



Health and Safety
Executive



Environment
Agency

New nuclear power stations Generic Design Assessment

GUIDANCE ON THE MANAGEMENT OF GDA OUTCOMES

(including the scope of GDA, Provision of HSE Design Acceptance Confirmations and Environment Agency Statements of Design Acceptability, and the resolution of Issues and assessment findings raised during GDA)

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Background

1. The Generic Design Assessment (GDA) process has been set up to improve clarity and certainty in the new nuclear power station regulatory process. It provides a structured process for early engagement between reactor designers and regulators, with HSE and Environment Agency working together. It allows safety cases for the generic new reactor designs to be assessed well ahead of any construction in the UK, and for safety issues to be identified and resolved early in the project. GDA also allows the possibility of using a generic safety case as the basis for the regulation of a fleet of reactors, based on a common design. We therefore believe that GDA enables industry to plan with improved confidence.
2. Clearly, a judgement has to be made as to when to start this regulatory engagement on a future design. Key to that decision is the need for the regulators to have confidence that the proposed reactor design, and, importantly for the GDA, its safety case, is sufficiently complete to allow for the start of GDA, and that was indeed the argument provided to the regulators by the design companies (Requesting Parties) for the reactors currently in the GDA process.
3. For these reactors, full design details were not available when GDA started, and will still not be available when GDA is complete. This was foreseen at the outset of GDA: the important point is that the safety case that is assessed in GDA envelopes the key safety parameters that then need to be adopted during the forthcoming design, procurement, construction and commissioning phases of the project. Regulators will then ensure compliance with the GDA safety case as the project progresses.
4. This guidance document sets out the process for managing the outcomes from the GDA, and outlines the process for taking those outcomes into the ongoing design, procurement, construction and commissioning phases of specific power stations. It also outlines the arrangements that will be applied by regulators for management of the end of the GDA process.
5. The guidance has been developed from the principles set out in the earlier GDA guidance documents (Ref: 1,2,3) and further discussions with stakeholders in the light of experience of assessment to-date. It also builds on and reflects upon comments received on the initial discussion document on the management of GDA Design Acceptance Confirmations (Ref: 4) that was published on our website in May 2009. It is aimed at providing advice to GDA Requesting Parties (RPs), potential future operators and other stakeholders. It also provides the general public with transparency about how the end of GDA will be managed.
6. This guidance caters for a variety of potential outcomes from the GDA including the possibilities that a meaningful assessment cannot be completed, or that regulators cannot conclude in favour of the proposed designs.

Meaningful GDA

7. A meaningful GDA will be one where:
 - the regulators have received sufficient information on the generic reactor design in the safety, security and environment submissions to allow assessment in all relevant technical topic areas; and
 - the regulators have completed a sufficiently thorough and detailed assessment of the information in the generic safety, security and environment submissions.
8. In the above, 'thorough and detailed assessment' means that we have looked in detail at the generic design submissions and judged them against our regulatory assessment principles, including the need to demonstrate that risks are reduced, or are capable of being reduced, ALARP (As Low As Reasonably Practicable). The assessment relates only to the safety case information provided on the generic design and does not mean that the regulators have received and assessed all the information necessary to permit construction and operation of a plant, based on that design, at a specific site in the UK.
9. The depth and scope of our assessment is unlikely to be the same in all technical areas, reflecting likely variation in the information available, and also of its specific relevance to the safety case. However, we will need to be satisfied that our sampling of the information that is available, together with any work programmes to resolve technical issues arising during our assessment, has allowed us to come to a balanced judgement on the overall acceptability of the safety case for the proposed generic design, covering safety, security and environmental factors.
10. If the supply of information on the design and the safety, security and environmental submissions are inadequate, then it follows that we will not be able to complete a meaningful GDA.
11. It is vital, therefore, that the RPs provide design safety case submissions of high quality, to an agreed timetable. Crucial to the delivery of a meaningful GDA is complete clarity on what documents constitute the RP's GDA submissions, and how the information they contain addresses the requirements in the earlier guidance documents (Ref: 1,2,3).

Scope of GDA

12. Whilst regulators require a certain minimum level of detail to complete GDA, they recognise that full engineering details of the design will not be available at the GDA stage, as it is normal to finalise some of these as part of the procurement and construction programme.
13. The scope of what is included within the regulators' generic design assessments is dependent on the information supplied by the RP (remembering that GDA is a voluntary process, undertaken at the request of the RP). However, the required information for GDA needs to be sufficient in scope and detail to underpin the generic safety case for the design. Should there be omissions in that information that may jeopardize the completion of a meaningful assessment under the GDA

process, then the regulators will insist on the scope of the submissions for GDA being expanded to include such essential information.

14. The GDA submissions should include the GDA Design Reference and the GDA Safety, Security and Environment Submissions. These documents and their control arrangements are described below.

(i) GDA Safety, Security and Environment Document Submissions

RPs are required to provide comprehensive, generic Pre Construction Safety, Security and Environmental Reports (as set-out in the GDA Guidance documents. (Ref 1,2,3)), supported by reference documents. These will include information that defines the characteristics assumed for the generic site envelope.

As the regulators progress through GDA they will request submission of a selection of these references so that more detailed information can be examined. There will also be developments in the safety case, design modifications, and responses to regulator assessment questions. The GDA information submitted by the RPs can therefore become a complicated mix of documents. In order to keep appropriate control of this mix, project management arrangements are required to keep track of the documents submitted, of subsequent changes to these documents, and of documents removed from the submission, etc. Key to these arrangements is a Master Document Submission List, which is a 'live' document that allows the regulators to understand and reference precisely what constitutes the latest versions of the GDA submissions.

(ii) GDA Design Reference and Design Reference Point

RPs are also required to submit a Design Reference which lists all the documents that describe the design of the reactor and associated plant that the GDA submissions refer to. Regulators expect this to be 'frozen' at a specific date known as the Design Reference Point.

The Design Reference and its Design Reference Point will be agreed on a case-by-case basis with each RP, but will need to be in place early in HSE's GDA Step 4 and before the Environment Agency's consultation.

(iii) Design Reference Change Control

Following the Design Reference Point, a GDA change control process will be required.

The details of the change control system are for the RP to propose and regulators to agree. However, regulators will expect this to be based on a robust system such as those required to satisfy Nuclear Site Licence Condition 20 (modification to design of plant under construction).

Features that the regulators will expect to see include: a categorisation system reflecting the potential safety, security or environmental impact of the change; change control committees to oversee the categorisation and the operation of the process; and a route for alerting regulators to the more

significant changes to the safety case. Regulators will inspect these arrangements as part of GDA.

Changes proposed at an advanced stage in GDA may jeopardize the ability of the regulators to complete a timely and meaningful assessment. Consequently, the regulators will take a view on whether the proposed changes should be brought within the scope of GDA.

(iv) GDA Submission Quality Assurance Arrangements

As well as ensuring that each RP's safety case submission is well defined, regulators also require that it is produced under robust quality assurance arrangements. The RP's arrangements will be required to ensure that this is achieved, and examination of these arrangements forms part of the regulators' assessment during GDA.

(v) GDA Submission Consolidation

Towards the end of GDA, there will be a need for the RP to re-consolidate the Design Reference and generic Pre Construction Safety, Security and Environmental Reports and supporting documentation made available, to take into account:

- all the additional information that has been provided in response to regulator technical questions or arising from the Environment Agency's consultation; and
- any RP proposed GDA submission changes that the regulators have agreed can be included in the GDA scope.

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

15. One outcome from GDA is a commitment from regulators not to further assess at the site specific stage of the project aspects of the safety case already assessed and accepted at the generic design stage. However, should the RP or operator (Licensee) later make either generic or site-specific safety significant changes that affect the basis of the GDA outcome, then those aspects of the GDA safety submission may well require re-assessment by the regulators.

The Conclusion of the GDA Assessment

16. The output from GDA will be set out in a public statement from the regulators on their conclusions. For HSE this will take the form of a summary assessment report for each design (known as the Step 4 report), supplemented by a series of detailed technical topic reports. For the Environment Agency this will take the form of a decision document following their consultation.

17. There could be three different outcomes:

- a) If the regulators are fully content with safety, security and environmental aspects of the safety case for the generic design, then they will provide the RP with an HSE Design Acceptance Confirmation (DAC) and Environment Agency Statement of Design Acceptability. That would mark

the end of the Generic Design Assessment of the safety case for that particular generic design and the end of GDA.

- b) If the regulators are largely content with safety, security and environmental aspects of the safety case for the generic design, then they will provide the RP with an HSE Interim Design Acceptance Confirmation (DAC) or Environment Agency Interim Statement of Design Acceptability and identify the unresolved GDA Issues. These Issues would need to be cleared before a Final HSE DAC or Environment Agency Statement of Design Acceptability could be provided. Consequently, before providing such an Interim DAC or Statement of Design Acceptability, the regulators would need to be content that all of the Issues referenced in the Interim DAC or Statement of Design Acceptability were amenable to timely resolution. Consequently, the RP would need to have submitted an agreed Resolution Plan covering each Issue, and through this Resolution Plan the RP would set out the work they needed to do to address the relevant issue and identify how long this work would take. However, the provision of an Interim DAC or Statement of Design Acceptability would still mark the end of the regulators' assessment of the submitted safety case for that particular design, with only the Issues covered by the Resolution Plan still considered as covered by the ongoing GDA assessment.
- c) If the regulators are not content with safety, security or environmental aspects of the safety case for the generic design, then no Design Acceptance Confirmation (DAC) or Statement of Design Acceptability will be issued. This would be the case where regulators judge that there is a significant, unacceptable shortfall in the design or safety submissions. It would be a matter for the RP to decide whether to propose additional work to address the shortfalls, which may allow a Final or Interim Design Acceptance Confirmation or Statement of Design Acceptability to be provided at some future date.

HSE Design Acceptance Confirmation (DAC)

- 18. If HSE provides a DAC to a RP it will mean it is confident that, based on the submitted generic safety case, the design is capable of being built and operated in the UK, on a site bounded by the generic site envelope, in a way that is safe and secure. HSE would take the DAC into consideration in assessing the adequacy of any future Licensee's case for requesting a Consent for the start of the nuclear island safety related construction for that type of reactor design at a specific site in the UK licensed for that purpose.
- 19. Provision of an Interim DAC to a RP will mean that HSE is confident that the design is capable of being built and operated in the UK on a site bounded by the generic site envelope, in a way that is safe and secure, but that there are some GDA Issues that need resolution before it could consider granting permission for the start of nuclear island safety related construction. Before issuing an Interim DAC, HSE will need to be satisfied that the GDA Issues are resolvable and that there are no generic design 'show-stoppers' present or anticipated.

20. The Interim and Final DACs will refer to a consolidated GDA Submission (safety and security submissions, the Design Reference and master submissions list) as the basis of what has been included within the scope of GDA.

Environment Agency Statement of Design Acceptability

21. The Statement of Design Acceptability will state the Environment Agency's view on the acceptability of the design to be permitted, under the relevant environmental legislation, for:

- the disposal of radioactive waste (gaseous, liquid and solid);
- the discharge of non-radioactive substances to controlled waters;
- the operation of conventional plant (for example, combustion plant used as auxiliary boilers), where applicable;
- the disposal or recovery of non-radioactive waste, where applicable; and
- the abstraction of water from inland waters or groundwater, where applicable.

22. The Environment Agency's view on the acceptability of the design with respect to the environmental requirements of the COMAH regulations will also be stated.

23. If the Environment Agency provides an Interim Statement of Design Acceptability to a RP, it will mean that it is confident that the design is capable of being built and operated in the UK on a site bounded by the generic site envelope, in a way that is environmentally acceptable, but that there are some Issues that it wants to see further progressed before HSE consideration be given to granting a Consent to a Licensee for the start of nuclear island safety related construction for that type of reactor design at a specific site in the UK licensed for that purpose.

24. As for the DAC, a Statement of Design Acceptability will refer to the consolidated GDA Submission (environment submissions and the Design Reference) as the basis of what has been included within the scope of GDA.

The resolution of Issues and assessment findings raised during GDA

25. The output from the GDA assessment will be a series of reports from the regulators on their conclusions and, if appropriate, a Design Acceptance Confirmation and Statement of Design Acceptability.

26. At the end of GDA Step 4, there may remain significant regulatory issues that HSE or the Environment Agency would require to be resolved before GDA could be considered as having been completed. In this case, the regulators may decide to issue an Interim DAC or Statement of Design Acceptability (see paragraph 17b). The provision of an Interim DAC or Statement of Design Acceptability would still mark the end of the regulators' assessment of the submitted generic safety case for that particular design, with only the Issues covered by the Resolution Plan still considered as covered by the ongoing GDA assessment.

27. If an RP decided to develop and resubmit its safety case to allow the Interim DAC or Statement of Design Acceptability to move to a Final DAC or Statement

of Design Acceptability, the subsequent focus of the RPs and regulators working on the GDA programme would then be on closing out the issues identified within the Resolution Plan. The closing out of the Resolution Plans would then mark the end of GDA, with the overall timescales dependent on the Issues and the timely provision of quality responses by the RPs.

28. The generic safety case that forms the basis of the GDA submission, will also inform any site-specific safety case. GDA was designed to assess the generic safety case for future reactor designs, and not the adequacy of the actual final design. It was also not intended to provide a complete assessment of the final reactor design, as there will be other issues, operator specific or site specific, that we would expect to be considered during the environmental permitting and site licensing stages. In some instances the safety case can inevitably only be validated by procurement or later testing or commissioning. This validation process is normal regulatory business and will be subject to appropriate regulatory controls. Where we identify findings of this type during our GDA assessment, we will highlight them in HSE's GDA Step 4 Reports and the Environment Agency's GDA Decision Document. We would expect them to be addressed either by the designer or by a future Operator/Licensee, as appropriate, during the detailed design, procurement, construction or commissioning phase of the new build project.
29. These other assessment findings will not come as a surprise to the RP. The subject areas in which they arise will have been discussed with the RP during the GDA assessment process.

Legal Status of GDA Design Acceptance Confirmation and Statement of Design Acceptability

30. A DAC or Statement of Design Acceptability will represent the regulators' expert and professional judgement at the time they are provided. Being based on a generic design and the associated generic safety case submissions, they do not guarantee that regulators will grant any site-specific permissions for a station based on that design. Any Interim or Final GDA DAC or Statement of Design Acceptability would remain valid for a period of 10 years, similar to the process generally adopted by existing licensees in their arrangements for Periodic safety Reviews under Nuclear Site Licence Condition 15. Renewal / updating of a DAC would be undertaken on a case-by-case basis to a programme agreed between regulators and a RP.
31. The Statement of Design Acceptability is provided by the Environment Agency as advice to the RP, in accordance with Section 37 of the Environment Act 1995, and has no other formal legal status. Similarly, a DAC issued by HSE has no legal status and is not a legal requirement of the UK's nuclear licensing regime for new nuclear power stations.

Site-Specific Regulatory Assessment

32. The relationship between GDA and the regulators' site-specific work is identified in the GDA guidance documents (Ref: 1,2,3). In particular, a successful GDA outcome does not guarantee that regulators will permit the construction of a

nuclear power station based on that design. That will depend on regulators being satisfied with site specific safety case submissions. However, the Final DAC will be required before regulatory consideration is given to granting Consent, under a Nuclear Site Licence, for nuclear island safety related construction.

33. In the site-specific phase of a project based on a reactor design that has been through GDA, regulators will expect the Final GDA Submission documentation to be incorporated largely unchanged within the potential operator's site-specific Pre-Construction Safety, Security and Environment Reports, supplemented as necessary with detailed site-specific information. To improve the efficiency of the regulators' site-specific work, it is essential that the potential operator ensures that the use of the GDA information is clearly identified in their submissions. Likewise, the potential operator must ensure that there is a programme in place to address, during the ongoing design, procurement, construction, testing and commissioning programme, the other assessment findings from GDA.
34. As mentioned earlier, one outcome from GDA is a commitment from regulators not to further assess at the site specific stage of the project aspects of the safety case already assessed and accepted at the generic design stage. However, should the RP or operator (Licensee) later make either generic or site-specific safety significant changes that affect the basis of the GDA outcome, then those aspects of the GDA safety submission may well require re-assessment by the regulators.
35. It is intended that the GDA DAC and Statement of Design Acceptability can be used to underpin the regulatory permissions needed by one or more operators to construct a fleet of reactors based on a common safety case design. This is a key advantage of the GDA process over a more traditional site-specific safety case assessment process undertaken as part of the licensing process.

References

1. HSE's New nuclear power stations Generic Design Assessment, Guidance to Requesting Parties <http://www.hse.gov.uk/newreactors/ngn03.pdf>
2. Environment Agency's Process and Information Document for Generic Assessment of Candidate Nuclear Power Station Designs <http://publications.environment-agency.gov.uk/pdf/GEHO0107BLTN-e-e.pdf>
3. OCNS Guidance document for Generic Design Assessment Activities <http://www.hse.gov.uk/nuclear/ocns/ocnsdesign.pdf>
4. Discussion document on the Management of GDA Design Acceptance Confirmations Version 1 dated 30 April 2009

Glossary

GDA Issues	<p>Unresolved issues considered by regulators to be significant, but resolvable, and which require resolution before nuclear island safety-related construction of such a reactor could be considered. Where there are GDA Issues, the Design Acceptance Confirmation or Statement of Design Acceptability would be designated as 'Interim', and the regulators will expect the RPs to produce a Resolution Plan which identifies how the Issues would be addressed.</p> <p>Example: before giving permission to proceed with nuclear safety-related construction, we would need to be satisfied that the safety case for the nuclear safety related buildings demonstrated that the buildings could withstand the impact of external factors, such as high winds and earthquakes.</p>
Other GDA assessment findings	<p>Other issues / findings identified during the regulators' GDA assessment, but not considered critical to the decision to start nuclear island safety-related construction of such a reactor. The findings will be included in HSE's GDA Step 4 Reports or the Environment Agency's GDA Decision Document. They will need to be addressed, as normal regulatory business, either by the designer or by a future Operator/Licensee, as appropriate, during the design, procurement, construction or commissioning phase of the new build project.</p> <p>Example: we may highlight the need for the mechanical test programmes for safety critical equipment to cover the specific test criteria needed to ensure compliance with the safety case.</p>
Interim DAC	An Interim DAC (Design Acceptance Confirmation) while there are remaining GDA Issues in place.
Final DAC	The DAC provided when all GDA Issues have been addressed to the satisfaction of HSE. A Final DAC is required before consideration will be given to granting Consent to start nuclear island safety related construction for that type of reactor design at a specific site in the UK licensed for that purpose.
GDA Submissions	These include the totality of documents presented to regulators in GDA, including the GDA Design Reference, the GDA Safety, Security and Environment Submissions and related supporting documentation.
GDA Master Document Submission List	This is a 'live' document that lists precisely what constitutes the latest versions of the GDA submissions.
Generic Site Envelope	The RP-specified generic siting characteristics for a range of UK sites against which HSE assess the acceptability of the safety case for the generic design. These characteristics, such as seismic hazard, extreme weather events and other external hazards, should, so far as possible, envelop or bound the characteristics of any potential UK site, so that the reactors could potentially be built at a number of suitable UK locations.
Nuclear Site Licence Condition 20	Licence Condition 20 to a Nuclear Site Licence relates to the modification to design of plant under construction and nuclear site licensees are required to satisfy this through appropriate change control arrangements.
Nuclear island safety related construction	This relates to construction of the main nuclear island, which includes the main reactor building and nuclear auxiliary buildings (such as diesel generator buildings), but does not include, for example, sea defences or the cooling water pump houses that are located away from the nuclear island.