory regime enforced by ONR is, in general, non-prescriptive and there are therefore few numerical legal requirements. However ONR is guided in its safety case assessments by certain numerical targets in the SAPs and will therefore seek sufficient information for it to be able to judge that the targets are likely to be achieved and that the overall risk is ALARP. Further guidance on ONR expectations relevant to PSA and to fault analysis can be found in the SAPs and in the TAGs on accident analysis (Ref. 6).

Life Cycle: construction to decommissioning/ waste and spent fuel management

- 93 ONR will expect the safety and security submissions to cover all aspects of the plant's life-cycle, including construction, operation, maintenance activities, spent fuel and radioactive waste management and decommissioning. The level of detail of the information required may vary according to the significance of each aspect to the GDA.
- 94 RPs should identify the management arrangements for the spent fuel and radioactive waste arising from the full projected life of the plant. This should include:
- strategies for the management of spent fuel, all radioactive wastes and substances that might become wastes;
 - the safe storage of radioactive wastes pending disposal;
 - the disposability of radioactive wastes;
 - a demonstration of how the design and its proposed operation will avoid or minimise the generation of radioactive waste; and
 - the strategy for decommissioning the plant.
- 95 This information may be captured in a Radioactive Waste Management Case, which can form part of the generic PCSR. This should show how the safe management and disposal of waste produced over the life of the power station can be achieved. When providing this

case, the RP should take into account the radioactive waste facilities expected to be available in Great Britain. There should also be consideration of the need to transport waste and spent fuel and the implications of this for its long term management.

- 96 The Government has set out its framework for managing higher-activity wastes through geological disposal Ref. 7. This process is based on the current radioactive waste inventory in Great Britain (Ref. 8) but it is intended to be capable of accommodating waste and spent fuel arising from any new build programme. RPs will be expected to seek assurance that the anticipated waste streams will be acceptable for disposal in such a facility; the Nuclear Decommissioning Authority (NDA) has published a protocol to facilitate the necessary assessments (Ref. 9).

Safety Management

- 97 The GDA process requires RPs to provide information on the quality management arrangements for the design and safety case production.
- 98 In addition, the arrangements for RPs to support licensees to put in place a Design Authority should be described in Step 4. For guidance on Design Authority aspects, see Ref. 10.
- 99 If key safety-related items, intended or potentially for use in Great Britain, have been or are in the process of being manufactured, the RP should specify what quality management arrangements have been or will be used during all stages of the manufacturing process.
- 100 Existing guidance on some aspects of ONR's assessment of the design process, Design Authority, change control, design QA and intelligent customer capability is given in the relevant ONR Technical Assessment Guide (Ref. 6).

Processes for development of the safety case

- 101 The process used to produce safety cases needs to consistently deliver good-quality, fit-for-purpose cases. For a safety case to claim that the plant under consideration is very reliable or highly unlikely to fail, the process used to derive such claims should have a commensurate level of robustness.
- 102 The RP therefore needs to demonstrate that the process for safety case production has included, for example, having suitably qualified and experienced (SQEP) safety case authors, appropriate verification controls, a formal approval procedure, and an independent review. The RP should also demonstrate that the rigour of this independent review is consistent with the safety importance of the subject matter.
- 103 In view of this, ONR's assessment may involve inspection of the originating organisation's processes as well as assessment of the safety cases themselves. Further information on ONR's expectations regarding safety case due process is given in the SAPs, and in TAG T/AST/051 (Ref. 3).

Section 4 – Outputs from GDA

Openness, transparency, progress reporting and public involvement

- 104 Consistent with ONR's commitment to openness and transparency in its decision-making process, regular progress reports will be issued throughout GDA and published on the Joint Regulators website. These will include metrics to indicate the performance of ONR and the RP and progress against programme. In addition, ONR will publish its assessment reports and other associated documentation at appropriate points in the process.
- 105 Arrangements will be agreed between ONR and the RP to enable the public to view the safety case (with the exception of commercially confidential and security sensitive

information) on a website hosted by the RP. An opportunity should also be given for the public to comment to the RP on that information, who will be expected to respond to any relevant issues raised. The regulators will oversee this public involvement process and at key stages ONR will publish its views on the main issues raised and responded to.

- 106 Although ONR will give due consideration to issues that are raised in the public involvement process and to the RP's responses, ONR will remain wholly responsible for decisions it makes on the acceptability or otherwise of the design put forward by the RP.
- 107 ONR also has duties to provide information to the public when requested to do so under the Freedom of Information Act 2000 and the Environmental Information Regulations 2004. Even if the information is protectively marked, ONR will still be obliged to consider whether it is in the public interest for it to be released.

Generic Design Assessment reporting by ONR

- 108 On completion of each GDA step, ONR will make a decision on the acceptability of the RP's submissions made in support of that step. ONR will announce this decision in a public statement, and will publish a summary report to support the decision. This will be supplemented by relevant technical assessment reports at the end of steps 2 & 4. The summary reports will describe the assessments undertaken and reasons for ONR's decision. The reports will identify, where appropriate, outstanding issues or requirements for subsequent phases / steps.
- 109 If ONR decides that the RP's submissions have not allowed the step to be successfully completed then ONR will identify the issues that it considers unacceptable or which require further elaboration. ONR may agree to delay the closure of a step if the RP wishes to make further information available for ONR to take into account before reaching a decision. In this event, ONR will make a public statement explaining the reason for the delay.
- 110 Similarly, if it becomes apparent part-way through a step that the RP is unlikely to be able to meet its commitments for that step, then ONR may decide to suspend its assessment work to allow the RP time to gather the information needed for it to proceed. This would however be undesirable, as ONR may need to remobilise its assessment team at the end of the pause.

Regulatory Observations and Regulatory Issues

- 111 In addition to the open reporting described above, the regulators will publish, at regular intervals, all Regulatory Observations (RO) and Regulatory Issues (RI) (see Section 6 for definitions) that are raised throughout GDA, together with information on the RP resolution plans (see below).

Design Acceptance Confirmation

- 112 If ONR provides a DAC to an RP it will mean it is confident that, based on the GDA submissions, the design is capable of being built and operated in Great Britain, on a site bounded by the generic site envelope, in a way that is acceptably safe and secure. This is of course subject to site specific assessment and licensing.
- 113 Where a design has been subject to GDA, a DAC will need to have been provided before ONR will consider granting permission for the start of nuclear island safety-related construction for a power station based on that design. ONR would take the DAC into consideration in assessing the adequacy of the licensee's case for starting such construction.
- 114 One outcome from GDA, following provision of a DAC, is a commitment from ONR not to further assess at the site-specific stage those aspects of the safety and security case already

assessed and accepted at the generic design stage. However if the RP or operator make subsequent generic or site-specific design changes that affect the basis of the GDA outcome, then aspects of the GDA submission affected by such changes may require re-assessment by ONR (see below on the period of validity of the DAC).

Interim Design Acceptance Confirmation

- 115 If, at the end of step 4, the outcome of ONR’s assessment is largely satisfactory then ONR may be able to provide an iDAC. Provision of an iDAC would mean that ONR is confident that the design is capable of being built and operated in Great Britain, on a site bounded by the generic site envelope, in a way that is safe and secure. However, it also means that there are some GDA Issues remaining that need to be addressed to ONR’s satisfaction before nuclear island safety-related construction of a reactor based on that generic design could commence.
- 116 Before an iDAC could be provided the RP would need to demonstrate to ONR that all the GDA Issues are amenable to timely resolution. This would require the RP to submit resolution plans (see below) setting out the work needed to address each issue and how long this would be expected to take.
- 117 Provision of an iDAC would mark the end of ONR’s planned assessment of the submitted safety case (and security provisions) for the generic design, with any subsequent GDA work being focused on resolution of GDA Issues.
- 118 When all of the GDA Issues have been addressed to ONR’s satisfaction and the safety case has been updated, ONR would consider whether a final DAC could be issued.

GDA Issues

- 119 At the end of GDA Step 4 there may remain significant regulatory issues that, while not so serious as to prevent ONR from issuing an iDAC, would need to be resolved before the issue of a DAC. These are called GDA Issues and are uniquely numbered and listed in the iDAC. The successful closing out of all GDA Issues will mark the end of GDA.
- 120 GDA Issues are defined as follows:
unresolved issues judged by regulators to be significant but resolvable, requiring resolution before regulatory permission for the start of nuclear island safety-related construction of such a reactor could be considered.
- 121 The shortfalls set out in each GDA Issue will be known in advance by the RP, as they will have been discussed with ONR during the GDA assessment process. The timescales for each Issue close-out will be dependent on the Issues themselves and the timely provision of technically acceptable responses by the RP.
- 122 When GDA Issues have been addressed satisfactorily, the RP will need to update the GDA submissions to reflect this (including Design Reference, generic PCSR and, where appropriate the environment report) so that these can be referenced in the final DAC. The need for this activity should be included within each resolution plan. ONR may identify the requirement for these submissions to be updated as a GDA Issue in itself, particularly if there are, for example, numerous design modifications that the RP wishes to roll into the final DAC.

Requesting Party resolution plans

- 123 ONR will require resolution plans to be submitted by the RP in response to ROs, RIs and (in the closure-phase following an iDAC) to GDA Issues. The resolution plans should set out the

work the RP needs to do to address the matters raised by ONR and identify how long this work is expected to take. The plans should include the work required to update the GDA submissions (including the Design Reference and generic PCSR)

- 124 Resolution plan contents will vary depending on the topic in question but will need to have sufficient detail to satisfy ONR that all relevant aspects can be addressed within the timeframe identified. Subject to security classification, information on the resolution plans will be published on the Joint Regulators website.
- 125 ONR accepts that the work and timeframe set out in a resolution plan should be treated as indicative since the RP may subsequently choose to adopt an alternative approach to achieving an acceptable safety / security outcome. Where a resolution plan is significantly changed, the relevant information on the Joint Regulators' website will be updated as appropriate.

Legal status of DAC and period of validity

- 126 A DAC represents ONR's expert judgement at the time it is provided. As it relates to a generic design and the associated generic safety and security case, a DAC does not guarantee that ONR will give permission for the start of construction of a nuclear power station based on that design.
- 127 A DAC has no legal status and is not a formal requirement of Great Britain's nuclear licensing regime for new nuclear power stations. Intending nuclear operators could choose to apply directly to ONR for a site licence based on a design which has not been subject to GDA. However ONR expects most intending operators will prefer the proposed design to have acquired a DAC via the GDA process as this is likely to be the most business efficient approach.
- 128 A DAC or iDAC would apply for a period of ten years from the date of issue. This period of validity is consistent with the requirement for licensees in Great Britain to undertake periodic safety reviews of their existing nuclear facilities every ten years. If during that period any new information emerges which calls into question the basis of ONR's original assessment of the design, such as changes to the design basis threat, then ONR would need to consider whether the DAC (or iDAC) remains valid.
- 129 If an RP wishes to seek renewal of a DAC at the end of this ten-year period, ONR will require the RP to review the generic safety and security case in the same manner that a nuclear site licensee would carry out a periodic safety/security review, and report to ONR. DAC renewal should be much less resource intensive than the original assessment, but some design improvements might be needed to gain renewal if these were found to be reasonably practicable at that time, e.g. in the light of emerging international practices or change in the design basis threat (NIMCA).

Residual matters

- 130 GDA is designed to assess the generic safety/security case for future reactor designs; it is not intended to provide a complete assessment of the final reactor design, as there are other factors, operator specific or site-related, that ONR will consider during the site-specific stages. Some aspects of the licensee's safety or case can only be completed when the detailed design of equipment is developed by a manufacturer / supplier, or when the facility is being constructed and is in the process of being tested. Such safety/security case development is normal regulatory business for ONR and is subject to appropriate regulatory controls.

- 131 It is to be anticipated, therefore, that during the course of GDA ONR will identify a number of 'Residual Matters'. Some of these will be identified as Assessment Findings (see below) which ONR will require the nuclear site licensee to resolve when the design is proposed for construction at a particular site. Others will be recorded by ONR assessors as 'Minor Shortfalls' concerning the safety or security case, but which are not considered serious enough to require specific action to be taken by the RP.
- 132 A Residual Matter will be recorded by ONR assessors as a Minor Shortfall if it does not:
- undermine ONR's confidence in the safety or security of the generic design;
 - impair ONR's ability to understand the risks associated with the generic design;
 - require design modifications; and
 - require further substantiation to be undertaken.
- 133 A list of safety or security case Minor Shortfalls will be included in the ONR assessment reports for each topic area at the end of GDA. Following this, ONR will review the totality of reported Minor Shortfalls to identify significant commonalities or groupings which may justify ONR issuing Assessment Findings covering groupings of Minor Shortfalls in specific technical areas.
- 134 ONR's Minor Shortfalls may be of significant value to a future site licensee in developing the generic safety or security case into a robust site specific version. ONR therefore anticipates that the licensee's safety case development team will consider the Minor Shortfalls identified during GDA and take account of them where it considers appropriate. However the precise contents of the site-specific safety/security case will be a matter for the licensee to decide and it would be disproportionate for ONR to expect the licensee to track (or for ONR to monitor) any actions taken to address the identified minor shortfalls.

Assessment Findings

- 135 Residual Matters which are not recorded as Minor Shortfalls will generally be designated as Assessment Findings (AF). These are primarily concerned with the provision of site-specific safety/security case evidence which will usually become available as the project progresses through the detailed design, construction and commissioning stages. AFs may emerge during Step 4 as well as in the GDA Issue closure phase and will be identified in the detailed assessment reports for each technical topic area.
- 136 A Residual Matter will generally be recorded as an AF if one or more of the following apply:
- to resolve this matter site-specific information is required;
 - the way to resolve this matter depends on licensee design choices;
 - the matter raised is related to operator-specific features / aspects / choices;
 - the resolution of this matter requires licensee choices on organisational matters;
 - to resolve this matter the plant needs to be at some stage of construction / commissioning;
 - to resolve this matter the level of detail of the design needs to be beyond what can reasonably be expected in GDA (e.g. manufacturer/supplier input is required; or areas where the technology changes quickly, and so to avoid obsolescence of design).
- 137 Before an ONR assessor raises a matter as an AF, a check will be made for related or repeated AFs arising in other topical areas. Wherever possible, AFs will be consolidated into common 'themes' to facilitate the development by the licensee of a manageable number of AF closure plans.

- 138 It will be the responsibility of the licensee to ensure that AFs are addressed as appropriate during the detailed design, procurement, construction or commissioning phase of a new nuclear power station.
- 139 Assessment Findings will be subject to appropriate control as part of ONR's normal regulatory oversight of new nuclear power station projects and ONR would expect the licensee to address each one in site-specific plans. The target date for resolution of an AF will be a matter for the licensee to determine as appropriate to its project.
- 140 Identifying AFs in GDA alerts future licensees to matters which will require their attention and maximises the time available for them to be addressed. This provides for further reduction in regulatory uncertainty and represents one of the key benefits of the GDA process.
- 141 Other regulatory matters will arise as ONR's site specific assessment progresses. The licensee will be responsible for the completeness and correctness of its safety case, and addressing AFs and other regulatory matters is only one element in the delivery of an acceptable safety or security case.
- 142 Some examples of Assessment Findings are:
- Example AF1: *"The list of Initiating Event Groups in the generic PSA does not meet ONR's expectations in T/AST/030. The licensee should undertake the following actions to clear this finding..."*;
 - Example AF2: *"As part of the commissioning test programme the licensee shall perform a load-follow demonstration or alternatively provide justification of why such testing of plants overseas is applicable to the UK plant"*;
 - Example AF3: *"The licensee shall perform thermal analysis to confirm the timescales for consequential loss of C&I and electrical equipment following loss of [xxx] building HVAC train due to failure of its supply from a) the 690 V and b) the 10 kV switchboards"*.

Section 5 – Additional information on ONR's GDA process

Meaningful GDA

143 In order to be able to provide a DAC, ONR must have completed a 'meaningful assessment'. A meaningful GDA will be one where ONR has:

- received sufficient information on the generic design in the safety and security submissions to allow assessment in all relevant technical topic areas; and
- completed a sufficiently thorough and detailed assessment of that information.

144 In the above:

- 'sufficient information' will have been received if ONR judges that it has been provided with submissions that cover the full scope and depth necessary for ONR to carry out its technical assessments;
- 'thorough and detailed assessment' means that ONR has looked in detail at the submissions and judged them against the SAPs, including the need to demonstrate that risks are reduced, or are capable of being reduced, ALARP. The assessment relates only to the information provided on the generic design and does not mean that ONR has received and assessed all the information necessary to permit construction and operation of a plant, based on that design.

145 The depth and scope of ONR's assessment is unlikely to be the same across all technical areas, as this will depend on the relevance of each area to the safety and security case. However, ONR will need to be satisfied that the sampling assessments it has carried out of the RP's submissions, along with information provided by the RP to resolve technical issues arising during GDA, is sufficient to allow it to make a balanced judgement on the overall acceptability of the generic safety and security case.

146 In order for ONR to be able to provide a DAC, it is vital that the RP provides submissions of high quality, to an agreed timetable. Crucial to the delivery of a meaningful GDA is complete clarity on what documents constitute the RP's GDA submissions, and how the information they contain addresses the requirements in this guidance document.

Assessment topics

147 The scope of ONR's technical assessment will depend on a number of factors including the details of the reactor design under consideration. However, the topic areas listed in Appendix 2 would typically be covered.

Progress decision 'gates'

148 Progress from one GDA step to the next will depend on whether the preceding step has been completed satisfactorily and the ability of the RP to provide sufficient and suitable submissions to enable ONR to complete the next step. Agreement to start an assessment step will depend on ONR being satisfied with timeliness, scope, content and quality of the submissions which have been or are planned to be supplied by the RP.

149 It should be noted that in order to preserve the integrity of step-wise approach to GDA, a step will only be considered for closure when ONR is satisfied that the work scheduled for all technical assessment topics has been satisfactorily completed. Similarly, the next step will only start when work can commence across all technical assessment areas. This is to avoid the planning difficulties and confusion that might arise if assessments in different technical areas were allowed to start at different times.

- 150 If the RP is not ready to begin the next step, then it may request an extension of the current step to allow time for the necessary documentation to be submitted. In the absence of a request from the RP for an extension, ONR may decide to defer the start of the next step until it has received the information it judges necessary to proceed. If a step is paused then ONR may need to reallocate some or all of its technical assessment resource to other projects during the pause; there may be a delay in the resumption of GDA while those resources are remobilised.

Legal duties

- 151 The GDA process is undertaken within the existing nuclear regulatory framework for Great Britain, which is fully described in *Licensing Nuclear Installations* (Ref. 11). The main element of this is the Nuclear Installations Act 1965 (NIA65), which is a relevant statutory provision of the Energy Act 2013. NIA65 sets down the requirement to obtain a nuclear site licence from ONR before installing a nuclear reactor on a site. It is underpinned by the more general Health and Safety at Work Act 1974, which places a fundamental responsibility on duty holders to reduce risk SFAIRP.
- 152 When assessing GDA submissions ONR will also take into account other relevant statutory provisions (as described in Ref. 11) including the Ionising Radiations Regulations 1999 (Ref. 12).

ALARP

- 153 For ONR's safety assessment purposes the terms ALARP and SFAIRP are interchangeable and require the same tests to be applied. ALARP is also equivalent to the phrase '*as low as reasonably achievable*' (ALARA) used by other bodies in radiation protection nationally and internationally.
- 154 ONR's decision-making process is based on the approach described in *Reducing risks, protecting people* (Ref. 13). This includes an explanation of the concept of ALARP and describes the legal requirement in Great Britain to demonstrate that risks are reduced ALARP, such that any further measures to reduce the risk would entail a gross disproportion between the sacrifice (time, trouble and money) and the risk averted by their adoption. The way in which ONR assesses claims from licensees, or RPs, that they have reduced risks ALARP is set out in detail in ONR Technical Assessment Guide T/AST/005 (Ref. 6).
- 155 The development of standards defining relevant good practice often includes ALARP considerations, so in many cases meeting these standards may be sufficient to demonstrate that the design would satisfy legal requirements in Great Britain. In other cases, for example where standards and relevant good practice are less evident or not fully applicable, or the demonstration of safety is complex, the onus will be on the RP to implement risk reduction measures to the point where it can demonstrate to ONR that the costs of any further measures would be grossly disproportionate to the risk averted.
- 156 While meeting good practice is a fundamental requirement for safety cases, this is expected to be supported by a demonstration of how risk assessments have been used to identify any potential weaknesses in the design and operation of the proposed facility, showing where improvements have been considered and to demonstrate that safety is not unduly reliant on a small set of particular safety features.
- 157 In addition, the WENRA documents that set out safety reference levels, safety objectives and common positions for new reactors (Ref 14) can be considered to be relevant good practice and showing that these have been met would be one way of contributing to the demonstration that risks have been reduced ALARP.

158 It is important that the information provided by the RP in the safety case is suitable and sufficient to demonstrate to ONR that risks have been reduced ALARP. As part of this demonstration, the RP will be required to show that the technical standards it has used result in a design in which risk has been reduced ALARP. This will need to include consideration of any updates to those technical standards since the original design and safety analysis were completed.

Safety Assessment Principles

- 159 ONR assessors are guided in their judgement by ONR's SAPs (Ref. 15), which set out relevant good practice for a wide range of nuclear facilities. To ensure consistency with international requirements, the SAPs have been benchmarked against the nuclear safety standards of the International Atomic Energy Agency (IAEA).
- 160 ONR assessors will use SAPs when reaching a judgement on the acceptability of the safety case for the proposed design. The SAPs are not criteria but are an aid to regulatory judgement. Priority is given to achieving an overall balance of safety rather than satisfying each principle or making an ALARP judgement against each principle. The principles themselves are applied in a reasonably practicable manner and the judgement made is always subject to consideration of ALARP.
- 161 Examination of the SAPs will allow RPs to inform themselves of the regulatory principles against which their safety provisions will be assessed and judged by ONR. However, the SAPs have been developed as guidance for assessing safety cases and as such they are not intended, nor are they sufficient, to be used as design or operational standards. Similarly, the SAPs are not sufficient to be used as an outline for, or as the determinant of, the scope and depth of any safety case.
- 162 The RP may choose to enhance their understanding of the basis for regulatory decision making by undertaking their own comparison of the plant's design safety principles against the SAPs. This may allow the RP to anticipate any issues or shortfalls, and to include in their submissions explanations as to how the safety goals underlying the SAPs are met, or by providing evidence that equivalent safety is achieved by other means.
- 163 It is ONR's expectation that any comparison of a safety submission against the SAPs that an RP wishes to present should not form part of a safety submission itself, but would be a separate document. Where such comparisons have been undertaken, these will be of interest to ONR assessors and may be requested.
- 164 RPs should note that not all SAPs are intended for use in nuclear power station assessments, nor are all the SAPs relevant for the GDA process. ONR assessors will therefore use their judgement to evaluate the various aspects of the RP's submission against those SAPs that are relevant. Additional guidance to ONR assessors on interpretation of the SAPs is given in TAGs (see below). It should be noted that ONR assessment will always be based on the latest versions of SAPs and TAGs.

Security Assessment Principles (SyAPs)

** SyAPs and associated supporting TAGs will be published in March 2017 replacing the National Objectives, Requirements and Model Standards. These will form the basis of ONR judgement of the GSR.

Technical Assessment and Inspection Guides

- 165 ONR provides guidance for its inspectors in its TAGs and Technical Inspection Guides (TIGs). These give detailed interpretation of the SAPs and guidance in their application. The SAPs and TAGs are an integrated suite of guidance to ONR's nuclear inspectors carrying out assessment of safety cases and these will be used for GDA. Most of the TAGs and TIGs are published on ONR's website (see Refs 6 and 16), except for a small number that are withheld for security reasons.
- 166 TIGs are mainly aimed at nuclear site inspectors carrying out Licence Condition compliance inspections. However, the GDA process will involve ONR carrying out inspections of the RP's processes, and some of these guides are therefore relevant, in particular NS-INSP-GD-017 *Management Systems* (Ref. 16) which also deals with quality assurance (QA).

Taking account of overseas regulator assessments

- 167 If a reactor design has been subject to assessment by nuclear regulators in other countries, ONR sees great value in being able to draw on such experience, as well as sharing its own experiences. This is an extension of the normal information exchanges that take place between national nuclear regulators through bilateral arrangements and via organisations such as the IAEA, the International Nuclear Regulators Association (INRA), and the Nuclear Energy Agency (NEA) of the Organisation for Economic Cooperation and Development (OECD), in particular through its Committee on Nuclear Regulatory Activities (CNRA). In addition, ONR is participating in the work of the Multinational Design Evaluation Program (MDEP – see www.oecd-nea.org/mdep).
- 168 Throughout the GDA process ONR will seek to take advantage of information arising from regulatory assessments of the design undertaken in other countries. ONR assesses on a sampling basis and therefore the availability of information from assessments carried out elsewhere may enable ONR to concentrate its attention on areas of the design specific to Great Britain.
- 169 However, it should be noted that it is the responsibility of the RP to demonstrate the safety and security of its design, including highlighting and directing ONR to previous outputs and assessments of regulators in other countries, not for ONR to seek out and assemble information from such sources.
- 170 IAEA guidance states that even if a similar design has been authorised in another member state, the national regulatory body should still perform its own independent review and assessment (Ref. 17, paragraph 3.37). The Convention on Nuclear Safety, to which the UK is a signatory, states that each country must undertake safety assessment of its own nuclear facilities and make its own regulatory decisions about the safety of those facilities. In line with these international expectations, ONR therefore undertakes its own assessment of the generic safety case and comes to its own judgements.
- 171 ONR will not necessarily accept that a matter it judges to be of regulatory concern can be considered to be resolved simply because an overseas regulator has considered a similar issue and agreed its resolution. ONR may, as it considers necessary, test the robustness of such claims. ONR's position on this international context is given in Ref. 18.
- 172 The extent to which overseas assessments can be taken into account will depend on a number of factors including:
- the date of the assessment and its continuing validity;
 - the level of detail and the purpose of the assessment;

- the local conditions of use in the country where the assessment was undertaken;
- the depth of information provided by the RP including the evidence of issue resolution;
- whether assumptions (e.g. on plant operating regime) will remain valid if the technology is adopted in Great Britain;
- whether a demonstration can be made satisfying the requirement that the risks have been reduced to a level that is ALARP;
- the scope of ONR's formal information exchange agreements with the particular national regulator;
- ONR's knowledge of the overseas regulatory system; and
- the willingness of the national regulator to engage with ONR on issues of primary interest to Great Britain, including providing access to detailed information.

International guidance

- 173 As they prepare their submissions, RPs may wish to take account of the requirements of IAEA safety and security standards and guides. ONR's SAPs have been benchmarked against these standards to ensure that ONR requirements fully reflect international nuclear safety standards.

Utilities Requirements Documents

- 174 Reactor vendors often claim that their designs are compliant with Utilities Requirements Documents (e.g. US or European). ONR regards these documents as being guidance for the designers and will not endorse the utilities' standards or use them for assessment purposes. ONR will assess the safety of the design using the SAPs.

Regulatory uncertainty

- 175 Although GDA is intended to be a predictable process against a reasonably certain timescale, the outcome and timing depends on certain factors which are out of ONR's control, including the quality of the RP's submissions and their answers to ONR's questions. The assessment timetable given in Table 1 can therefore only be indicative.
- 176 By allowing the completion of elements of the design safety assessment process before major investment in site selection, equipment ordering, manufacture and construction, the GDA process provides a mechanism for reducing regulatory uncertainty for the RP and potential licence applicants, while maintaining the rigour of ONR's regulatory assessment. The process is also designed to facilitate increased public involvement and enhance confidence, both in the regulatory process itself and, ultimately, in any decisions regarding the safety of the proposed design.
- 177 To help provide certainty in the GDA processes, ONR will establish agreements with the RP setting out in detail what it expects from them, as well as the scope of the assessment etc. The detailed working arrangements are set out in an Interface Arrangements document, as described in Section 6 below. ONR will engage with the RP throughout the assessment process, and will provide progress statements. ONR will require the RP to respond to assessment questions within an agreed timeframe.
- 178 While ONR believes that the GDA process offers the potential for a stepwise reduction in regulatory uncertainty, it cannot eliminate the possibility that ONR will require design changes as a result of its assessments during subsequent site specific, detailed design and construction stages.

Safety and security case ownership and involvement of future licensees in GDA

- 179 In Great Britain, the licensee has the ultimate responsibility in law for ensuring the safety and security of the plant. Therefore, the safety and security case produced in GDA must be developed with a potential licensee's legal duties in mind, not as a means to satisfy ONR. By the end of GDA, ONR will expect the generic safety case and security report to be fit for use by a future licensee, and in the site-specific licensing phase, ONR will assess the degree to which the prospective site licensee understands and takes responsibility for the safety and security case.
- 180 In general, DBEIS would expect an RP's request to enter GDA to have support from a prospective licensee wishing to constructing a plant based on the generic design on an identified site (or sites). It is recognised however that GDA may take place well before a prospective licensee has made a final technology choice, and so its involvement in GDA cannot be mandatory. Nevertheless, ONR encourages a prospective licensee to make arrangements with the RP for it to be involved in GDA wherever possible as this will be of significant benefit to them in being able to demonstrate, during the nuclear site licensing process:
- an understanding of the safety case;
 - an understanding of the security case
 - knowledge of the plant's hazards and how to control them;
 - that it can be an intelligent customer for any work it commissions externally; and
 - that it understands the nuclear regulatory framework.
- 181 Although the RP (or that part of it that constitutes the 'responsible designer') has the detailed knowledge of the design, involvement of a prospective licensee will demonstrate intent to transfer knowledge throughout the GDA process. ONR will look for evidence that this knowledge transfer is occurring and that any prospective licensee has plans for incorporation of the GDA information within its site specific safety and security submissions.

Age of design

- 182 If the original reactor design has been frozen or 'fixed' for several years prior to entering GDA, evidence should be provided by the RP that adequate learning has been taken into consideration, including:
- developments in nuclear technology since the design was frozen;
 - operating experience in similar plants elsewhere;
 - significant changes in the design basis threat
 - relevant new research findings; and
 - any other factors arising that may have an impact on the safety and security of the design.

These will be taken into account in ONR's regulatory assessment.

Technical Support Contractors

- 183 It is common practice across all of its operational programmes for ONR to engage specialist contractors to provide technical support to its regulatory assessment. In GDA, ONR may choose to place work packages with contractors, including organisations outside Great

Britain, to help it carry out its detailed technical assessment. However, ONR's decision making during GDA is not contracted out and all regulatory decisions are made by ONR alone, based on its expert judgement.

- 184 ONR will therefore need to make relevant RP documentation, including third party information, available to its technical support contractors, as appropriate, to allow the required technical support to be provided. The costs of any such contracts will be charged to the RP.

Research

- 185 ONR's expectation is that adequate research and technical studies will have already been completed before the start of GDA. These should be made available to ONR by the RP where necessary, including research findings relevant to ONR's assessment for which the RP does not hold the intellectual property rights.
- 186 Factors affecting research requirements include:
- departure from proven technology;
 - uncertainties in performance; and
 - degree of defence-in-depth.
- 187 ONR may carry out its own confirmatory research, using external contractors, to support its regulatory decisions, and the costs of such research will be charged to the RP. Factors affecting the need for such research include:
- knowledge and experience with the technology in Great Britain;
 - issues arising from early steps of the safety case assessment;
 - other research and development programmes, including research information from overseas regulators who have reviewed the design.

Review of decision

- 188 Where an RP is dissatisfied with a decision by ONR it may make representations to the appropriate ONR decision maker and their line management, and ultimately to the Chief Nuclear Inspector. If the RP remains dissatisfied it may request a formal review by ONR of the process by which the decision was made. This decision review process is set out in Ref 19.

Section 6 - Project management and administration

Joint Programme Office

- 189 The co-ordination of the GDA processes undertaken by the two nuclear regulators (ONR and the Environment Agency) is described in a top-tier guidance document: *New nuclear power stations Generic Design Assessment: A guide to the regulatory process* (Ref. 1). To help administer both regulators' GDA process, a Joint Programme Office (JPO) has been set up. The JPO provides a single point of contact between the RP and the regulators.

Interface arrangements

- 190 An interface document will be developed by the regulators during Step 1 setting out the working arrangements with the RP. This will set out the agreed system for transmission and tracking of submissions, correspondence, meetings, and issue tracking.
- 191 The interface document will also identify that a system of metrics will be used to indicate the performance of ONR and the RP against the agreed GDA programme, and this will be published as part of ONR's regular progress reporting. The interface document will be agreed with the RP in Step 1.
- 192 The RP will also be required to agree, in Step 1, to a Regulatory Nuclear Interface Protocol that addresses the essential values and behaviours expected in all interactions between the RP and the regulators. These values and behaviours facilitate the achievement of effective ways of working and are expected to apply throughout GDA.

Requesting Party project office

- 193 The RP will be expected to establish an office in Great Britain for the day-to-day management of its GDA project, and for interfacing with ONR. The majority of project and technical meetings should take place in Great Britain. All of the GDA documentation, which should be in English, including any protectively marked documents, must be made available to ONR (and its technical support contractors, as required), via the JPO in ONR's headquarters in Merseyside UK.

Regulatory Questions

- 194 A management system for handling regulatory questions will be agreed with the RP and set out in the interface arrangements. This will use a tiered approach as follows:
- Regulatory Query – RQs are requests by ONR for clarification and additional information and are not necessarily indicative of any perceived shortfall;
 - Regulatory Observation – an RO is raised when ONR identifies a potential regulatory shortfall which requires action and new work by the RP for it to be resolved. Each RO can have several associated Actions. ROs will be published on the Joint Regulators website;
 - Regulatory Issue – an RI is raised when ONR identifies a serious regulatory shortfall which has the potential to prevent provision of a DAC, and requires action and new work by the RP for it to be resolved. Each RI can have several associated Actions. RIs will be published on the Joint Regulators website.
- 195 RQs, ROs and RIs may be raised jointly by ONR and the Environment Agency where the matters concerned are relevant to both regulators.

- 196 It is possible that a question raised as an RQ could escalate to an RO or to an RI if it is not satisfactorily addressed by the RP.

Recovery of ONR costs

- 197 The RP will be required to pay all ONR costs in connection with the GDA. The arrangements for cost recovery will be agreed with the RP before work begins on Step 1.

Section 7 - Interface between GDA and nuclear site licensing

Nuclear site licence assessment

- 198 The GDA process is not mandatory and a prospective licensee may choose to submit a site licence application for a design that has not been subject to GDA. However, ONR expects the GDA process to be followed by most prospective power station licensees as this is likely to be a more business efficient approach. In either case, ONR would undertake a rigorous assessment of the proposed design before considering a request to start construction.
- 199 Where GDA has been followed, ONR's assessment of an application for a nuclear site licence will consider the site-specific design taking full account of the assessments undertaken throughout GDA. In addition ONR will consider the suitability of the site for the proposed design, as well as the organisational structure, governance arrangements and capabilities of the prospective licensee.
- 200 It is likely that there will need to be a significant period of discussion between the intending licence applicant and ONR during which the applicant will prepare the licence application documents and will develop its organisational capabilities and competences. Such a period could typically be between 18 months and two years. If the applicant subsequently provides detailed and adequate submissions, ONR's assessment of that application could take between 12 to 18 months.
- 201 The safety case submissions for licensing assessment may reference and incorporate the documentation submitted in GDA with additional site-specific information. In addition:
- site-specific aspects not covered by the generic site envelope will need to be assessed; and
 - proposed changes to the generic design would also need reassessment on a case-by-case basis.
- 202 Guidance on applying for a nuclear site licence is given in Licensing Nuclear Installations (Ref. 11). Potential site licence applicants are encouraged to contact ONR as early as possible to discuss the process.

Nuclear Site Security Plan

- 203 For security aspects, the overall aim of GDA is for the RP to develop an acceptable generic security report to allow close out. This report would provide the basis for the Nuclear Site Security Plan.

Design variants

- 204 The future operator may wish to vary aspects of the generic design that was the basis for a DAC to meet its particular needs, and such design changes would need reassessment on a case-by-case basis. However, ONR considers that ALARP arguments are likely to lead to a high degree of standardisation in a series of reactors based on the generic design.

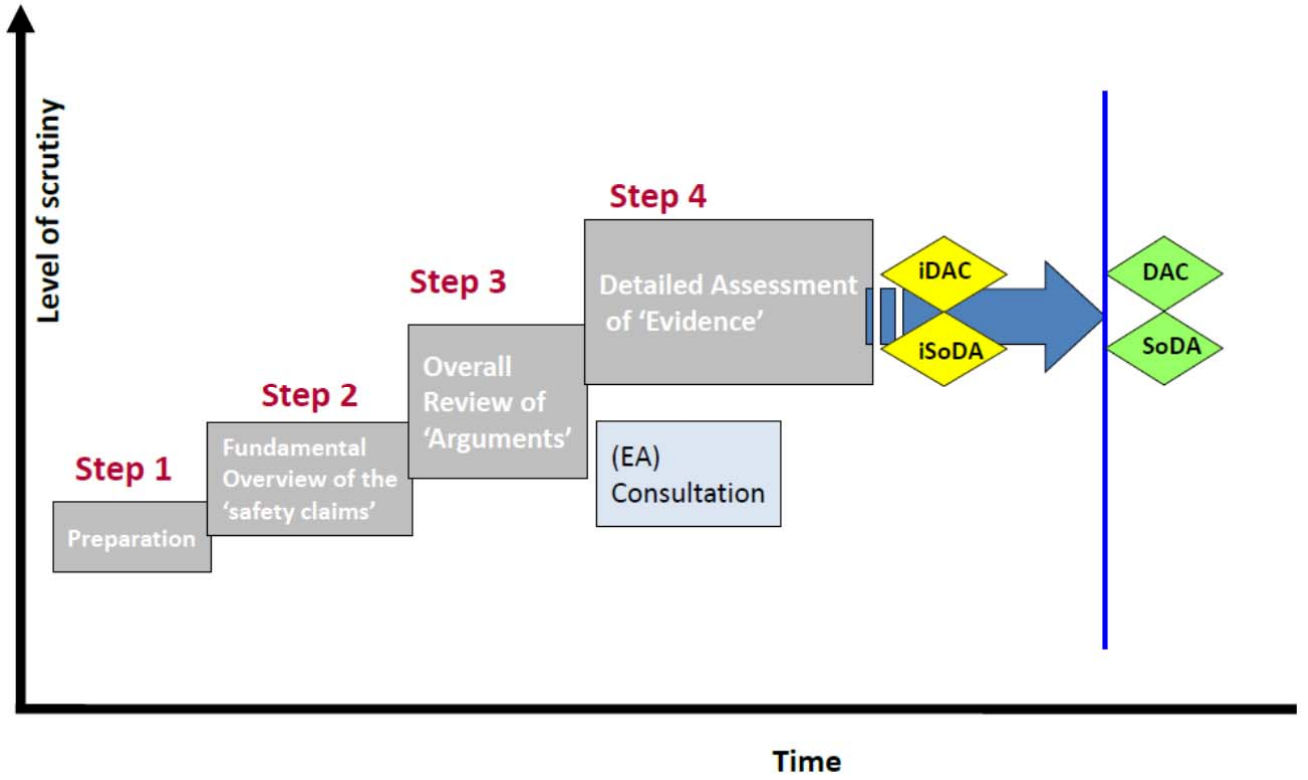
Transfer of knowledge from vendor to licensee

- 205 The nuclear site licence requires that the licensee is fully in control of activities on its site, understands the hazards of its activities and how to control them, and is an intelligent customer for any work it commissions externally. This requires the licensee to have suitably qualified, and experienced staff undertaking all activities that could affect safety on the site.
- 206 The licensee will need to put in place a Design Authority, and to establish a process for the transfer of knowledge from the designer. Ref 10 provides guidance on design authority aspects.
- 207 Usually, expert knowledge will initially rest with the RP and an appropriate strategy to transfer knowledge and information to a potential licensee will need to be in place before an application is made for a nuclear site licence. While GDA is underway, prospective licensees will have an opportunity to develop their competences, build up qualified and experienced staff, and to ensure the necessary transfer of knowledge from the RP. ONR will expect knowledge transfer from the RP to be well advanced by the time the nuclear site licence application is made.

Relationship of Generic Design Assessment and site-specific detailed design, construction and commissioning

- 208 A successful GDA outcome does not guarantee that ONR will permit the start of construction of a nuclear power station based on that design. That will depend on ONR being satisfied that the licensee's site-specific safety and security submissions justify the start of construction. A site licence may have been granted before GDA is completed, but the licensee will need to show that a DAC has been issued for the proposed design before regulatory consideration is given to granting consent, under the site licence, for nuclear island safety-related construction.
- 209 ONR will expect the final GDA submission documentation to be incorporated largely unchanged within the licensee's site-specific Pre-construction Safety and Security Reports, supplemented as necessary with detailed site-related information. When preparing GDA submissions the RP should write them in such a way that they can be readily useable by a future licensee as part of a site specific safety or security case.
- 210 To improve the efficiency of ONR's site-specific assessment work, it is essential that the licensee ensures that information derived from GDA is clearly identified in its submissions.
- 211 Similarly, the licensee will need to put in place a process to address any GDA Assessment Findings during the detailed design, procurement, construction, testing and commissioning programme.
- 212 It is anticipated that a DAC will be used to underpin the regulatory permissions needed by one or more operators to construct a number of reactors based on a common design. This is a key advantage of the GDA process.

Appendix 1: The Generic Design Assessment Approach



Appendix 2: Typical assessment topics

The scope of ONR's technical assessment will depend on a number of factors including the details of the reactor design under consideration. Although ONR will take an integrated approach to its assessment of the safety case, the following are typical of the technical areas that will need to be covered.

Internal Hazards

ONR's safety assessment within this topic would typically include hazards such as fire, explosion, flood, dropped loads, pressure part failure, and steam release etc. within the reactor buildings. ONR would consider the adequacy of: the identification of hazards; prevention of hazards; and the protective barriers, segregation, separation, and active protection systems that are included within the design to provide mitigation in the event that such internal hazards should occur.

Civil Engineering and External Hazards

ONR's assessment of civil structures would normally include consideration of the integrity of structural components such as steel-framed buildings, concrete structures such as walls and the containment, and the reactor building foundations.

ONR's assessment of external hazards would typically include those natural or man-made hazards that originate externally to both the site and the process and over which the operator has little control. External hazards include earthquake, aircraft impact, extreme weather, and flooding, and the effects of climate change. Terrorist or other malicious acts are also assessed as external hazards.

Probabilistic Safety Analysis

ONR would examine the RP's PSA in detail. PSA is an integrated, structured, logical safety analysis that combines engineering and operational features in a consistent overall framework. It is a quantitative analysis that provides indications of the overall risk to the public that might result from a range of faults (for example, failure of equipment to operate, human errors, or hazards such as fires). PSA enables complex interactions, for example between different systems across the reactor, to be identified and examined and it provides a logical basis for identifying any relative weak points in the proposed reactor system design.

Fault Studies, Transient Analysis and Severe Accidents

Fault Studies and Transient Analysis

ONR's assessment would include the transient analysis and fault studies, which are the safety analyses of nuclear reactors on matters such as reactor core physics, thermal hydraulics, heat transfer and a wide range of other physical phenomena under steady state, transient and fault conditions. Fault analysis involves a detailed study of the reactor system, its characteristics and mode of operation, with the aim of identifying possible faults that might occur and lead to the release of radioactive material. This is followed by a thorough examination of the conditions brought about by those faults. In particular, for those conditions that might affect the integrity of the nuclear fuel, the aim is to demonstrate the adequacy of the engineered protection systems in preventing a release of radioactive material.

Severe Accidents

Included within the fault studies area is the topic of severe accident analysis. Here ONR would typically look at safety arguments for challenges to the containment from high pressure or temperature in accident conditions and design features that are provided to cope with events such as core melt.

Control and Instrumentation (C&I)

Control systems are typically those that are used to operate the plant under normal conditions and reactor protection systems are those safety systems that are used to maintain control of the plant if it goes outside normal conditions, including during maintenance. ONR's assessment in this topic area would include reviews of both hardware and software aspects of these systems.

Electrical Engineering

Many of the important systems on a nuclear power station require electrical power for their operation (pumps, valves, etc). Therefore, the safety assessment in this topic area typically would cover the engineering of the essential electrical power supply systems, examine these under a wide range of transient and fault conditions, and consider their likely reliability, and the performance of protection devices.

Fuel Design

Within this topic ONR would typically look at the performance of the reactor fuel under a wide range of in-reactor and storage conditions, both in normal operation and in fault conditions.

Reactor Chemistry

ONR's assessment would normally include the effects of coolant chemistry on pressure boundary integrity, fuel and core component integrity, fuel storage in cooling ponds, radioactive waste (generation, accumulation, treatment and storage), and radiological doses to workers.

Radiation Protection

ONR's assessment would consider the radiation doses to workers and the public, the adequacy of engineering controls (such as material selection or radiation shielding), measures to control radioactive contamination, and criticality safety.

Mechanical Engineering

ONR assessment would typically include the essential mechanical items important to the plant's safety such as pumps, valves, lifting equipment including cranes, fuel handling equipment, ventilation systems etc. It also includes the layout and routing of the mechanical equipment and systems to ensure that appropriate maintenance regimes can be developed, and that equipment is protected from hazards and degradation. This assessment topic would also consider the capability of the systems to deliver their functions.

Structural Integrity

This topic includes ONR's assessment of nuclear safety-related metal pressure vessels, piping, other structural components and their supports, including material selection, design, fabrication, in-manufacture examination and testing, the analysis of structural integrity under normal load and faulted conditions (including fracture mechanics based analyses), and lifetime ageing of materials assessment (including effects of neutron irradiation).

Human Factors

ONR's assessment of the human factors (HF) aspects would examine the feasibility and acceptability of the claims for human actions that are needed to contribute to safety, the vulnerability to human errors, the adequacy of the (generic) Human Reliability Analysis, and the engineering systems' maintenance reliability from a HF perspective. This would be complemented by a broader holistic assessment across a range of important HF aspects.

Management of Safety and Quality Assurance (MSQA)

ONR's assessment would examine the RP's QA and Management of Safety organisational and procedural arrangements to deliver the GDA safety and security submissions. This would also include examination of the control and updating of the GDA submissions, including the arrangements for freezing and updating the Design Reference.

Radioactive Waste and Spent Fuel Management

ONR's assessment would examine the proposals for the safe minimisation, handling, storage and disposal of radioactive waste arising from all parts of the power station, and would include the proposals for decommissioning and wastes arising.

Chemical (Process) Engineering

Chemical (Process) Engineering is a bridging discipline which relates many specialist areas to give an overall view of a process. ONR's assessment would typically examine the RP's approach to chemical engineering design, hazard identification, process selection and optioneering. It may also include assessment of nuclear safety related pressure systems, control systems and equipment providing containment of radioactive material.

Design for Decommissioning

New nuclear power stations should be designed and operated so that they can be safely decommissioned, with decommissioning being carried out as soon as is reasonably practicable after final shutdown. ONR's assessment will include the examination of the RP's design for safe decommissioning and its generic decommissioning strategy for the station.

Cross-cutting Topics

Certain safety aspects cut across a number of different technical topic areas and so these are managed in a transverse manner. Examples might include:

- Definition of the Design Reference.
- Design changes.
- Safety Function Categorisation and Safety Classification of SSCs.
- Operating Limits and Conditions and Examination, Maintenance, Inspection, and Testing.
- ALARP
- Lessons learnt from the Fukushima accident.

Security

Under this topic ONR would consider whether the security protection provided on the nuclear power station is adequate to protect against the theft of nuclear or other radioactive materials or sensitive nuclear information or the sabotage of facilities from both external adversaries and insiders.

Conventional Safety and Fire

ONR's assessment would consider aspects of the design that might impact on conventional (i.e. non-nuclear) safety during construction, operation and decommissioning of the power station, on COMAH (Control of Major Accident Hazards regulations) and compliance with fire safety regulations (includes compliance with the general requirements of the Health and safety at Work etc Act 1974, the Construction (Design and Management) Regulations 2007, and the Regulatory Reform (Fire Safety) Order 2005).

Appendix 3: The generic site envelope

Although many details of a power station design will be independent of the location chosen for its construction, some assumptions about the characteristics of the plant's environment must be considered in developing the design of certain safety-related features. To ensure that a design submitted for GDA will be suitable for construction on a variety of sites within Great Britain, the RP should specify the 'site envelope' within which the plant is designed to operate safely. The definition of the site envelope can be as broad or narrow as the RP wishes. However, it should be unambiguous and specify any site-related characteristics which have been explicitly included within or excluded from that definition.

If a subsequent site licence application is made for a site which has characteristics bounded by the generic site envelope then the time taken for ONR's licensing assessment will be minimised. If the intended site has characteristics which lie outside the generic site envelope, the applicant will need to demonstrate that the proposed plant is acceptable at the intended site; this may involve additional safety analysis and / or plant redesign.

This note provides a brief overview of ONR's expectations for a generic site envelope:

- **Heat sink**

The type and capacity of potential heat sinks should be specified.

- **Grid connections**

Assumptions about the type and reliability of grid connections should be identified. The need to satisfy the UK Grid Code should also be taken into account.

- **Density and distribution of local population**

When considering the generic site envelope, account should be taken of factors that might affect the protection of individuals and populations from radiological risk. Key factors include assumptions about the local population distribution and density, and the provision for effective emergency preparedness and accident management.

Assumptions regarding the density and distribution of the local population should also take account of UK Government policy on determining the strategic suitability of potential nuclear sites in Great Britain. The current Government policy is given in the National Policy Statement for Nuclear Power Generation (Ref. 20)

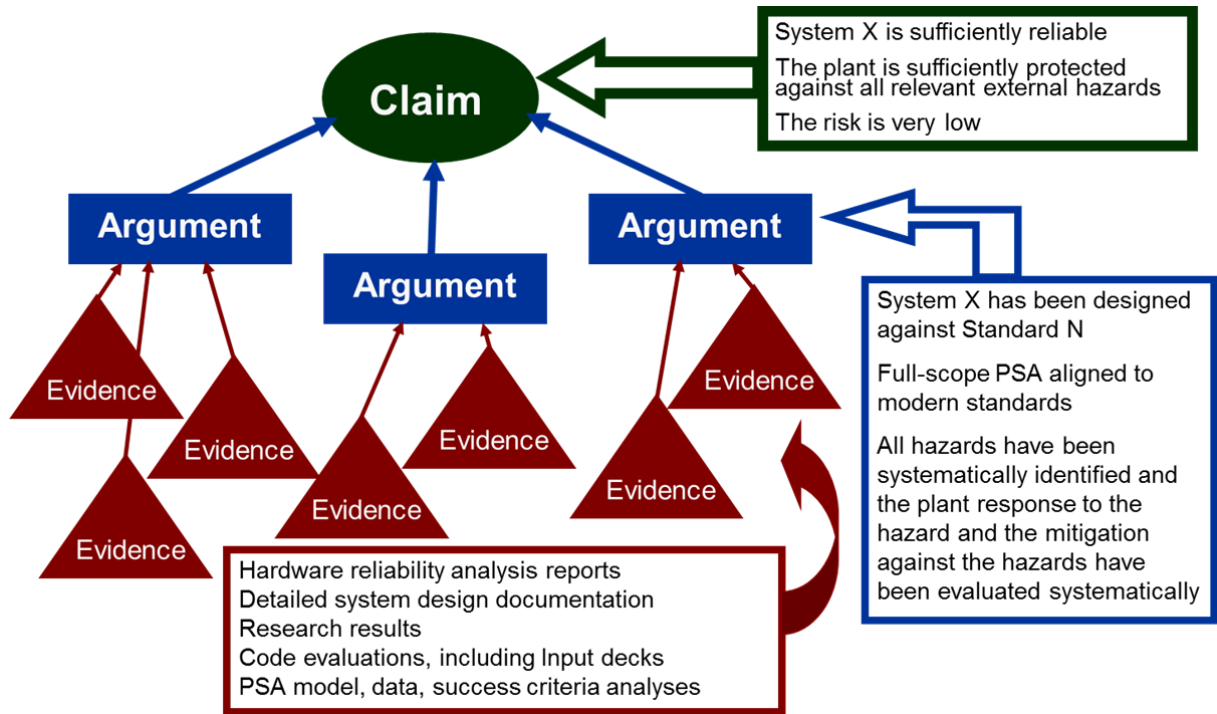
- **External hazards**

External hazards that could affect the safety of the plant should be identified and treated as events that can give rise to possible initiating faults. The RP should demonstrate that an effective process has been applied to identify typical external hazards and potential environmental changes such as climate change (e.g. a change in sea level) which may affect sites in Great Britain. Foreseeable variations in these factors during the expected lifetime of the site should be identified and taken into account. Further guidance is available in ONR's SAPs.

For a generic list of external hazards that may influence the plant design see WENRA report Safety of new NPP designs (Ref. 14). Also, refer to TAG T/AST/013 (Ref. 6). The sensitivity of the design to the magnitude of external hazards should be well understood. This will be particularly important at the site-specific application stage, where a rigorous comparison of the generic site envelope against the characteristics of the proposed site will be undertaken.

Appendix 4: Safety Case structure - the Claims-Arguments-Evidence chain

The following diagram illustrates the claims-arguments-evidence structure for safety case submissions for an engineered system.



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While every effort has been made to ensure the accuracy of the references listed in this report, their future availability cannot be guaranteed.

Glossary and abbreviations

ALARP	As Low As Reasonably Practicable
C&I	Control and Instrumentation
CNRA	Committee on Nuclear Regulatory Activities (of the OECD-NEA)
DAC	Design Acceptance Confirmation
DBA	Design Basis Analysis
DBT	Design Basis Threat
DECC	Department of Energy and Climate Change
GDA	Generic Design Assessment
GSR	Generic Security Report
HSE	Health and Safety Executive
HSWA74	Health and Safety at Work etc. Act 1974
IAEA	International Atomic Energy Agency
iDAC	Interim Design Acceptance Confirmation
ILW	Intermediate Level Waste
INRA	International Nuclear Regulators Association
JPO	Joint Programme Office
LLW	Low Level Waste
MDEP	Multinational Design Evaluation Programme
MSL	Master Submission List
NDA	Nuclear Decommissioning Authority
NEA	Nuclear Energy Agency (of the OECD)
NIMCA	Nuclear Industries Malicious Capabilities (Planning) Assumptions
OECD	Organisation for Economic Cooperation and Development
ONR	Office for Nuclear Regulation
ONR (CNS)	Civil Nuclear Security Programme (part of the Office for Nuclear Regulation)
PCSR	Pre-construction Safety Report
PRA	Probabilistic Risk Analysis
PSA	Probabilistic Safety Analysis
PSR	Preliminary Safety Report
QA	Quality Assurance
RI	Regulatory Issue
RO	Regulatory Observation
RP	Requesting Party
RQ	Regulatory Query
SAP	Safety Assessment Principles
SNI	Sensitive Nuclear Information
SFAIRP	So far As Is Reasonably Practicable
SoDA	Statement of Design Acceptability (Environment Agency)

SSC	Structures, Systems and Components
TAG	Technical Assessment Guide
TSC	Technical Support Contractor
WENRA	Western European Nuclear Regulators' Association
VA	Vital Area

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