



New Nuclear Power Plants: Generic Design Assessment Guidance to Requesting Parties

ONR-GDA-GD-006 Revision 0
October 2019



© ONR 2019

The text of this document (this excludes, where present, the Royal Arms and all departmental or agency logos) may be reproduced free of charge in any format or medium provided that it is reproduced accurately and not in a misleading context.

The material must be acknowledged as Office for Nuclear Regulation copyright and the document title specified. Where third party material has been identified, permission from the respective copyright holder must be sought.

Any enquiries regarding this publication should be sent to us at onr@onr.gov.uk

This publication is available at www.onr.gov.uk

ABBREVIATIONS AND GLOSSARY

ALARP	As Low As Reasonably Practicable	
ANT	Advanced Nuclear Technology	<p>ANTs encompass a wide range of innovative nuclear reactor technologies, including Small Modular Reactors (SMRs) and Advanced Modular Reactors (AMRs):</p> <ul style="list-style-type: none"> • The term AMR is used to refer to Gen IV-type reactors which use novel cooling systems or fuels to offer new functionality (such as industrial process heat). • The term SMR is used to refer to Generation III water-cooled reactors, similar to existing nuclear power station reactors but on a smaller scale.
BEIS	Department for Business, Energy and Industrial Strategy	
DAC	Design Acceptance Confirmation	A potential GDA output. Section 2.8
DR	Design Reference	Section 3.5
DRP	Design Reference Point	Section 3.5
FSyP	Fundamental Security Principle	
GB	Great Britain	
GDA	Generic Design Assessment	
GDA Statement		A potential GDA output. Section 2.8
GSR	Generic Security Report	
GTGA	Government to Government Assurance	GTGAs need to be in place to enable relevant export licences to be obtained
HSWA	Health and Safety at Work etc. Act 1974	
IAEA	International Atomic Energy Agency	
JPO	Joint Programme Office	
NISR	Nuclear Industries Security Regulations 2003 (as amended)	
NPP	Nuclear Power Plant	A nuclear power plant is a facility that converts the energy release by nuclear fission into usable power, usually electricity (although it can also provide non-electric uses of energy)
NSSP	Nuclear Site Security Plan	
ONR	Office for Nuclear Regulation	
PCSR	Pre-Construction Safety Report	

RI	Regulatory Issue	A type of regulatory question. Section 5.6
RO	Regulatory Observation	A type of regulatory question. Section 5.6
RP	Requesting Party	Those parties who request to undertake a GDA. Section 1.1
RQ	Regulatory Query	A type of regulatory question. Section 5.6
SAP	Safety Assessment Principle	
SNI	Sensitive Nuclear Information	
SoDA	Statement of Design Acceptability	Environment Agency equivalent to a DAC
SyAP	Security Assessment Principle	
TAG	Technical Assessment Guide	
TIG	Technical Inspection Guide	
WENRA	Western European Nuclear Regulators Association	

TABLE OF CONTENTS

1 INTRODUCTION 7

2 THE GENERIC DESIGN ASSESSMENT PROCESS 11

3 SAFETY AND SECURITY DOCUMENTATION 24

4 ONR ASSESSMENT 33

5 FACILITATING GENERIC DESIGN ASSESSMENT 40

6 REFERENCES 43

APPENDIX 1: THE GDA PROCESS 45

APPENDIX 2: STEP 1 - INITIATION..... 46

APPENDIX 3: STEP 2 - FUNDAMENTAL ASSESSMENT..... 51

APPENDIX 4: STEP 3 - DETAILED ASSESSMENT 55



Introduction

1 INTRODUCTION

1.1 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 new Nuclear Power Plants (NPP). This process will be applied where ONR is asked to assess a proposed design in advance, or in parallel to an application for a nuclear site licence.
2. This document is primarily intended to inform those parties who request such an assessment (the 'Requesting Party' (RP)). The RP will normally be the vendor for a NPP, although it may also be a consortium including the vendor and other partner organisations. The term RP is therefore used throughout this document to identify the organisation(s) undertaking GDA, irrespective of its composition.
3. The objective of this guidance document is to provide a RP with clarity regarding:
 - the GDA process and indicative timescales;
 - ONR's requirements to enable progress through the GDA Steps;
 - the outputs from undertaking a GDA; and
 - the principles that ONR will apply when judging the adequacy of the RP's submissions.
4. The environment protection aspects of the generic design are assessed by the Environment Agencies with which ONR works closely in GDA. There is separate guidance (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 updated guidance to RPs on its GDA process (Ref. 2).

1.2 BACKGROUND

5. ONR is the independent regulator of safety and security at nuclear licensed sites in Great Britain (GB). It also regulates radioactive materials transport and ensures that nuclear safeguards obligations for the UK are met. ONR's mission is to provide efficient and effective regulation of the nuclear industry, holding it to account on behalf of the public.
6. The GDA process was developed in response to the Government's 2006 Energy Review; in particular lessons learned from experience with new NPPs indicated that 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 address any potential regulatory uncertainty for a future site licensee wishing to build such a design. Although GDA is not a mandatory process, because of its inherent benefits, it is expected that it will usually be requested for new NPPs intended for construction in GB.
7. The first round of GDA started in 2007 when ONR and the Environment Agency began assessment of four designs, although two of these first round designs were withdrawn by the RP part-way through the assessment process. The remaining two designs, the EDF and AREVA UK EPR™ and the Westinghouse AP1000® designs, subsequently completed GDA in 2012 and 2017 respectively (noting the latter included a pause of several years). In 2013 the Hitachi-GE UK ABWR entered the GDA process and this was completed in 2017. Also in 2017, the CGN/EDF/GNI UK HPR1000 started a GDA.

1.3 OBJECTIVE OF THE GENERIC DESIGN ASSESSMENT PROCESS

8. GDA is designed to offer a number of advantages for both the regulators (ONR and the Environment Agency) and the RP.

The objective for GDA is to provide confidence that the proposed design is capable of being constructed, operated and decommissioned in accordance with the standards of safety, security and environmental protection required in GB. For the RP, this offers a reduction in uncertainty and project risk regarding the design, safety, security and environmental protection cases so as to be an enabler to future licensing, permitting, construction and regulatory activities.

9. This is achieved by:

- enabling the regulators to interact with designers at an early stage, where they can have maximum beneficial influence. Any 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;
- employing a stepwise process, with the assessment becoming increasingly detailed at each Step. This allows the regulators 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;
- being open and transparent regarding both the RP's design and submissions, and the regulators assessments. Both the RP and the regulators will publish detailed information and the RP will promote a public comments process; and
- distinguishing between generic and site-specific matters. This is particularly beneficial where a generic design is intended for construction on a number of different sites or where such detailed information is not yet available to the RP.

10. Other key features of the GDA process are that it:

- gives the RP the earliest possible opportunity to demonstrate that a design is capable of meeting the legal requirements of GB;
- facilitates a rigorous assessment by the regulators;
- will be completed within reasonable and defined timescales, subject to the provision of timely, quality and complete submissions by the RP;
- facilitates efficient and effective joint working between the regulators;
- gives clarity to the regulators requirements, processes and timescales;
- has clear regulatory outcomes; and
- leads to generic safety, security and environmental protection cases which can be used as part of subsequent licensing, permitting, construction and future regulatory activities.

1.4 UPDATES TO THIS GUIDANCE

11. ONR's 'Guidance to Requesting Parties' was first published in 2007. This has been updated a number of times to take into account the experience gained by ONR throughout GDA. The current revision (Ref. 3) is being used to undertake the assessment of the CGN/EDF/GNI UK HPR1000 design.
12. This guidance has been produced for all future GDA activities. In addition to incorporating the latest lessons learned, it considers the changes in the nuclear industry in the decade since GDA was devised, in particular the recent nuclear sector deal (Ref. 4) and the potential for more mature Advanced Nuclear Technologies (ANTs) to enter GDA in the short term. While large portions of the text within this guidance remain unchanged, a number of improvements have been made to enhance

the efficiency and flexibility of the GDA process, whilst maintaining the high standards of safety and security achieved previously and the robustness of the regulatory decision making. The key improvements include:

- conducting the assessment over three Steps, together with amending the emphasis and focus of the assessment during each Step;
- ensuring that greater emphasis is placed on earlier engagement, agreement of scope and of submissions to be submitted throughout the process;
- enhancing the flexibility in the assessment activities conducted by ONR;
- introducing additional outputs from the GDA process;
- making explicit the opportunities to make better informed and more effective use of existing safety and security documentation prepared for overseas regulators, supplemented so as to meet ONR's regulatory expectations;
- providing better integration of safety and security requirements;
- capturing lessons learned at the technical assessment topic level in additional guidance; and
- simplifying and improving clarity.

13. The Tables in Appendix 2 to 4 are a key part of this guidance. They summarise ONR's requirements for each of the GDA Steps to allow the RP to become familiar with these before entering and throughout any GDA. This will give the RP the greatest opportunity to provide quality documentation that meets these expectations in a timely manner.



The Generic Design Assessment Process

2 THE GENERIC DESIGN ASSESSMENT PROCESS

2.1 OVERALL PROCESS AND TIMESCALES

14. From its inception, GDA was designed to progress in Steps, allowing for a progressive development of the RP's generic safety and security cases, alongside ONR's assessment, with ONR reporting progress upon completion of each Step. For the RP this offers a reduction in regulatory uncertainty and project risk regarding the design and safety and security cases. Furthermore this should provide greater certainty for the future operators and their investors before major financial commitments to a site-specific project are made.
15. GDA has 3 Steps which represents the most efficient way for ONR to conduct the assessment. This is based on the scope and content for each Step as detailed later in this guidance (Appendix 2 to 4). The overall intent is that:
 - Step 1 is the initiation Step where matters such as the scope and timescales are agreed, and ONR's knowledge of the design and the RP's safety and security cases increases. Importantly, this Step includes the RP identifying any immediate gaps in meeting regulatory expectations and proposing how these will be subsequently resolved;
 - Step 2 is the fundamental assessment of the generic safety and security cases, to identify any potential 'showstoppers' that may preclude deployment of the design; and
 - Step 3 is the detailed assessment of the generic safety and security cases on a sampling basis.
16. Step 1 will be preceded by the administrative work necessary to start a GDA. Notably, this includes the agreement enabling ONR to recover its costs from the RP, and for the RP to provide assurances regarding the viability of the GDA process for the proposed design. The timescales for these activities are largely outside of ONR's control, and driven by the RP and GDA entry arrangements set by the UK government.
17. The GDA process is summarised in Table 1, along with indicative ONR's assessment timescales. The process is shown schematically in Appendix 1.

Table 1 – The GDA Process Timescales

Step	Description	Indicative ONR Assessment Timescales
1	Initiation	12 months
2	Fundamental	12 months
3	Detailed	24 months
-	Resolution of GDA Issues*	Agreed between ONR and the RP

* Note: It is ONR's expectation that such a period will only be necessary by exception, and should not routinely form part of any GDA

18. The timescales in Table 1 are indicative based on past experience and assume that ONR's requirements detailed in Appendix 2 to 4 are fully met; target assessment timescales would be agreed between ONR and the RP during Step 1. The actual timescales will depend on factors such as:
 - the agreed GDA scope;
 - the maturity of the generic design;
 - the content, quality and timeliness of the RP's submissions;

- the capability and resourcing of the RP's organisation;
 - the significance of any issues identified during ONR's assessment;
 - the responsiveness of the RP to ONR's challenges and questions;
 - the availability of sufficient ONR's resources;
 - access to relevant information from overseas nuclear regulators; and
 - ONR's knowledge of similar 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 insufficient quality then this may cause delays to the completion of that Step.
20. There may be instances where a further period of assessment is necessary (after Step 3) to resolve some residual safety and/or security concerns (known as GDA Issues, Section 2.8.3). An important objective of GDA is to identify such matters early, so that resolution can be progressed during GDA. If necessary, the timescales for this additional work are largely driven by the scope and nature of the activities required to resolve these matters, and would need to be agreed between ONR and the RP on a case by case basis. ONR would expect that the duration of these activities is minimised.
21. At the end of each Step, ONR will provide an output which summarises its regulatory position at that point in time, in addition to supporting assessment information. Which of these outputs is provided will vary in accordance with the Step, and the nature of the assessment undertaken. The outputs are:
- GDA Statement
 - interim Design Acceptance Confirmation (iDAC)
 - Design Acceptance Confirmation (DAC)
22. These are described further in this guidance (Section 2.8). The outputs that are expected to be provided (upon successful completion) will be agreed between ONR and the RP as part of Step 1, based upon the agreed GDA scope.

2.2 AGREEMENT OF GDA SCOPE AND OUTPUTS

23. A key aspect to be discussed and agreed during Step 1 is the 'GDA scope'. In this context the GDA scope refers to the boundaries of the assessment. This will need to include factors such as what systems, structures or components or technical assessment topics are considered, and at which Step the GDA is proposed to conclude. It does not extend to include the detailed content of specific documents, for example.
24. It is expected that most RPs would undertake a GDA with the objective of achieving a DAC, as for all previous GDAs completed to date. This provides the RP with the opportunity to address the most significant safety and security aspects. As a consequence this offers the largest reduction in the uncertainty and project risks associated with the regulatory process for the proposed design, providing greater certainty for the intended operators and potential investors.
25. However, it is acknowledged that some RPs may not wish, or may not be able to target achieving a DAC at the commencement of a GDA. While this would not lead to the same level of reduction in uncertainty and project risk associated with the regulatory process as achieving a DAC, it may be better aligned with their overall project requirements. Such an approach is not precluded by the GDA process, but would be subject to the agreement of ONR. The decision to accept the scope, or otherwise, will be based on consideration of whether the assessment can be considered 'meaningful',

including whether the deployment of regulatory resource is warranted, as described in more detail later in this guidance (Section 4.1). It is important to note that the decision to undertake, and continue, a GDA is made solely by the regulators, and is separate from the request by the UK government to commence a GDA (Section 2.5). An important consideration in deciding on whether the proposed GDA scope is meaningful is whether the design, safety and security cases are sufficiently mature that the risk of ONR becoming part of the RP's design process is minimised. Therefore, there will be some proposed GDA scopes that ONR may not consider meaningful, and therefore it would not consider undertaking a GDA. Typical examples of how this process may be applied are given in Table 2 – noting that agreement of the GDA scope will be part of Step 1 of the GDA.

26. The agreement of scope will also impact on the technical assessment topics considered by ONR, the number of Steps and the outputs from the process. Importantly a DAC will not be issued for GDA assessment activities where the overall scope is considered less than for GDAs carried out previously which concluded with the issue of a DAC.

Table 2 – Examples of GDA Activities

Example	Description	Technical Assessment Topics	Steps	Output
Full plant design	This would be comparable to what has been completed for UK EPR™, AP1000® and UK ABWR (for example a comprehensive review of reactor, nuclear steam supply system, fuel route, balance of plant and major essential support systems on a generic NPP site).	All	1, 2 and 3	DAC, iDAC or no DAC
Major portions of a well-developed plant design (for example; one complete reactor module of a multi-module design where the interactions between modules are potentially safety significant but are declared out of scope by the RP)	A RP may wish to gain regulatory confidence on the acceptability of one reactor module, but does not consider interactions between modules to be within scope. While ONR may consider it meaningful to assess the full safety and security justifications for one module in isolation, consideration of the interactions between modules would be needed to obtain a DAC from GDA. For those major portions that form part of the assessment the full breadth and depth of evidence expected by ONR would need to be available.	All	1, 2 and 3	GDA Statement
Major portions of the plant design (of limited design maturity)	A RP may wish to gain confidence that major portions of the plant design, that are integral to the design, are not 'showstoppers'. While all of the safety and security justifications for the full design would not be expected, significant supporting safety analysis and design justifications would still be required in order to understand the nuclear safety implications and interfaces of the systems, structures and components, to ensure that the assessment is meaningful.	Most	1 and 2	GDA Statement

Example	Description	Technical Assessment Topics	Steps	Output
Conceptual full plant design	A RP may wish to gain regulatory confidence on the acceptability of a full plant design, but where the design and substantiation are not yet mature enough to complete a detailed assessment, then it would be possible to identify if there are any potential 'showstoppers'. This would need to include all significant aspects of safety and security in order for it to be considered meaningful.	Most	1 and 2	GDA Statement
Partial plant design (for example, a design where the deployment model relies on out of scope supporting systems, structures and components)	A RP may wish to gain regulatory confidence in some aspects of a plant design. The proposed scope does not include design features and safety significant systems, structures and components that ONR considers it necessary to assess in order to come to a reasoned regulatory judgement. It would therefore not be considered meaningful to assess this proposal, in the context of the objective for GDA (para. 8), and deployment of regulatory resource is not warranted.	Assessment not considered meaningful – no GDA undertaken		
Distinguishing safety system (for example, the control and instrumentation technology and architecture)	A RP may wish to gain regulatory confidence on a different approach to an important safety system that is inherent to the design concept. The proposed scope does not include sufficient analysis and context to enable ONR to undertake a full and balanced assessment of the design. ONR is not in the position to qualify specific systems, structures or components which may be used in a range of applications. It would therefore not be considered meaningful to assess this proposal, in the context of the objective for GDA (para. 8), and deployment of regulatory resource is not warranted.	Assessment not considered meaningful – no GDA undertaken		

2.3 TECHNICAL ASSESSMENT TOPICS

27. In order to undertake a meaningful GDA assessment that leads to a DAC, ONR would typically expect to consider the adequacy of the RP's generic safety and security cases across twenty two distinct technical assessment topics, as defined in Table 3. In addition, a number of matters which may span more than one of these topics may also be assessed (for example, safety case development). Recognising the overlap between these topics, ONR undertakes its assessment in an integrated manner. Further details for each of these topics are given in Ref. 5.

TABLE 3 – TYPICAL TECHNICAL ASSESSMENT TOPICS

Topic		
Chemistry	Fault Studies	Radioactive Waste Management
Civil Engineering	Fuel and Core	Safeguards
Control and Instrumentation (C&I)	Human Factors	Security
Conventional Fire Safety	Internal Hazards	Severe Accident Analysis (SAA)
Conventional Health and Safety	Management for Safety and Quality Assurance	Spent Fuel Management
Decommissioning	Mechanical Engineering	Structural Integrity
Electrical Engineering	Probabilistic Safety Analysis (PSA)	
External Hazards	Radiological Protection	

28. The GDA scope agreed with the RP will impact on the technical assessment topics which ONR will assess. This will be agreed with the RP during Step 1, although it may evolve in discussion with the RP, as the assessment progresses to ensure that the GDA remains meaningful.

2.4 STEPWISE ASSESSMENT AND PROGRESSION

29. The decision to progress from one GDA Step to the next will be controlled as part of a formal 'readiness review' process. Progression will depend on whether ONR judges that:
- the preceding Step has been satisfactorily completed, including consideration of the timeliness, scope, content and quality of the submissions which have been made by the RP;
 - there is confidence in the ability of the RP to provide sufficient and suitable submissions to enable ONR to complete its assessment during the next Step;
 - ONR is ready to proceed with the assessment in the next Step; and
 - the RP is providing adequate capability and capacity to support the next Step.
30. It is possible that, should significant deficiencies be identified, an outcome from the 'readiness review' may be that ONR considers that proceeding to the next Step may not be warranted. In these circumstances the RP will need to resolve those deficiencies to the satisfaction of ONR before progression can be agreed.

31. An important aspect of the 'readiness review' will be the RP's own review of its adequacy to proceed with the next Step. Before commencing each of the assessment Steps, ONR requires the RP to conduct its own self-assessment to confirm that it can fulfil all the requirements for that Step. This should include an internal challenge process within the RP's organisation. The results of the RP's review should be provided to ONR to support the request to continue. An outcome from these reviews, either the RP's or ONR's, may be improvement actions. The RP will need to demonstrate that it has a plan to satisfactorily address these, in a timely manner, before progression to the next Step can be considered.
32. To preserve the integrity of the stepwise approach, progression to the next Step will only be agreed once ONR is satisfied that the work necessary across all technical assessment topics has been satisfactorily completed. Similarly, the next Step will only start when work is able to commence concurrently across all relevant technical assessment topics. This approach avoids planning difficulties and the difficulties presented where there are dependencies between different technical assessment topics.
33. To maximise efficiency, ONR expects the GDA process to proceed without delays between Steps. However, if the RP is not ready to begin, then a request to defer the start of the next Step may be made. If ONR agrees to defer commencing a Step then additional delays may be introduced, since some or all of ONR's technical assessment resource may need to be redeployed. Even in the absence of such a request, ONR may deem it necessary to defer the start of the next Step until it has received the information it judges necessary to proceed. In such instances, the duration and implications of any deferral will need to be agreed by the RP, otherwise ONR will need to stop the GDA.

2.5 STARTING A GENERIC DESIGN ASSESSMENT

34. Embarking upon a GDA is a significant undertaking for both the RP and ONR; for the RP the costs will be significantly higher than ONR's charges, while for ONR it entails the commitment of a team of specialists for a period of several years. Subject to satisfactory progress being made through all of the GDA Steps, it is ONR's intention that once Step 1 begins, the process will run uninterrupted to completion (noting the caveats given in para. 33). It is appropriate, therefore, to have a robust process in place to ensure the viability of the project from the outset, so that the risks of nugatory effort for both ONR and the RP are minimised.
35. To begin a GDA the RP must have engaged with the UK government and the regulators must have been requested to carry out a GDA. The request for ONR (and the Environment Agency) to undertake a GDA must therefore be made to the Department for Business, Energy and Industrial Strategy (BEIS) as this department oversees UK government policy on nuclear power. If satisfied that the request is consistent with UK government policy, and meets the requirements defined in the GDA entry process (Ref. 6), the relevant Minister will write to both regulators asking them to undertake a GDA of the design proposed by the RP.
36. As part of the GDA entry process, administered by BEIS, the RP will need to provide information and assurances, such as the organisational nature of the RP including finances and governance arrangements. This is so that BEIS, with support from ONR as required, can gain assurance of the capability and capacity of the RP to meet the requirements of undertaking a GDA. In addition, the RP will need to confirm that it understands and will comply with the expectations set out in this guidance including legal obligations under nuclear security regulations (Ref. 7) and the need to be open and transparent and engage with the public (Section 5.7). Further evidence will be sought by ONR once a GDA begins.

37. ONR will not commence a GDA until 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. Wherever possible, the limit of liability value in this agreement should cover all Steps of the GDA. However, where the agreement of scope is necessary during Step 1 the cost recovery agreement may initially be limited to Step 1 and subsequently be extended or revised.
38. Finally, ONR will not commence a GDA until it has confirmation that any required Government to Government Assurances (GTGAs) are in place to enable the necessary export licences to be obtained.

2.6 THE GENERIC DESIGN ASSESSMENT STEPS

39. A detailed description of each of the GDA Steps, including the objectives, details of what the RP is required to do and what ONR will do is given in Appendix 2 to 4.
40. The requirements contained within Appendix 2 to 4 are for completion of a GDA to obtain a DAC. Some aspects listed here may not be relevant, or only partially relevant, depending on the GDA scope agreed between ONR and the RP. This will be agreed between the RP and ONR during Step 1.
41. ONR will use Appendix 2 to 4 as the basis for planning and undertaking its assessment. It is important therefore, that the RP is familiar with the requirements contained therein and is able to provide quality documentation that meets these expectations in a timely manner. Failure to do so represents the largest risk to completion of a GDA.

2.7 COMPLETING A GENERIC DESIGN ASSESSMENT

42. The GDA will complete once ONR has finished its intended assessment, and we have been able to make those judgements necessary, in line with the requirements and expectations in this guidance.
43. There are a number of potential outputs that can be provided upon completing a GDA. The output provided will depend on the GDA scope agreed, the meaningfulness of the assessment undertaken, the adequacy of the safety and security cases submitted and the significance of any residual safety or security concerns that remain to be resolved.
44. For a GDA that completes at Step 2, ONR will provide a GDA Statement.
45. There are four potential outputs for a GDA that completes Step 3:
 - A GDA Statement; or
 - A DAC, an iDAC or no DAC
46. An iDAC will also identify those residual safety and/or security concerns that remain to be resolved (known as GDA Issues). In addition, a Step 3 GDA Statement, iDAC or DAC will also include the identification of Assessment Findings (AFs), as described in Section 2.8.

2.8 OUTPUTS FROM A GENERIC DESIGN ASSESSMENT

47. The output from a GDA represents ONR's expert judgement on the adequacy of the safety and security of the proposed design at the time it is provided. None of the outputs from GDA have a binding legal status and are not a formal requirement of the GB nuclear licensing regime; since it is possible to apply directly to ONR for a site licence based on a design which has not been subject to GDA. Further details on nuclear site licensing are provided in Ref. 8.

48. It should be noted that:

- there is no guarantee that completion of GDA will lead to a particular output - this will depend on whether the design and generic safety and security cases meet ONR's expectations;
- GDA and nuclear site licensing are separate assessment processes - provision of an output from a GDA does not guarantee that a subsequent site licensing application will be successful;
- granting of a nuclear site licence does 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 any nuclear safety related construction can commence; and
- nuclear safety and security remains the responsibility of the licensee.

49. However, ONR anticipates that future licensees are likely to want the design they are proposing to construct and operate to have undertaken a GDA, as this will demonstrate some regulatory certainty and thereby reduce the project risk. Notwithstanding the successful completion of a GDA, there are further regulatory requirements that remain, which must be met before construction and operation of a new NPP can be permissioned.

50. Clearly the generic safety and security cases used as the basis for GDA, and as defined within the output from that GDA, are not in themselves sufficient for a future licensee to seek a regulatory permission. However, in line with the objective of GDA (para. 8), the intent is that these would form the foundation for the site-specific safety case which is a requirement to commence nuclear safety related construction. A key aspect of ONR's assessment during GDA will therefore be focussed towards ensuring that the generic safety and security cases are suitable for this purpose, and that the RP is able to provide evidence as to how this may be achieved. This is discussed further in Section 3.

51. The output from GDA remains valid for a period of ten years from the date of issue. This period is consistent with the requirement for licensees in GB to undertake periodic safety reviews of their existing nuclear facilities every ten years. If during that period any new information emerges (for example, due to changes to the design or codes and standards) which impacts the basis of ONR's original assessment of the design, then ONR would need to consider whether the output remains valid.

52. Should a RP wish to seek renewal of the output at the end of this ten-year period, ONR will require the RP to review the generic safety and security cases for the proposed design in the same manner that a nuclear site licensee would carry out a periodic safety or security review, and provide this review to ONR. This renewal should be 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.

53. Each of the potential outputs is described further below.

2.8.1 GDA STATEMENTS

54. A GDA Statement will be provided to indicate the commencement of Step 1, and upon completion of Steps 1 and 2. A further GDA Statement may be provided at the end of Step 3, depending on the agreed GDA scope. The nature and content of the GDA Statements will by necessity evolve alongside the assessment.

55. At the start of Step 1, the GDA statement will simply reflect that a GDA has commenced for a given RP's design.

56. At the end of Step 1, the GDA Statement will be focussed on defining the agreed basis for subsequent Steps. It will identify matters such as the GDA scope that has been agreed, the scope of RP's initial submissions and target timescales for subsequent Steps, amongst other relevant matters.
57. At the end of Steps 2 and 3, the GDA Statement will reflect the agreed GDA scope and the assessment to that point in time, in the context of the objectives for ONR's assessment during that Step. It will provide an indication of confidence, based upon the assessment conducted to date, on ONR's judgement of whether the design is potentially capable of being built and operated on a site bounded by the generic site envelope, in a way that is acceptably safe and secure. It will also identify matters which might be in conflict with UK government policy.
58. The Step 2 and Step 3 GDA Statements will clearly identify areas where future regulatory scrutiny will be necessary in order to achieve a DAC, or be given regulatory permission to start nuclear safety related construction, alongside an indication of the significance of any identified gaps to meeting regulatory expectations. It will also contain other relevant information including the scope and basis of assessment, details of the submissions assessed and any open regulatory questions.
59. ONR would take a valid Step 2 or Step 3 GDA Statement into consideration if:
 - further GDA is undertaken to achieve a DAC for that design; or
 - the RP's GDA outputs form part of the basis for a licensee's case for starting nuclear safety related construction for that design.
60. Wherever possible ONR will not re-assess those aspects considered as part of the GDA Statement, and judged to be adequate. However, given the targeted nature of the assessment, and the likely GDA scope to achieve a GDA Statement, some limited consideration would be required as part of these later regulatory activities.

2.8.2 DESIGN ACCEPTANCE CONFIRMATION

61. If, at the end of Step 3, ONR provides a DAC to a RP it will mean it is confident that, based on the generic safety and security cases, the design is capable of being built and operated 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.
62. ONR would take a valid DAC into consideration in assessing the adequacy of a licensee's case for starting nuclear safety related construction, if the GDA outputs form part of that case. ONR will not further assess, at the site-specific stage, those aspects of the safety and security cases already assessed during GDA. However if the RP or licensee make subsequent generic or site-specific design changes that affect the basis of the GDA, then those aspects affected by such changes, including consequential effects in other areas, may require re-assessment.

2.8.3 INTERIM DAC AND GDA ISSUES

63. If, at the end of Step 3, ONR is largely satisfied with the design and generic safety and security cases then it may be possible to provide an iDAC. Provision of an iDAC will mean that ONR is confident that the design is capable of being built and operated 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 residual safety and/or security concerns that have yet to be resolved (known as GDA Issues). GDA Issues are defined as unresolved issues judged by regulators to be significant but resolvable, requiring resolution before regulatory permission for the start of nuclear safety related construction of such a

design could be considered. The GDA Issues will be uniquely identified and listed in the iDAC.

64. ONR would take a valid iDAC into consideration in assessing the adequacy of the licensee's case for starting nuclear safety related construction. For those aspects not covered by GDA Issues, ONR will not further assess these at the site-specific stage unless any subsequent changes make this necessary.
65. The provision of an iDAC would only be considered when the RP is able to provide credible (in ONR's judgement) resolution plans that identify how it will address each of the GDA Issues, and the timescales for doing so. It is notable that resolution of a given GDA Issue may require inputs and assessments across a number of technical assessment topics.
66. Provision of an iDAC would mark the end of ONR's planned GDA assessment of the generic safety and security cases for the proposed design. If the RP wishes to continue and resolve the GDA Issues as part of GDA, this would be subject to the agreement of ONR. ONR would encourage the resolution of GDA Issues in a timely manner following provision of an iDAC, for efficiency purposes.
67. The process to resolve the GDA Issues will be the same as that used throughout earlier GDA Steps. Namely, this will include an in-depth ONR assessment of the additional design and safety or security cases submitted in response to the GDA Issues, and the RP will be required to respond to matters raised by ONR during its assessment and to relevant matters arising from public comments. The final GDA submissions (including the Design Reference (DR) and Master Document Submission List (MDSL) – Section 3.5) will also need to be updated to reflect any additional work. The scope and timescales for this stage will depend on the programmes identified in the resolution plans provided by the RP, and agreed by ONR.
68. If ONR completes sufficient assessment to be able to judge that all the GDA Issues have been satisfactorily addressed, the provision of a DAC will then be considered. Information on ONR's assessment will be published.
69. It is expected that the GDA Issue resolution stage will follow closely on from provision of an iDAC. For instances where there is a lengthy pause in-between the two, it is likely that the generic design will be subject to continual development leading to a number of design changes being proposed by the RP. If such design changes have wider impacts in the generic safety and security cases that were 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 resolution stage.

2.8.4 NO DESIGN ACCEPTANCE CONFIRMATION

70. If, at the end of Step 3, ONR is not content with the design or generic safety or security cases then no DAC would be issued. This would be the case where ONR judges that there is a significant, unacceptable shortfall in the design or generic safety or security cases. ONR will publish the conclusions of its assessment.
71. It would be for the RP to decide whether to propose additional work to address the identified shortfalls, which may allow an iDAC or DAC to be provided at some future date.

2.8.5 ASSESSMENT FINDINGS

72. GDA is not intended to provide a complete assessment of the final as-built design, as there are other factors, operator specific or site-related, that ONR will consider during the site-specific stages. Some aspects 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 developments of the safety and security cases are normal regulatory business for ONR and are subject to appropriate regulatory controls.
73. During the course of GDA, ONR will identify a number of 'Residual Matters' from its assessment. At the end of GDA, a sub-set of these will be considered more significant to the future safety or security of the design and will therefore be identified as Assessment Findings (AF) which ONR will require the nuclear site licensee to resolve when the design is proposed for construction at a particular site. AFs will be identified during Step 3 as well as during the resolution stage for any GDA Issues. Any AFs will be uniquely identified as part of any Step 3 GDA Statement, DAC or iDAC issued for the design.
74. A Residual Matter will generally be recorded as an AF where ONR considers that the generic case is sufficient, but further evidence will be necessary at some later stage, and 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's design choices;
 - the matter raised is related to operator-specific features / aspects / choices;
 - the resolution of this matter requires licensee's choices on organisational matters;
 - to resolve this matter, the plant needs to be at some stage of construction or commissioning;
 - to resolve this matter, the level of detail of the design needs to be beyond what can reasonably be expected in GDA.
75. It will be the responsibility of a licensee to ensure that AFs are addressed as appropriate during the detailed design, procurement, construction or commissioning phase of a new NPP. Resolution will be monitored as part of ONR's normal regulatory oversight. Identifying AFs during 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 project risk.



Safety and Security Documentation

3 SAFETY AND SECURITY DOCUMENTATION

3.1 INFORMATION REQUIREMENTS

76. In order to complete a GDA it is expected that the RP will submit to ONR those parts of the generic safety and security cases for the proposed design, as relevant to ONR's assessment and the agreed GDA scope, such that a meaningful assessment can be undertaken.
77. The most efficient way to achieve a DAC would be to enter GDA with a complete and comprehensive suite of documentation. For example, in nuclear safety terms, the documentation (the 'safety case') would be at a level of development akin to a Pre-Construction Safety Report (PCSR) for the generic site. For security, the equivalent would be a Generic Security Report (GSR).
78. ONR recognises that, in practice, it is unlikely that a RP will have fully developed documentation on entering GDA, given the benefits to a RP of undertaking a GDA when the design is not yet fully detailed. This is also relevant where the RP is proposing a design produced in another country under a regulatory regime which has different expectations, rules or arrangements for safety and security justifications. The most significant differences are likely to be associated with the requirement to demonstrate that risks are reduced to As Low As Reasonably Practicable (ALARP) and GB's specific security expectations.
79. The GDA process takes this into account by using a stepwise process, which allows the RP time to develop the generic safety and security cases required to support GDA, and by undertaking the preparatory work (in particular the gap analysis) described under Step 1 to understand what additional documentation may be required, and the timescales over which it can be produced.
80. In line with the overall objective for GDA (para. 8), the intent is for the RP to produce generic safety and security cases which can be used by a future licensee to support the development of their site-specific safety case needed for the start of nuclear safety related construction and production of a Nuclear Site Security Plan (NSSP). It is intended that the documentation that forms the basis for GDA, and therefore the GDA Statements, DAC or iDAC, will also be used as the basis for these future licensee produced cases. Therefore, ONR expects the RP to produce suitable and sufficient documentation to facilitate GDA and also to demonstrate, through the production and application of adequate arrangements, how this could be used successfully as part of future site-specific submissions.

3.2 THE GENERIC SAFETY CASE

81. The RP is required to develop a comprehensive generic safety case, including relevant supporting reference documents. In line with ONR's Safety Assessment Principles (SAPs) (Ref. 9), the term 'safety case' is used to encompass the totality of the documentation developed by a designer, licensee or duty-holder to demonstrate high standards of safety. ONR SAPs state that:

A safety case is a logical and hierarchical set of documents that describes risk in terms of the hazards presented by the facility, site and the modes of operation, including potential faults and accidents, and those reasonably practicable measures that need to be implemented to prevent or minimise harm. It takes account of experience from the past, is written in the present, and sets expectations and guidance for the processes that should operate in the future if the hazards are to be controlled successfully. The safety case clearly sets out the trail from safety claims through arguments to evidence.

82. The information which ONR chooses to sample from the safety case to commence its assessment will be agreed during Step 1. The breadth and depth of sampling will be targeted and expand during ONR's assessment throughout GDA.
83. The SAPs include a section on the regulatory assessment of safety cases. This is supported by ONR's Technical Assessment Guide (TAG) on the purpose, scope and content of nuclear safety cases (Ref. 10). ONR expects the safety case developed during GDA to be consistent with these expectations. 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 to ALARP.
84. ONR expects the generic safety case to cover all aspects of the plant's life-cycle. This should include a proportionate consideration of construction, operation, maintenance activities, spent fuel and radioactive waste management and decommissioning to allow the objective for GDA to be met. The generic safety case may include matters relating to both nuclear and conventional health and safety, or these may be separated depending on the choice of the RP. The level of detail of the information required may vary according to the significance of each aspect to the agreed GDA scope.
85. For a generic safety case, ONR accepts that much of the evidence and associated confirmatory analysis cannot be gathered until the structures, system and components 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. The capturing of assumptions, commitments and requirements from the safety case is further detailed in Section 3.4.7.
86. The generic safety case should include information that defines the characteristics assumed for the generic site envelope, to the extent applicable to the agreed GDA scope. 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 potential deployment sites. ONR's preferred approach is that these characteristics should, as far as reasonably practicable, bound the characteristics of the potential deployment sites such that the proposed design could potentially be built at a number of suitable locations. If the RP chooses the characteristics for an actual site to act as the generic site during GDA, ONR would subsequently need to revisit the applicability of the output from the GDA to other sites during site-specific assessments, with a potential increase in regulatory uncertainty for that project. Guidance on ONR's expectations on generic site characterisation is contained in Ref. 5.
87. ONR requires the RP to make relevant safety case and key supporting reference information available for public comment (with the exception of any commercially confidential and security sensitive information). The information to be published will need to be agreed with ONR during Step 1.

3.3 THE GENERIC SECURITY CASE

88. The RP is required to develop a comprehensive generic security case, comprised of a GSR including relevant supporting reference documents. Guidance on the content of the GSR is provided in Ref. 11.
89. In summary, the GSR should describe the security features of the proposed design. It should document the categorisation from both theft and sabotage to determine the protective security outcomes and applicable security postures to be applied. The GSR

must provide evidence that regulatory expectations can be met, in respect of the Fundamental Security Principles (FSyPs) from the Security Assessment Principles (SyAPs) (Ref. 12). As with the generic safety case produced during GDA, the GSR should form the basis for the NSSP prepared by the future licensee, which is approved by ONR under the Nuclear Industries Security Regulations (NISR) 2003 (as amended) (Ref. 7).

90. ONR requires the RP to make relevant security case and key supporting reference information available for public comment (with the exception of any commercially confidential and security sensitive information). The information to be published will need to be agreed with ONR during Step 1.

3.4 PRODUCTION OF THE SAFETY AND SECURITY CASES

3.4.1 DEVELOPMENT PROCESSES

91. The processes used to produce the safety and security cases need to consistently deliver good-quality, fit-for-purpose cases. For a safety case to state that the design under consideration is very reliable or highly unlikely to fail, the process used to produce the safety justifications should have a commensurate level of robustness. Similarly it is important that a robust process is used to develop the security case, to ensure that any security measures required can be achieved by the design.
92. The RP therefore needs to demonstrate that the process for safety and security case production are suitably robust and have included, for example, using Suitably Qualified and Experienced Personnel (SQEP) authors, appropriate verification controls, a formal approval procedure, and an independent review. The RP should also demonstrate that the rigour of the processes applied is consistent with the safety or security importance of the subject matter. ONR will assess these processes during Step 1. Further information on ONR's expectations regarding safety and security case production processes are given in the SAPs, SyAPs and TAGs (Refs 7, 10 and 11) and GDA specific guidance in Ref. 5.
93. As well as ensuring that a RP's safety and security case submissions are well defined, ONR requires that they are produced under robust QA arrangements. The same applies to the design itself. 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.
94. An essential element of the safety and security case development process during a GDA is the capturing of assumptions, commitments and requirements, as described further in Section 3.4.7. This will need to include any changes which result as part of on-going safety and security case developments during GDA. ONR will assess the RP's arrangements and implementation during Steps 1 and 2 respectively. These arrangements become more relevant to GDA if key safety-related items, intended or potentially for use in GB, have been or are in the process of being manufactured. In such cases, the RP should specify what quality management arrangements have been or will be used during all stages of the manufacturing process, to ensure that the generic safety case is realised in the constructed plant.

3.4.2 CAPTURING DESIGN DEVELOPMENTS

95. If the design has been fixed for several years prior to entering GDA, evidence should be provided by the RP as part of the generic safety and security cases that adequate learning has been taken into consideration, including:
 - developments in nuclear technology;
 - changes to relevant codes and standards;

- relevant construction, commissioning or operating experience;
- significant changes to the security threats that need consideration;
- relevant new research findings; and
- any other factors arising that may have an impact on the safety and security of the design.

3.4.3 MAKING USE OF RESEARCH

96. ONR's expectation is that adequate research and technical studies will have already been completed before the start of GDA, and included within the safety and security cases as appropriate. Relevant research findings that emerge during the course of a GDA should also be considered by the RP. These should be made available to ONR, and may include research findings for which the RP does not hold the intellectual property rights.

3.4.4 MAKING USE OF INTERNATIONAL GUIDANCE

97. The RP should take account of the requirements of International Atomic Energy Agency (IAEA) safety and security standards and guides. At a high-level, ONR's SAPs and SyAPs have been benchmarked against these standards to ensure that ONR's requirements reflect international nuclear safety and security standards.
98. However, in many cases, IAEA and other sources of international guidance (for example Western European Nuclear Regulators Association (WENRA) reference levels and positions, or other overseas regulatory requirements) provide specific and technology-focused information. While these can go beyond the expectations in ONR's guidance, they may remain relevant to GDA in the context of demonstrating that relevant good practice has been followed (and ALARP has been demonstrated). The RP is therefore encouraged to consider a wide range of international guidance and consider its relevance, applicability and value to the safety and security cases developed during GDA.
99. Whilst vendors may state that their designs are compliant with Utilities Requirements Documents (e.g. US or European), ONR is only able to regard these documents as being guidance for the designers. ONR does not endorse the utilities' standards or make use of them for assessment purposes.

3.4.5 MAKING USE OF EXISTING SAFETY OR SECURITY DOCUMENTATION

100. ONR recognises that the RP may choose to make use of existing design, safety and security justifications that were written to address the regulatory requirements of countries other than GB. This is likely to be an efficient approach. However, it is unlikely that such documents will be sufficient, on their own, for the purposes of GDA because:
- the GB regulatory regime for safety is largely goal-setting, rather than prescriptive, and is based on the ALARP principle; and
 - for security, the threat is determined by the UK government and is therefore particular to GB.
101. The RP may therefore need to produce and submit additional and specific submissions that provide evidence of how the regulatory requirements of GB have been, or can be met. Understanding and agreeing suitable documentation that will resolve any identified gaps is an important element of Step 1, as is the submission of these during Step 2.

102. Further details of lessons learned, and gaps identified in previous GDAs, are described in Ref. 5. This includes a number of areas where the GB regulatory approach influences the scope and nature of what needs to be considered as part of the safety and security cases.
103. Where existing documentation is used, ONR requires that the generic safety and security cases are presented in, and the NPP will be built and operated using SI (International System) Units. The safety and security cases should be written in English.

3.4.6 THE SAFETY AND SECURITY CASE STRUCTURE

104. ONR encourages the RP to make efficient use of existing documentation during GDA, but this may have implications for the safety or security case structure.
105. ONR's guidance to its assessors (Refs 7, 10 and 11) sets out its expectations for safety and security cases but makes clear that, consistent with its goal-setting approach, ONR would be flexible regarding the structure of the safety or security case provided for regulatory assessment. Nevertheless, the guide emphasises the need for the case to be intelligible, with a clear trail from claims, through the arguments, to the evidence that fully supports the conclusions. This 'golden thread', linking the claims with the supporting evidence, is a vital part of an adequate safety or security case and will be important for successful completion of a GDA, and for future use of the generic safety and security cases. Further information on this topic can be found in Ref. 5.
106. It is also important that the RP gives consideration to how the generic safety and security cases produced during GDA would evolve and expand to form the foundation for future site-specific cases produced by a licensee. ONR will assess during GDA how the arrangements put in place by the RP can allow this to be achieved.
107. Inevitably the safety and security cases for a new NPP will be large and complex. In such instances, ONR considers it beneficial to include a top tier summary document, sometimes known as a 'Head Document'. This approach can significantly improve the usability and accessibility, and in particular highlight the key aspects of safety and security to the users and decision makers. Further details are given in Ref. 5. This summary should be meaningful if read in isolation, as well as providing the main entry point and clear links to the safety and security case documentation as a whole.
108. During Step 1, ONR will engage with the RP to understand its strategy for safety and security case development. This will allow regulatory input as early as possible, such that ONR has a clear understanding of what is proposed and can provide appropriate feedback.

3.4.7 CAPTURING ASSUMPTIONS, COMMITMENTS AND REQUIREMENTS FROM THE SAFETY AND SECURITY CASES

109. The safety and security cases will contain numerous assumptions, commitments and requirements upon which the demonstration of safety and security is based. These will relate to matters such as operating rules, maintenance requirements, emergency arrangements and commissioning or construction requirements. The RP will need to capture these on an on-going basis throughout GDA as the safety and security cases develop, such that they can be applied consistently across the documents but also as part of a demonstration that the safety and security cases will be suitable for implementation as part of an operating regime. This includes the ability to transfer knowledge and these arrangements to the future licensee so they can be put into practice.

110. During Step 1, ONR will assess the RP's arrangements for capturing these safety and security case outputs. During later GDA Steps ONR will assess the application of these arrangements. At the end of GDA the RP should consolidate these as part of its submissions which will form the basis for ONR to grant a GDA output.

3.4.8 DEVELOPMENT OF SITE-SPECIFIC SAFETY AND SECURITY CASES POST-GDA

111. The intent for GDA is that it is an enabler to future regulatory activities required to construct and operate a new NPP. The RP will need to provide evidence during Step 3, and to a proportionate extent during Step 2, of how the GDA safety and security cases can be used to produce the site-specific PCSR, necessary for permissioning nuclear safety related construction, and NSSP, required under NISR. The effective capture of safety and security related assumptions, commitments and requirements identified during the GDA is a vital part of this.

3.4.9 INVOLVEMENT OF FUTURE LICENSEES OR OPERATORS

112. In GB, the licensee has the ultimate responsibility in law for ensuring the safety and security of the plant. Therefore, the safety and security cases produced in GDA must be developed with a potential licensee's legal duties in mind, rather than as a means to satisfy ONR. By the end of GDA, ONR will expect the generic safety and security cases to be fit for use by a future licensee. In any subsequent site-specific licensing phase, ONR will assess the degree to which the prospective site licensee understands and takes responsibility for the safety and security cases.
113. It is recognised that GDA may take place well before a prospective licensee has finalised its choice of reactor technology; therefore their involvement in GDA cannot be mandatory. Nevertheless, ONR encourages such collaborations during GDA wherever possible as this will be of significant benefit to the licensee in being able to demonstrate, during the nuclear site licencing 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 of GB.
114. In addition, ONR considers that there are benefits in the involvement of plant operators during GDA. This is particularly useful in helping to ensure that the proposed design, commitments or assumptions or any design changes that are considered necessary during GDA, not only satisfy GB regulatory expectations, but can be considered practicable and cost effective from an operational perspective. Plant operators can also provide an input into whether the design is financeable, constructible, and maintainable and provides the operational flexibility they would be looking for from the facility. A prospective operator may also be able to offer operational insights to the RP. The RP should consider how such input can be provided to further reduce regulatory uncertainty and project risk.

3.5 CONTROL OF THE SAFETY AND SECURITY CASE INFORMATION

115. Given the breadth and depth of information exchanged between the RP and ONR within a GDA, it is vital that the RP implements suitable control arrangements. This is important for enabling ONR's assessment and also before a GDA output is provided. The documents produced as part of these control arrangements, as described below, will be key references to any GDA output provided (GDA Statement, iDAC or DAC).

3.5.1 GDA DESIGN REFERENCE AND DESIGN REFERENCE POINT

116. The RP is required to submit a Design Reference (DR) which lists all the documents that define the design of the NPP that the GDA submissions refer to. ONR will expect this to be 'frozen' at a specific date known as the Design Reference Point (DRP). ONR will agree the DR arrangements during Step 1, and first DRP during Step 2, with the RP.
117. The generic safety and security cases must align exactly with the plant described in the DR. The DR will be an important reference to any GDA output provided.

3.5.2 DESIGN REFERENCE CHANGE CONTROL

118. As part of its normal design development process, the RP may wish to make changes to the generic design after the DRP has been agreed. Changes to the design may also be necessary to respond to ONR's regulatory questions. However, ONR would expect any changes to the DRP to be minimised as far as practicable, unless necessary for safety or security purposes. It is therefore important that DR change control arrangements are implemented by the RP.
119. The details of the DR change control arrangements should be proposed by the RP for ONR's agreement during Step 1. The expectation is that this will be a robust system similar to those implemented by licensees to satisfy nuclear site Licence Condition 20 (modification to design of plant under construction) (Ref. 14), and include:
 - a categorisation process 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 method for alerting ONR to the more significant changes to the safety or security case.
120. ONR will inspect the applications of these arrangements during Steps 2 and 3.
121. Significant design changes proposed at a later stage in GDA may pose a threat to the delivery of a timely and meaningful ONR assessment. ONR will therefore need to agree whether such design change proposals can be accepted within the GDA scope. Any such agreed design changes should be consolidated into the DR and an updated DRP agreed with ONR.

3.5.3 MASTER DOCUMENT SUBMISSION LIST

122. As GDA progresses, ONR will request submission of a sample from the generic safety and security cases so that more detailed information can be assessed. 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.
123. 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. Key to these arrangements is a Master Document Submission List (MDSL), which is a living document that allows ONR to understand and reference precisely what constitutes the latest versions of the GDA submissions.
124. ONR will inspect these arrangements during Step 1 and will expect the first version of the MDSL to be submitted as part of the first submission made to the regulators. The MDSL should be updated at regular and appropriate intervals throughout GDA and

submitted to ONR, which should be captured as part of the RP's arrangements. The MDSL will be an important reference to any GDA output provided.

3.5.4 SUBMISSION CUT-OFF DATES AND CONSOLIDATION

125. 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 there needs to be an agreed cut-off date for submission of new information within that Step. A cut-off date will be agreed between ONR and the RP for each Step, which will also include the responses to any regulatory questions.
126. In addition, towards the end of GDA and prior to any output being provided by ONR, there will be a need for the RP to consolidate the DR and generic safety and security cases in a consistent manner. ONR will refer to the consolidated safety and security cases, the DR and MDSL in the issue of any GDA Statement, iDAC or DAC. This consolidation will need to take into account:
 - all the additional information that has been provided in response to ONR regulatory questions;
 - any design (and safety or security case) changes that ONR has agreed can be included in the GDA scope; and
 - a record of any commitments made by the RP during GDA which have not yet been fully incorporated into the design.



ONR Assessment

4 ONR ASSESSMENT

4.1 UNDERTAKING A MEANINGFUL GDA

127. In order to be able to provide a GDA Statement, iDAC or DAC, ONR must have completed a 'meaningful' assessment.
128. A meaningful assessment will be one where ONR has, in line with the agreed GDA scope, delivered on the objective for GDA (para. 8) and has:
 - received sufficient information in the generic safety and security cases to allow assessment in all relevant technical assessment topics; and
 - completed an appropriately thorough and detailed assessment of that information on a sampling basis.
129. In the above:
 - 'sufficient information' will have been received if ONR judges that it has been provided with generic safety and security cases that cover the full breadth and depth necessary for ONR to carry out its intended assessments;
 - 'thorough and detailed assessment' means that ONR has sampled the submitted information and judged it against applicable standards and guidance, including the need to demonstrate that risks are reduced, or are capable of being reduced, to ALARP.
130. ONR will apply the concept of a meaningful assessment throughout the GDA process. This means that:
 - A key input to the agreement of the GDA scope during Step 1 will be consideration of whether the resulting GDA assessment can be considered meaningful, and therefore warrants the deployment of regulatory resources.
 - At any point whilst undertaking a GDA, if ONR considers that the assessment is unlikely to be meaningful then this will need to be resolved through agreement with the RP, which may lead to changes to the GDA scope.
 - An important part of the decision to move between Steps will be confirmation that the assessment, both completed to that point and planned during the next Step, remains meaningful.
 - In exceptional circumstances, and for limited durations, ONR may agree to extend a Step in order to ensure its assessment remains meaningful.
131. It is vital that the RP provides submissions of high quality, to an agreed schedule. Crucial to the delivery of a meaningful GDA is clarity on what documents constitute the RP's GDA submissions (as included in the MDSL), and how the information they contain addresses the requirements in this guidance document.
132. The breadth and depth of ONR's assessment is unlikely to be the same across all technical assessment topics, as this will depend on the relevance of each topic to the generic safety and security cases and the GDA scope. However, ONR will need to be satisfied that the sampling assessment it has carried out is sufficient to allow a balanced judgement on the overall acceptability of the safety and security of the generic design.
133. As described earlier (Section 2.2), an important requirement of Step 1 is to agree the GDA scope. At the more detailed level below this, the scope of what is included within the assessment is dependent on the information supplied by the RP, which in some instances may be constrained by the availability of data before the site-specific procurement and construction phases. The information that is provided still needs to

be sufficient to allow ONR to undertake a meaningful assessment of the generic safety and security cases for the design. If ONR considers that the RP's information is too narrow or excludes essential information, the scope of the GDA submissions will need to be expanded to address such shortfalls.

4.2 THE SAMPLING PROCESS

134. In line with ONR's regulatory assessment approach, and to be able to reach an independent and informed judgement on the adequacy of the safety and security cases, ONR will choose to sample aspects of the RP's generic safety and security cases. Sampling is used to improve the overall efficiency of the assessment process and to reveal if there are any generic weaknesses in the case as a whole.
135. The breadth and depth of ONR's sampling will be informed by the GDA scope, by the findings of its assessment, and will evolve as GDA progresses. In general, ONR would expect to conduct a broad review of the highest level claims and arguments (and associated safety and security case documentation), while undertaking sampling in areas of high significance, since weaknesses in these areas are potentially very serious. Some may also be taken from lower significance areas or areas where the risks appear least well controlled.
136. ONR will identify to the RP its intentions for the assessment sample. This should be used by the RP to prioritise and schedule the agreed submissions for each GDA Step, but should not be interpreted as the entirety or focus for what the RP may need to do.
137. The sampling process and the step-wise nature of GDA work together to achieve the gradual reduction of regulatory uncertainty and project risk expected. This is inherent in the GDA process and why ONR focuses on, in broad terms:
 - the adequacy of the RP's arrangement during Step 1, and their application in later Steps;
 - the overall design and safety and security claims, as well as the methodologies, approaches, codes, standards and philosophies during Step 2; and
 - the substantiation and evidence for the application of those methodologies, approaches, codes, standards and philosophies in Step 3, including where ONR may also choose to undertake confirmatory analysis for selected aspects of the safety case.

4.3 NUCLEAR SAFETY ASSESSMENT

4.3.1 REGULATORY FRAMEWORK

138. The GDA process is undertaken within the existing nuclear safety regulatory framework for GB, which is described in 'A guide to Nuclear Regulation in the UK' (Ref. 15). The legal framework is based around the Health and Safety at Work etc. Act 1974 (HSWA), the Energy Act 2013 and the Nuclear Installations Act 1965 (NIA65). NIA65 sets down the requirement to obtain a nuclear site licence from ONR before installing a nuclear reactor on a site. HSWA places a fundamental responsibility on duty holders to reduce risk to ALARP.
139. When assessing GDA submissions, ONR will also take into account other legislation (as described in Ref. 15) including the Ionising Radiations Regulations 2017.

4.3.2 REDUCING RISKS TO AS LOW AS REASONABLY PRACTICABLE

140. ONR's decision making process is based on the approach described in 'Risk Informed Regulatory Decision Making' (Ref. 16). This includes an explanation of the concept of

ALARP and describes the legal requirement in GB to demonstrate that risks are reduced to ALARP. The way in which ONR will assess claims from the RP that they have reduced risks to ALARP is set out in detail in the associated TAG (Ref. 10). Note that for ONR's safety assessment purposes the terms ALARP, and the legal term of So Far As Is Reasonably Practicable (SFAIRP), are interchangeable and require the same tests to be applied.

141. 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 to 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 to ALARP. This will need to include consideration of any updates to those technical standards since the original design and safety analysis were completed.
142. 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.

4.3.3 RELEVANT ONR STANDARDS AND GUIDANCE - SAPs, TAGs AND TIGs

143. ONR's judgement on the adequacy of the RP's generic safety case are guided by the SAPs (Ref. 9), which set out relevant good practice for a wide range of nuclear facilities. The SAPs are not criteria or a design tool, but are an aid to consistent regulatory judgement. 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. The RP should note that not all SAPs are intended for use in the assessment of a new NPP, nor are all the SAPs relevant for the GDA process. To ensure consistency with international requirements, the SAPs have been benchmarked against the nuclear safety standards of the IAEA and WENRA guidance. Where appropriate, ONR will also assess against such international standards.
144. In ONR's assessment, 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.
145. Examination of the SAPs will allow the RP to inform themselves of the regulatory principles against which their generic safety case will be judged by ONR. 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. ONR does not expect an explicit comparison of the RP's generic safety case against the SAPs to form part of a safety submission.
146. Additional guidance to ONR's assessors on interpretation of the SAPs is given in associated TAGs. 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. Technical Inspection Guides (TIGs) are mainly aimed at nuclear site inspectors carrying out Licence Condition compliance inspections, but as the GDA process will involve ONR carrying out inspections of the RP's processes, some of these guides may therefore be relevant.
147. In addition, ONR has produced additional technical guidance for GDA, Ref. 5.

4.4 CONVENTIONAL HEALTH AND SAFETY ASSESSMENT

4.4.1 REGULATORY FRAMEWORK

148. In addition to nuclear safety, ONR also has responsibility for regulating non-nuclear, or conventional, health and safety matters on nuclear licensed sites. The overall aim is to ensure that the site has reduced risks to employees and other persons so far as is reasonably practicable (or to ALARP). The legal framework is based around HSWA, but there are many relevant statutory provisions that apply. During a GDA, ONR considers these in the context of the Conventional Health and Safety and Conventional Fire Safety technical assessment topics, where the aim is to ensure that the proposed design is capable of meeting UK regulatory expectations for protecting the health and safety of personnel.
149. For Conventional Health and Safety, given the breadth of this topic, the approach is to sample a number of known risk areas (for example, work at height, confined spaces or lifting operations) and the RP's responsibilities under the Construction (Design and Management) Regulations 2015 (CDM).
150. For Conventional Fire Safety the approach is to consider Fire Safety design against existing UK published guidance for building, design, use and management. The fire engineering principles used by the RP in the design for achieving adequate life safety protection from fire are assessed utilising existing UK codes of practice.

4.4.2 RELEVANT STANDARDS AND GUIDANCE

151. Relevant documented sources of good practice against which ONR will assess the proposed design include relevant Approved Codes of Practice (ACOPs), Health and Safety Executive's (HSE) guidance on legal standards and relevant international and British Standards.

4.5 SECURITY ASSESSMENT

4.5.1 REGULATORY FRAMEWORK

152. 'A guide to Nuclear Regulation in the UK' (Ref. 15) describes the nuclear security framework which is also used as the basis for a GDA. The Nuclear Industries Security Regulations 2003 (as amended) (NISR) place significant obligations on the operators of civil licensed nuclear sites with regard to physical security measures for facilities, nuclear material and the security of Sensitive Nuclear Information (SNI). NISR also covers the vetting of permanent staff and contractors, the movement of nuclear material by road and rail within the UK and globally in UK flagged vessels. This legislation requires all civil nuclear operators to produce and implement a robust NSSP.
153. It is important to note that, for security, the threat is determined by the UK government and stems from an 'intelligent adversary' who acts in a deliberate, planned fashion that is not amenable to numerical risk estimation in the way that many safety concerns are. Hence the risk informed framework around ALARP is not used in making regulatory decisions on security matters.

4.5.2 RELEVANT STANDARDS AND GUIDANCE – SYAPs, TAGs AND TIGs

154. ONR use the Security Assessment Principles (SyAPs), together with supporting TAGs, to guide regulatory judgements when undertaking assessments of the RP's security submissions. These will form the basis of ONR's judgement of the GSR, although not all of the SyAPs are entirely applicable during a GDA.

155. The SyAPs provide the essential foundation for the introduction of outcome focussed regulation for all constituent security disciplines: physical, personnel, transport, and cyber security and information assurance. The primary purpose of the SyAPs is to provide ONR with a framework for making consistent regulatory judgements on the adequacy of security arrangements. Although it is not their primary purpose, the SyAPs may also provide guidance to RPs on the appropriate content of security plans, clarifying its expectations in this regard. However, they are not sufficient on their own to be used as design or operational standards, nor are they intended for that purpose.
156. The SyAPs are supported by a series of TAGs and TIGs to further assist decision making within the nuclear security regulatory assessment process; of particular relevance to GDA is the Guidance on the Security Assessment of Generic New Nuclear Reactor Designs (Ref. 11).

4.6 USE OF TECHNICAL SUPPORT CONTRACTORS

157. It is common practice for ONR to engage contractors to provide specialist technical support as an input to its regulatory assessments. In GDA, ONR may choose to place work packages with contractors, including organisations outside GB, to help it carry out its detailed technical assessment. ONR will make relevant RP's documentation, including third party information, available to its technical support contractors. The costs of any such contracts will be charged to the RP as part of ONR's costs.
158. It is important to note that all regulatory decisions are made by ONR, based on its expert judgement on the adequacy of the generic safety and security cases including where specialist technical support is undertaken.

4.7 RESEARCH

159. While ONR expects the RP to have undertaken its own research work, ONR may choose to 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 of the technology in GB;
 - issues arising during the assessment;
 - other research and development programmes, including research information from overseas regulators who have reviewed the design.

4.8 CONFIRMATORY ANALYSIS

160. During Step 2 or 3, ONR may choose to undertake independent confirmatory analysis on selected aspects of the RP's design or safety case. This is not intended to replace, supplement or be a substitute for the RP's own analysis provided as part of the safety case. The decision to undertake this work is not a function of the adequacy or completeness of the RP's analysis, but these factors may influence the scope of the confirmatory analyses conducted by ONR in supporting its regulatory decisions.

4.9 TAKING BENEFIT FROM OVERSEAS REGULATORY WORK

161. ONR's strategy for working with overseas regulators is based on three main strands:
 - enabling the RP to make use of information that already exists (Section 3.4.5);
 - working in co-operation with overseas regulators on new assessment work; and
 - participating in international forums for multi-national information sharing between regulators.

162. If the RP's proposed design has been subject to assessment by nuclear regulators in other countries, ONR sees benefit from being able to draw on that 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. In addition, ONR is actively participating in the work of the Multinational Design Evaluation Programme (MDEP), alongside other similar organisations.
163. Throughout the GDA process, ONR will seek to take advantage of information arising from such international working. However, it remains 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.
164. ONR considers there to be clear advantages in learning from international experience and considering this as part of regulatory decision making. When assessing new NPP designs as part of a GDA we aim to:
- take into account international good practice and international standards;
 - work with overseas regulators to benefit from their work, wherever appropriate; and
 - prevent unnecessary changes to designs.
165. However, it is ONR's responsibility to come to an informed and independent view on the adequacy of the safety and security of any design proposed for construction. This is also an international expectation, with both IAEA guidance and the Convention on Nuclear Safety, to which the UK is a signatory, stating that each country must make its own regulatory decisions about the safety of such facilities.
166. The extent to which overseas assessments can be taken into account as part of ONR's assessment will depend on a number of factors including:
- the date of the overseas assessment and its continuing validity;
 - the level of detail and the purpose of the overseas assessment;
 - the depth of information provided including the evidence for resolution;
 - whether assumptions will remain valid if the technology is adopted in GB;
 - 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, including providing access to detailed information.

4.10 REVIEW OF ONR DECISIONS

167. Where a RP is dissatisfied with a decision by ONR it may make representations to the appropriate ONR's 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. 17.



Facilitating Generic Design Assessment

5 FACILITATING GENERIC DESIGN ASSESSMENT

5.1 JOINT PROGRAMME OFFICE

168. The co-ordination of the GDA processes undertaken by the regulators (ONR and the Environment Agency) is described in Ref. 1. To help administer both regulators' GDA process, a Joint Programme Office (JPO) will be established. The function of the JPO is to act as a single point of contact between the RP and the regulators in order to facilitate the administrative matters necessary to undertake a GDA.

5.2 REQUESTING PARTY PROJECT OFFICE

169. The RP will be expected to establish a project office in GB for the day-to-day management of its GDA project and for interfacing with the regulators. For administrative matters this interface with the regulators will be via the JPO.

5.3 INTERFACE ARRANGEMENTS

170. 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 regulatory questions. Measures will be developed and used to monitor the performance of the regulators and the RP against the agreed GDA programme. The interface document will be agreed with the RP in Step 1.

5.4 SUBMITTED INFORMATION

171. All of the information submitted to the regulators should be in English. It must be made available to the regulators (and their technical support contractors, as required), via the JPO.
172. The regulators require that all the information submitted should carry an appropriate protective marking. The RP should use a protective marking scheme consistent with the Government Security Classifications (Ref. 18).
173. Where the RP considers that certain information should be protected because it is Sensitive Nuclear Information (SNI) or commercially confidential, or for other reasons, it should clearly mark it accordingly, and also give the reasons for designating the information in this manner. The RP should avoid overprotecting information as this can complicate the process for handling and may cause delays.
174. It is the responsibility of the RP to ensure that all necessary arrangements are in place to share any commercial information, intellectual property or information on the design or safety and security cases with the regulators (and their technical support contractors), as required for its assessment. This includes securing all necessary export control licenses for the transfer of relevant information to and from the UK. Delays in doing so can directly impact on the timeliness of the regulators' assessments.

5.5 MEETINGS

175. Throughout the course of a GDA it is expected that there will be the requirement to undertake many technical, progress and project meetings. A graded approach to meetings will be used, as specified as part of the interface arrangements. The regulators expect that the majority of such meetings should take place in GB; although meetings may be held abroad as dictated by the project's needs, and with the agreement of the regulators.

176. ONR may choose to bring our contractors to meetings with the RP. Similarly, the RP may bring third-parties to interactions with the regulators, as necessary.
177. The RP will also be required to agree, in Step 1, to use a Regulatory Nuclear Interface Protocol (RNIP) 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.

5.6 REGULATORY QUESTIONS

178. Regulatory questions will arise throughout the GDA process. A management system for handling such questions will be agreed with the RP and set out in the interface arrangements. This will use a tiered approach as follows:
 - Regulatory Query (RQ) – are requests by the regulators for clarification and additional information and are not necessarily indicative of any perceived shortfall;
 - Regulatory Observation (RO) – an RO is raised when the regulators identify 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;
 - Regulatory Issue (RI) – an RI is raised when the regulators identify a serious regulatory shortfall which has the potential to prevent provision of a DAC (or SoDA from the Environment Agency), and requires action and new work by the RP for it to be resolved. Each RI can have several associated Actions.
179. 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. This does not mean that all potential or identified shortfalls will be escalated in this manner, and shortfalls may instead be raised directly as an RO or RI depending on their significance.
180. The RP will need to submit resolution plans in response to ROs and RIs (and to GDA Issues). The resolution plans should set out the work the RP intends to do to address the matters identified, define how long this work is expected to take and should recognise any work required to update the GDA submissions (including the DR and generic safety and security cases). Resolution plan contents will vary but will need to have sufficient detail to satisfy ONR that all relevant aspects can be addressed within the timeframe identified. However, 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 and/or security outcome.

5.7 OPENNESS, TRANSPARENCY, PROGRESS REPORTING AND PUBLIC INVOLVEMENT

181. Consistent with ONR's commitment to openness and transparency in its decision-making process, progress updates will be issued during GDA. In addition, the regulators will publish their ROs, RIs, assessment reports and other associated documentation at appropriate points. Inevitably, these will contain some technical details, but commercial and security related information will be redacted.
182. Arrangements will be agreed between the regulators and the RP, during Step 1, to enable the public to view information on the design, safety, security and environment protection cases (with the exception of commercially confidential and security sensitive information) on a website hosted by the RP. This will include the opportunity 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 give due consideration to relevant issues that are raised in the public comments process and to the RP's responses, but

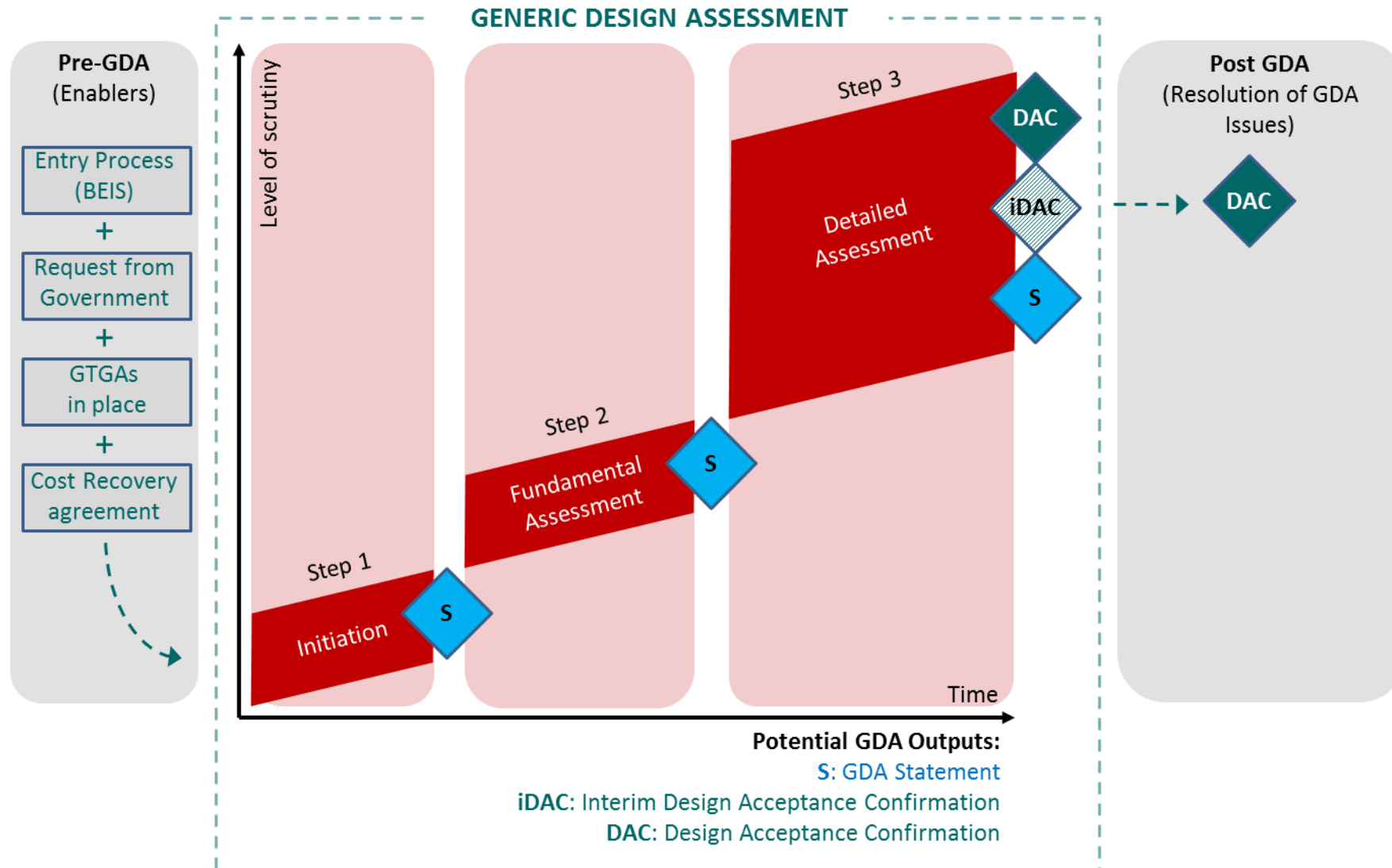
will remain wholly responsible for decisions on the acceptability or otherwise of the design put forward by the RP.

183. The regulators also have duties to provide information to the public when requested to do so under the Freedom of Information Act 2000 (Ref. 19) and the Environmental Information Regulations 2004 (Ref. 19). Even if the information is protectively marked, the regulators will still be obliged to consider whether it is in the public interest for it to be released.

6 REFERENCES

1. New Nuclear Power Plants Guide to the Nuclear Regulators' Approach. NGN01 Revision 0. September 2013. www.onr.org.uk/new-reactors/ngn01.pdf. An updated version coming soon.
2. New nuclear power plants: Generic Design Assessment Guidance for Requesting Parties. Environment Agency. October 2019. <https://www.gov.uk/government/publications/new-nuclear-power-plants-generic-design-assessment-guidance-for-requesting-parties>
3. New nuclear reactors: Generic Design Assessment Guidance to Requesting Parties. ONR-GDA-GD-001 Revision 3. ONR. September 2016. www.onr.org.uk/new-reactors/ngn03.pdf
4. Industrial Strategy - Nuclear Sector Deal. www.gov.uk/government/publications/nuclear-sector-deal
5. New nuclear power plants: Generic Design Assessment Technical Guidance. ONR-GDA-GD-007 Revision 1. May 2019. <http://www.onr.org.uk/new-reactors/reports/onr-gda-007.pdf>
6. GDA entry process. Department for Business, Energy and Industrial Strategy. To be available (at a time to be confirmed) on www.gov.uk/government/publications/advanced-nuclear-technologies/advanced-nuclear-technologies
7. The Nuclear Industries Security Regulations 2003 (as amended). www.legislation.gov.uk/ukdsi/2017/9780111152935
8. Licensing Nuclear Installations: September 2019. www.onr.org.uk/licensing-nuclear-installations.pdf
9. Safety Assessment Principles for Nuclear Facilities. 2014 Edition. Revision 0. www.onr.org.uk/saps/saps2014.pdf
10. Guidance on the Demonstration of ALARP (As Low As Reasonably Practicable). NS-TAST-GD-005 Revision 9. www.onr.org.uk/operational/tech_asst_guides/ns-tast-gd-005.pdf
11. Guidance on the Security Assessment of Generic New Nuclear Reactor Designs. CNS-TAST-GD-11.1 Revision 0. www.onr.org.uk/operational/tech_asst_guides/cns-tast-gd-11.1.pdf
12. Security Assessment Principles for the Civil Nuclear Industry. 2017 Edition. Version 0. www.onr.org.uk/syaps/security-assessment-principles-2017.pdf
13. Technical Assessment Guides. www.onr.org.uk/operational/tech_asst_guides/index.htm
14. Licence condition handbook. February 2017. www.onr.org.uk/documents/licence-condition-handbook.pdf
15. A guide to Nuclear Regulation in the UK. 2016 update. www.onr.org.uk/documents/a-guide-to-nuclear-regulation-in-the-uk.pdf
16. Risk Informed Regulatory Decision Making. 2017. www.onr.org.uk/documents/2017/risk-informed-regulatory-decision-making.pdf

17. ONR Decision Review and Appeals Process. ONR-PER-IN-006 Revision 003. December 2018. www.onr.org.uk/operational/assessment/ns-per-in-006.pdf
18. Government Security Classifications, Version 1.1, May 2018. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/715778/May-2018_Government-Security-Classifications-2.pdf
19. Freedom of Information (FOI) or Environmental information regulations (EIR). www.onr.org.uk/foi/index.htm

APPENDIX 1: THE GDA PROCESS

APPENDIX 2: STEP 1 - INITIATION

Description
<p>Step 1 is the project initiation part of the design assessment process. This will involve the RP establishing its project management and technical teams, its arrangements for undertaking a GDA and preparing and submitting submissions during Step 1 and for the commencement of Step 2. It will also involve discussions between the RP and ONR to ensure a full understanding of the requirements and processes that will be applied, in particular if gaps are evident in meeting regulatory expectations and what will be done to resolve them.</p>
Objective
<p>The objectives for Step 1 are for ONR and the RP to agree:</p> <ul style="list-style-type: none"> • the GDA scope; • the documentary basis for the generic safety and security cases that will be submitted for assessment throughout GDA; • the gaps that have been identified by the RP in meeting regulatory expectations and the resolution plans for how these may be resolved; • the RP's arrangements necessary to undertake the GDA; and • the schedule and associated programme for subsequent Steps.
Prerequisites
<p>In order to start Step 1 it is necessary for:</p> <ul style="list-style-type: none"> • ONR and the RP to have signed a cost recovery agreement; • ONR to obtain confirmation that the required GTGAs are in place; • ONR to have received a request from BEIS to begin a GDA on the design proposed by the RP; • ONR to have mobilised sufficient management, assessment and JPO resource; and • ONR to publish a statement indicating that it has decided to start a GDA for the proposed design.
The RP is required to, during the Step
<p>[1.1] <u>Agree with ONR</u> interface arrangements to be applied throughout GDA</p> <p>[1.2] <u>Agree with ONR</u> the GDA scope, to ensure that the assessment is meaningful</p> <p>[1.3] <u>Agree with ONR</u> the overall GDA timescales and associated schedule, including subsequent Steps</p> <p>[1.4] <u>Put arrangements in place</u> to 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 in ONR's offices</p> <p>[1.5] <u>Put arrangements in place</u> for handling and protecting security marked documentation, including identifying any SNI. ONR expects the RP's document classification scheme to be compatible with the Government Security Classifications (Ref. 18)</p> <p>[1.6] <u>Obtain</u> all necessary personnel security clearances for all staff who will be supporting GDA</p>

- [1.7] Obtain all necessary export licenses to ensure that information can be transferred to and from the UK, and other relevant countries where information transfer is necessary as part of GDA
- [1.8] Submit to ONR design familiarisation information. This should include sufficient information to provide ONR with an overall understanding of the safety and security of the proposed design, in line with the agreed scope for GDA. This should also include information on the current status of the design and the identification of any aspects where development is still required, alongside an indication of what this may entail and likely timescales. The RP should identify any distinguishing features of the design
- [1.9] Submit to ONR information on assessments performed by other regulators on the proposed design, including the current status of any reviews, any findings and any changes made or proposed as a result, including a judgement on their significance
- [1.10] Submit to ONR a description of the fundamental design philosophy and identification of the main safety and security claims including identification of hazards, control measures and protection systems
- [1.11] Submit to ONR a description of the process being adopted by the RP to demonstrate compliance with the legal duty to ensure that the risks to human health arising from the operation of a power station based on the proposed design are reduced to ALARP
- [1.12] Submit to ONR a description of the process being adopted by the RP to demonstrate compliance with the requirements of the Nuclear Industries Security Regulations (NISR)
- [1.13] Submit to ONR evidence of the RP's understanding of the nuclear regulatory framework and regulatory principles and how these have been (or will be) considered as part of the design and generic safety and security cases for the proposed design. This should include matters such as:
 - a. the approach to categorisation of safety functions and classification of structures, systems and components
 - b. the development of a schedule of faults (including internal events and internal and external hazards), including protection and mitigation measures and the links this has to the associated engineering
 - c. an understanding of the approach adopted to defence in depth and the hierarchy of controls, including consideration of matters such as common cause failure, segregation, redundancy and diversity
- [1.14] Submit to ONR information about the reference design (or designs) on which the generic safety and security cases are based, if appropriate
- [1.15] Submit to ONR the RP's own design, security and safety principles adopted in the proposed design
- [1.16] Submit to ONR a definition of the site characteristics to be used as the basis for the safety analysis (the 'generic site envelope')
- [1.17] Submit to ONR a description of the codes and standards which have been used as part of the proposed design, including the identification of any non-conformances
- [1.18] Put arrangements in place for development of the safety and security cases. Agree with ONR the approach for structuring the generic safety and security cases and their format, including the intentions for using existing information throughout GDA. This should include details of existing safety and security case information and its availability. Where existing information is to be used the scope, background and regulatory basis of this information should be specified
- [1.19] Agree with ONR a schedule of generic safety and security case information which will

- be submitted to ONR ahead of, and during Step 2. Submit to ONR any information agreed for submission during Step 1
- [1.20] Undertake a gap analysis of the submissions identified to support Step 2 against regulatory expectations. Where gaps are identified the RP should agree with ONR a resolution plan which identifies what those gaps are, how they may be resolved and the timescales for doing so. For any gaps which are within the GDA scope, any identified additional submissions should be made at a time agreed with ONR during Step 2
- [1.21] Agree with ONR the scope and contents (template) of the Master Document Submission List (MDSL) and any required arrangements for handling it, including provision of routine updates. Submit to ONR the MDSL in accordance with the RP's arrangements and any updates necessary throughout the Step
- [1.22] Agree with ONR the scope and contents of the Design Reference (DR) and any required arrangements for handling it, including routine updates, and the intent for the Design Reference Point (DRP)
- [1.23] Put arrangements in place for capturing commitments, assumptions and requirements identified in the generic safety and security cases. This should include matters relating to information which will need to be implemented in operational documentation; including operating limits, maintenance schedule, procedures (normal operation, emergency and accident management), training programmes, emergency preparedness, radiation protection arrangements for operators, lifetime records, construction and commissioning requirements etc. Submit to ONR a description of those arrangements and a demonstration of their adequacy for GDA
- [1.24] Submit to ONR responses to any questions raised by ONR during its assessment (RQs, ROs and RIs)
- [1.25] Obtain sufficient resources to support completion of GDA. This should include technical, regulatory, front office, interface and management resources, as necessary, and may include third-party support. The RP should submit to ONR information regarding its intentions for evolution of its GDA resources and a demonstration of the on-going sufficiency of resources to be applied through the Step
- [1.26] Put arrangements in place to facilitate meetings between ONR and relevant RP's personnel to share information and discuss technical matters
- [1.27] Submit to ONR a demonstration of the adequacy of the RP's arrangements, including:
- a. project management arrangements and quality management system
 - b. the DR change control process to be applied during GDA, including the RP's decision making arrangements for safety and security related matters
 - c. arrangements and timescales for responding to ONR assessment
 - d. arrangements for ensuring that the designers, and generic safety and security case authors and approvers are suitably qualified and experienced persons
 - e. the generic safety and security case developer's quality control, including peer review arrangements
- [1.28] Put arrangements in place to facilitate a public comment process which should run for the duration of GDA. This should include:
- a. Host a public website containing information on the proposed design and generic safety and security cases, and including the means to submit comments
 - b. Agree with ONR what information will be published on the RP's website (following removal of commercial and security related information) to allow

<p>comments to be made by the public during GDA, including updates when a significant change is made to the information submitted to ONR</p> <p>c. <u>Agree with ONR</u> the process and timescales to be adopted for responding to public comments</p> <p>[1.29] <u>Agree with ONR</u> any extended or revised cost recovery agreements. This should cover the remainder of all subsequent Steps</p> <p>[1.30] <u>Undertake</u> a review of its readiness to begin Step 2 and <u>submit to ONR</u> evidence to support the outcomes</p>	
ONR will, during the Step	
<p>[1.31] Assess the submissions made to ONR during the Step, in line with relevant standards and guidance, and provide feedback to the RP. This will specifically include:</p> <ul style="list-style-type: none"> a. The overall safety and security case scope, approach and extent b. The fundamental design safety and security philosophy, codes, standards and criteria used c. The approach to demonstrating compliance with the nuclear safety and security framework, including demonstrating risks are reduced to ALARP and the general concept of security operations d. The generic site envelope and its links to the safety case e. Whether the assessment remains meaningful, and if not, what changes are necessary to resolve this <p>[1.32] Raise with the RP regulatory questions and assess the responses, including reviewing resolution plans for ROs and RIs</p> <p>[1.33] Publish all ROs, RIs and associated RP's resolution plans, including confirmations once these have been satisfactorily resolved. This includes the resolution plan identified in [1.20]</p> <p>[1.34] Confirm the acceptability of the proposed agreements reached between ONR and the RP. This includes those relating to the GDA scope, submission plans and schedule</p> <p>[1.35] Provide advice and guidance to the RP on likely gaps to meeting regulatory expectations, including the development of the resolution plan identified in [1.20]</p> <p>[1.36] Engage with relevant overseas regulators to obtain information on assessments or design reviews conducted or underway on the design proposed by the RP</p> <p>[1.37] Agree the cost recovery for later Steps (if necessary)</p> <p>[1.38] Obtain any necessary export control licenses</p> <p>[1.39] Undertake a readiness review to determine if the RP can proceed to Step 2. This will include consideration of both ONR's and the RP's readiness to continue, and also whether Step 1 can be considered completed to ONR's satisfaction. Where improvement actions on the RP are identified the resolution and timescales for resolving these will be agreed with the RP. ONR will consider whether the resulting assessment will remain meaningful, and warrants the continued deployment of regulatory resources</p> <p>[1.40] Develop detailed assessment plans for Step 2 for each technical assessment topic, including any requirement for specialist technical support contracts</p>	
ONR will, at the end of the Step	
<p>[1.41] Produce and publish a report to record the completion and outcome of Step 1,</p>	

compiling the assessment undertaken and including the decision on whether to proceed to Step 2 or not.

[1.42] Produce and publish a GDA Statement summarising:

- a. details of the GDA scope that has been agreed, and the output from the GDA that is sought by the RP
- b. details of the status of the design and associated generic safety and security cases to support GDA, including the MDSL
- c. information on the agreed resources, submissions and timescales for subsequent Steps
- d. the assessment of the submissions provided by the RP during Step 1, including the gap analysis against regulatory expectations provided by the RP together with its resolution plan
- e. details of the readiness review conducted to determine if the RP can continue to Step 2 and its outcome
- f. any open regulatory questions (RQs, ROs and RIs)
- g. any areas of regulatory concern to be taken forward in later Steps

APPENDIX 3: STEP 2 - FUNDAMENTAL ASSESSMENT

Description
<p>Step 2 is the first substantive technical assessment Step. The focus of the assessment in this Step is towards the fundamental adequacy of the design and safety and security cases, and the suitability of the methodologies, approaches, codes, standards and philosophies which form the building blocks for the design and generic safety and security cases. This is expected to be undertaken at a breadth and depth of assessment akin to ONR's Assessment Principles (SAPs and SyAPs), with limited use of the detailed TAGs. During this Step it is expected that the RP will complete its understanding of the regulatory approach and incorporate this into submissions which resolve any gaps in meeting regulatory expectations, as identified during Step 1.</p>
Objective
<p>The objectives for Step 2 are for:</p> <ul style="list-style-type: none"> • ONR to undertake an assessment of the design against regulatory expectations to identify any fundamental safety or security shortfalls that could prevent ONR permissioning the construction of a power station based on the design; and • the RP to complete production of the submissions required to support the assessment during Step 2, as well as future submissions required to support Step 3 if necessary. This includes, but not limited to, any additional documentation identified in Step 1 as being necessary to resolve gaps in meeting regulatory expectations.
Prerequisites
<p>In order to start Step 2 it is necessary for:</p> <ul style="list-style-type: none"> • ONR and the RP to have a cost recovery agreement in place; • ONR to have fully mobilised the management, JPO and assessment resources required; • The RP to have submitted the information necessary to start the Step, including a credible plan for submissions to be made during the Step; and • ONR to have published a GDA Statement from Step 1, confirming the readiness of the RP to proceed to Step 2
The RP is required to, during the Step
<p>[2.1] <u>Agree with ONR</u> any changes necessary to the GDA scope, to ensure that the assessment remains meaningful</p> <p>[2.2] <u>Agree with ONR</u> any changes to the overall GDA timescales and associated schedule, including subsequent Steps</p> <p>[2.3] <u>Submit to ONR</u> any additional relevant information which arises due to on-going assessments performed by other regulators on the proposed design, including any significant findings and any changes made or proposed as a result</p> <p>[2.4] <u>Submit to ONR</u> a demonstration that the proposed design is likely to reduce risks to human health to ALARP</p> <p>[2.5] <u>Submit to ONR</u> a demonstration that the proposed design is likely to be compliant with the Nuclear Industries Security Regulations (NISR)</p> <p>[2.6] <u>Submit to ONR</u> a demonstration of the application of the RP's categorisation of safety functions and classification of structures, systems and components within the proposed design</p>

- [2.7] Submit to ONR a schedule of faults (including internal events, internal and external hazards), including protection and mitigation measures and the links this has to the associated engineering
- [2.8] Submit to ONR a demonstration of the application of the RP's approach adopted to defence in depth and the hierarchy of controls, including consideration of matters such as common cause failure, segregation, redundancy and diversity within the proposed design
- [2.9] Submit to ONR a demonstration of how the RP's own design, security and safety principles have been adopted in the proposed design
- [2.10] Submit to ONR information on the methodologies to be adopted for the identification of Vital Areas, the analysis of cyber security risks and the approach to security related defence in depth
- [2.11] Submit to ONR the agreed submissions, which align with the expectations given in the discipline technical guidance (Ref. 5), in accordance with the GDA scope. This should include:
- a. Sufficient detail for ONR to satisfy itself that relevant Assessment Principles (SAP and SyAPs) are likely to be satisfied
 - b. A safety and security case 'head document', or equivalent, which provides the overall safety and security narrative and structure; including a demonstration that the 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
 - c. Details on the methodologies, approaches, codes, standards and philosophies used and a justification that these are consistent with what would be considered as Relevant Good Practice (RGP). Identification and explanation of any deviations, including how these have been resolved or demonstrated to reduce risks to ALARP
 - d. Supporting safety analysis, including deterministic and probabilistic safety analyses to cover the GDA scope
 - e. Details of the verification and validation of any software or computer codes used within the supporting analysis
 - f. Detailed descriptions of system architectures and key structures, systems and components, their safety or security functions, and reliability and availability requirements
 - g. Identification of the safe operating envelope and the operating regime that maintains the integrity of that envelope
- [2.12] Submit to ONR the documentation identified within the resolution plans produced in response to the gap analysis against regulatory expectations [1.20]
- [2.13] Submit to ONR information regarding any outstanding information in the generic safety and security cases that remains to be developed and its significance
- [2.14] Agree with ONR a schedule of generic safety and security case information which will be submitted to ONR prior to the start of Step 3
- [2.15] Continue to maintain and update the Master Document Submission List (MDSL) in accordance with the RP's arrangements produced during Step 1, at regular intervals throughout the Step
- [2.16] Submit to ONR the first Design Reference Point (DRP) in accordance with the RP's arrangements produced during Step 1. Continue to update this as necessary

throughout the Step

- [2.17] Submit to ONR a demonstration that the arrangements for capturing assumptions, commitments and requirements from the safety and security cases have been applied. Continue to apply these arrangements throughout the Step
- [2.18] Continue to apply the DR change control arrangements throughout the Step. Submit to ONR any design change information specified under these arrangements
- [2.19] Put arrangements in place for developing the safety case into a site-specific Pre-Construction Safety Report which clearly demonstrates that this can be achieved by a future licensee. Submit to ONR a description of those arrangements and a demonstration of their adequacy for GDA
- [2.20] Put arrangements in place for developing the security case into a Nuclear Site Security Plan for the operating site, which clearly demonstrates that this can be achieved by a future licensee. Submit to ONR a description of those arrangements and a demonstration of their adequacy for GDA
- [2.21] Submit to ONR responses to any questions raised by ONR during its assessment (RQs, ROs and RIs)
- [2.22] Submit to ONR information regarding its intentions for evolution of its GDA resources and a demonstration of the on-going sufficiency of resources to be applied through the Step
- [2.23] Continue to facilitate meetings between ONR and relevant RP's personnel to share information and discuss technical matters
- [2.24] Continue to facilitate the public comment process including hosting a public website, containing relevant and updated generic safety and security cases, and responding to comments made by the public
- [2.25] Undertake a review of its readiness to begin Step 3 and submit to ONR evidence to support the outcomes

ONR will, during the Step

- [2.26] Assess the adequacy of the submissions made to ONR during the Step, in line with relevant standards and guidance, and provide feedback to the RP. The scope of ONR's assessment will be partly defined by experience from Step 1, and also by experience in previous GDAs. This will specifically include consideration of:
 - a. Any areas of regulatory concern identified during Step 1
 - b. Identification of any significant issues that may prevent ONR from issuing a DAC
 - c. Identification of any matters that might be in conflict with Government policy
 - d. Identifying the need for additional regulatory verification or analysis
 - e. Identifying where the design may not meet regulatory expectations
 - f. The adequacy of the arrangements in place which will ensure that the design and safety and security cases are controlled and can be used by a future licensee. This includes the design change control arrangements, DRP, MDL and transfer of the safety and security cases to an operating regime
 - g. Whether the assessment remains meaningful, and if not, what changes are necessary to resolve this
- [2.27] Raise with the RP regulatory questions and assess the responses, including reviewing resolution plans for ROs and RIs

- [2.28] Publish all ROs, RIs and associated RP's resolution plans, including confirmations once these have been satisfactorily resolved
- [2.29] Confirm the acceptability of the proposed agreements reached between ONR and the RP. This includes those relating to the GDA scope, submission plans and schedule
- [2.30] Engage with relevant overseas regulators to obtain information and seek to make use of it as part of ONR's assessment
- [2.31] Undertake a readiness review to determine if the RP can proceed to Step 3. This will include consideration of both ONR's and the RP's readiness to continue, and also whether Step 2 can be considered completed to ONR's satisfaction. Where improvement actions on the RP are identified the resolution and timescales for resolving these will be agreed with the RP
- [2.32] Develop detailed assessment plans for Step 3 for each technical assessment topic, including any required specialist technical support contracts

ONR will, at the end of the Step

- [2.33] Produce and publish a report to record the completion and outcome of Step 2, compiling the assessment undertaken and including the decision on whether to proceed to Step 3 or not.
- [2.34] Depending upon the agreed GDA scope, produce and publish assessment reports for the technical assessment topics considered
- [2.35] Produce and publish a GDA Statement summarising:
 - a. details of the status of the design and associated generic safety and security cases, including the MDSL and DRP
 - b. the assessment of the submissions provided by the RP during Step 2
 - c. details of the readiness review conducted to determine if the RP can continue to Step 3
 - d. any open regulatory questions (RQs, ROs, and RIs)
 - e. any areas of regulatory concern to be taken forward in later Steps
 - f. any significant issues that may prevent ONR from issuing a DAC, might prevent ONR permissioning construction of a NPP based upon that design or which might be in conflict with Government policy

APPENDIX 4: STEP 3 - DETAILED ASSESSMENT

Description
<p>Step 3 is the detailed assessment Step. The focus of the assessment is an in-depth assessment of the design and safety and security cases. This will involve a fully detailed examination of the available evidence, on a sampling basis, provided in the safety and security submissions. This is expected to be undertaken at a level of assessment akin to the TAGs and will fully consider whether the proposed design reduces risks to ALARP and meets the requirements of the NISR. To commence the Step, it is expected that the RP will have submitted all of the required evidence, and will resolve regulatory questions in a timely manner throughout the Step in order to support ONR's assessment. Prior to the end of the Step, the RP will need to consolidate the GDA submissions, and provide evidence for how these could be effectively used by a future licensee in producing their site-specific safety and security cases.</p>
Objective
<p>The objectives for Step 3 are for:</p> <ul style="list-style-type: none"> • ONR to undertake a detailed assessment of the design and supporting generic safety and security cases against regulatory expectations to come to a conclusion on the acceptability of the design for construction on a site bounded by the generic site envelope.
Prerequisites
<p>In order to start Step 3 it is necessary for:</p> <ul style="list-style-type: none"> • The RP to have submitted the information necessary to undertake the Step; and • ONR to have published a GDA Statement from Step 2, confirming the readiness of the RP to proceed to Step 3.
The RP is required to, during the Step
<p>[3.1] <u>Agree with ONR</u> any changes to the overall GDA timescales and associated schedule</p> <p>[3.2] <u>Agree with ONR</u> cut-off dates for responding to regulatory questions (RQs, ROs and RIs), providing submissions or including DR changes within GDA</p> <p>[3.3] <u>Submit to ONR</u> any additional information which arises due to on-going assessments performed by other regulators on the proposed design, including any significant findings and any changes made or proposed as a result</p> <p>[3.4] <u>Submit to ONR</u>, to commence Step 3, any outstanding information, safety or security case material and research results that provide evidence to underpin the cases, in accordance with the agreed GDA scope</p> <p>[3.5] <u>Continue</u> to maintain and update the Master Document Submission List (MDSL) throughout the Step</p> <p>[3.6] <u>Continue</u> to maintain and update the Design Reference Point (DRP) throughout the Step</p> <p>[3.7] <u>Continue</u> to apply the arrangements for capturing assumptions, commitments and requirements from the safety and security cases throughout the Step</p> <p>[3.8] <u>Continue</u> to apply the DR change control arrangements throughout the Step. <u>Submit to ONR</u> any design change information specified under these arrangements</p> <p>[3.9] <u>Submit to ONR</u> a demonstration that the arrangements for developing the safety case into a site-specific Pre-Construction Safety Report have been applied</p>

- [3.10] Submit to ONR a demonstration that the arrangements for developing the security case into a Nuclear Site Security Plan for the operating site have been applied
- [3.11] Submit to ONR responses to any questions raised by ONR during its assessment (RQs, ROs and RIs)
- [3.12] Submit to ONR information regarding its intentions for evolution of its GDA resources and a demonstration of the on-going sufficiency of resources to be applied through the Step
- [3.13] Continue to facilitate meetings between ONR and relevant RP's personnel to share information and discuss technical matters
- [3.14] Continue to facilitate the public comment process including hosting a public website, containing relevant and updated generic safety and security cases, and responding to comments made by the public
- [3.15] Submit to ONR, prior to the end of the Step, a consolidated GDA submission which rationalises the submissions into a consistent set of documentation and incorporates responses to regulatory questions and DR changes which have been agreed to be included within GDA. This should include the arrangements and outputs for ensuring the safety and security cases can be met in practice

ONR will, during the Step

- [3.16] Undertake a detailed assessment on a sampling basis of the adequacy of the submissions made to ONR during the Step, in line with relevant standards and guidance, and provide feedback to the RP. The scope of ONR's assessment will be partly defined by experience from earlier Steps, and also by experience in previous GDAs. This will specifically include consideration of:
 - a. Any areas of regulatory concern identified during Step 2
 - b. Identification of any significant issues that would prevent ONR from issuing a DAC
 - c. Identification of any matters that are in conflict with Government policy
 - d. Identifying where the design does not meet regulatory expectations
 - e. Establishing whether the system performance, safety classification, and reliability requirements are substantiated by the detailed engineering design
 - f. Establishing that the safety and security cases from GDA are suitable for moving to an operating regime
 - g. Whether the assessment remains meaningful, and if not, what changes are necessary to resolve this
- [3.17] Raise with the RP regulatory questions and assess the responses, including reviewing resolution plans for ROs and RIs
- [3.18] Publish all ROs, RIs and associated RP's resolution plans, including confirmations once these have been satisfactorily resolved
- [3.19] Confirm the acceptability of the proposed agreements reached between ONR and the RP. This includes those relating to the GDA scope, submission plans and schedule
- [3.20] Continue to engage with relevant overseas regulators to obtain information and seek to make use of it as part of ONR's assessment
- [3.21] Conclude any required specialist technical support contracts, including independent confirmatory analysis or substantiation

ONR will, at the end of the Step

[3.22] Produce and publish a report to record the completion and outcome of Step 3, compiling the assessment undertaken

[3.23] Produce and publish assessment reports for each of the technical assessment topics considered

[3.24] Dependant on the agreed GDA scope, either:

Publish the decision on whether to grant a DAC, iDAC or no DAC. As appropriate, produce and publish a DAC or iDAC. In the case of an iDAC ONR will also publish the GDA Issues and associated RP's resolution plans. Any DAC or iDAC will refer to the consolidated safety and security cases, the DR and MDSL.

OR

Produce and publish a GDA Statement summarising:

- a. details of the status of the design and associated safety and security cases, including the MDSL and DRP
- b. the assessment of the submissions provided by the RP during Step 3
- c. any open regulatory questions (RQs, ROs and RIs)
- d. any areas of regulatory concern that remain to be resolved
- e. any significant issues that may prevent ONR from issuing a DAC, might prevent ONR permissioning construction of a NPP based upon that design or which might be in conflict with Government policy