

A guide to the Regulatory Process

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1 INTRODUCTION

- 1 Generic Design Assessment (GDA) enables the safety, security and environmental implications of new nuclear power station designs to be assessed before applications are made for the permissions required to build that design at a particular site. The GDA process is undertaken by the main nuclear regulators, the Office for Nuclear Regulation (ONR, an agency of the Health & Safety Executive, HSE) and the Environment Agency¹. This document provides a brief overview of the processes followed by both regulators and how those processes are integrated. It also provides references to more detailed guidance.
- 2 GDA is designed to have a number of benefits:
 - It enables the regulators to get involved with designers at an early stage, where they can have maximum influence. Design changes required to address regulatory concerns are more easily implemented while designs are still on paper, rather than when construction has begun, or expensive plant items have been manufactured.
 - It is a step-wise process, with the assessments getting increasingly detailed. This approach enables the regulators to identify issues early in the process so progressively reducing financial and regulatory risks for potential operators.
 - It separates generic design issues from specific site-related issues, improving the overall efficiency of the regulatory process.
 - It is open and transparent. The public can view detailed design information on the internet and comment on it. The regulators also provide regular feedback on how their assessments are progressing and publish reports at the end of key steps.
- 3 Although GDA is not a mandatory process, because of its advantages for reactor vendors and developers, it is expected that it will form Phase 1 of regulatory assessment for new nuclear power stations in the UK. Phase 2 will be the regulatory assessment of a site-specific proposal to construct and operate a power station based on a design which had been through GDA.
- 4 While GDA and the Phase 2 site-specific permissions (relating to nuclear site licensing, security and environmental protection) are important elements of the regulatory process, they are only a part of a wider approvals process. Before construction of a new nuclear power station can begin:
 - The design must have undergone 'regulatory justification'. That is, it must be shown to the satisfaction of the Justifying Authority (the Secretary of State for Energy and Climate Change in the case of nuclear power stations) that its social, economic or other benefits outweigh the health detriment of ionising radiation.
 - The operator's Funded Decommissioning Programme must be approved by the Secretary of State for Energy and Climate Change. This sets out the operator's arrangements to meet the costs of decommissioning the power station, including the costs of waste management and disposal.

¹ The Environment Agency is the principal environmental regulator for nuclear sites in England. In Wales, the functions of the Environment Agency were transferred to a new body, Natural Resources Wales (NRW), on 1 April 2013. The Environment Agency will support NRW's regulation of nuclear sites in Wales via a service level agreement to provide Radioactive Substances Regulation staff. In Scotland environmental regulation of nuclear sites is undertaken by the Scottish Environment Protection Agency (SEPA). Currently there are no proposals for new nuclear power in Scotland and SEPA are not taking part in the GDA process. The Environment Agency is responsible for undertaking GDA and will consult with NRW and SEPA as appropriate. .

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- A Development Consent Order must have been issued by the Secretary of State for Energy and Climate Change. This is equivalent to giving 'planning permission' for the facility.
- 5 Before a permit for the disposal of radioactive waste can be issued, a favourable opinion must be obtained from the European Commission (under Article 37 of the Euratom treaty) on whether such disposals are liable to result in radioactive contamination of the water, soil or airspace of another EU Member State.
- 6 Ideally, GDA would be completed before Phase 2 began. However, we recognise that potential operators will want to make site-specific applications at an appropriate time for their project. For example, an operator may wish to coordinate applications for a nuclear site licence and environmental permits with an application to the Planning Inspectorate for a Development Consent Order. This may lead to some overlap of GDA with the site-specific phase.

2 THE NUCLEAR REGULATORS AND THEIR ROLES

- 7 ONR grants site licences to the intending operators of nuclear power stations. In assessing a licence application ONR addresses three key themes: the capability, organisation and resources of the applicant; the safety case for the site-specific design; and the nature and location of the site.
- 8 ONR also regulates security at all civil nuclear sites. It is concerned with physical security of nuclear material on-site and in transit as well as information security. ONR also has a role in relation to personnel security, requiring the vetting of persons who have access to nuclear sites or nuclear information. The holder of a nuclear site licence is required to submit a nuclear site security plan, which must be approved by ONR at the time that the licence is granted.
- 9 In addition, ONR regulates road transport of nuclear and radioactive materials, including new and spent nuclear fuel, as well as some aspects of their transport by rail. ONR advises/supports the Civil Aviation Authority and the Maritime and Coastguard Agency, as appropriate, in air and maritime transport matters.
- 10 The Environment Agency regulation includes:
- radioactive waste disposal, including discharges;
 - abstraction from and discharges to controlled waters, including rivers, estuaries, the sea and ground-waters;
 - operation of specific 'conventional' plant;
 - assessment and, where necessary, clean-up of contaminated land;
 - disposal of conventional waste;
 - certain flood risk management matters; and
 - with HSE as joint competent authority, requirements under the Control and Management of Major Accidents and Hazards Regulations (COMAH).
- 11 Operators have to satisfy the Environment Agency that discharges and disposals made into the environment are minimised and their effects are acceptable, such that people and the environment will be properly protected throughout the whole lifecycle of the plant, from construction to decommissioning.

3 PHASE 1 - GENERIC DESIGN ASSESSMENT

- 12 Requests for a GDA usually originate from a reactor designer/vendor. However, requests may also be initiated by vendor/operator partnerships. Consequently, the term 'Requesting Party' is used to identify the organisation seeking the GDA and to distinguish it from a nuclear site licence applicant.
- 13 It is helpful, wherever possible, for potential operators / licensees to engage with the Requesting Party during the GDA process, as ultimately they will be required to demonstrate sufficient knowledge of the design before receiving permission to construct and operate a nuclear power station. The operator may also wish to be part of the design process to allow the generic design to be adapted to its particular needs.
- 14 While the regulators will work together to provide an integrated approach to GDA, each has a different legislative regime which necessarily leads to some differences in approach. Figure 1 outlines how the regulatory processes (which are outlined below) fit together. Both ONR's and the Environment Agency's assessments will be undertaken in a staged manner which should provide for a progressive reduction of regulatory uncertainty as each step of the process is completed.
- 15 The regulators will undertake GDA on a full cost-recovery basis, and will enter into formal agreements with the Requesting Party to enable this.
- 16 The regulators expect Requesting Parties to seek advice from the Nuclear Decommissioning Authority to assure the regulators that adequate consideration is being given to the disposability of any radioactive wastes that will be produced by a power station based on the generic design.

ONR

- 17 ONR will carry out a detailed assessment of the safety elements of a design, based on a submission made by the Requesting Party. More information on this is set out in New Nuclear Reactors: Generic Design Assessment Guidance to Requesting Parties (Ref. 1).
- 18 ONR will also review security issues associated with the generic design, in particular the methodology for the identification of Vital Areas and the Conceptual Security Arrangements developed by the Requesting Party (Ref. 2).
- 19 In addition, ONR has a regulatory role with regard to the management of sensitive nuclear information during the GDA process (Ref.3).

Environment Agency

- 20 The Environment Agency's GDA process considers radioactive waste discharges and disposal matters; issues such as water abstraction and discharge; and the operation of conventional plant (see Process and Information Document for Generic Assessment of Candidate Nuclear Power Plant Designs, Ref. 4:). This work is carried out under section 37 of the Environment Act 1995 - the Environment Agency judges the acceptability of the Requesting Party's generic design from the environmental point of view and provides that advice to the Requesting Party. The Environment Agency may consult the Food Standards Agency, which has responsibilities relating to the food chain, during the course of this work.

Regulators' working arrangements

- 21 Although each regulator can only make its decisions on matters for which it is responsible, well-developed arrangements exist to ensure proper co-ordination of their activities.

These arrangements include a Memorandum of Understanding between HSE/ONR and the Environment Agency and joint project arrangements to closely co-ordinate the activities of ONR and the Environment Agency during the GDA and related site-specific licensing and permitting processes.

Administrative procedures

- 22 ONR and the Environment Agency have set up a Joint Programme Office, based within the ONR headquarters on Merseyside, as a single point of contact for GDA and for associated site licensing and permitting processes.
- 23 A Requesting Party seeking a GDA should prepare Safety, Security and Environmental submissions to address both regulators' requirements. The Requesting Party may choose to submit a single consolidated document as this would be useful to ensure a fully integrated assessment approach; in this case, 'Route-maps' indicating those parts of the submission relevant to each regulator should be provided. In all cases the Requesting Party should ensure that its submissions are complete and consistent.
- 24 The efficiency of the GDA process will be enhanced if the Requesting Party provides all the required information at the start of GDA or as soon as possible afterwards. The timetable for submissions will need to be agreed with both regulators. It should be noted that ONR and the Environment Agency may have different requirements for the timing of relevant submissions. The Requesting Party will be expected to put in place robust project management arrangements to ensure timely provision of quality submissions and timely, authoritative response to matters and issues raised by the regulators.
- 25 The regulators require submissions with a sufficient level of detail to enable them to carry out their assessments. It is recognised that design and submission changes may ensue. Requesting Parties should therefore notify the regulators of any such changes proposed during the course of the assessment, with the recognition that such changes might impact on the regulators' expected timescales for completion.
- 26 As part of the assessment, a management system for handling regulatory questions will be agreed with the RP. This will use a tiered approach as follows:
- Regulatory Query (RQ) – these are requests by the Regulator(s) for clarification and additional information and are not necessarily indicative of any perceived shortfall.
 - Regulatory Observation – an RO is raised when the Regulator(s) identifies a potential regulatory shortfall and requires action and new work for it to be addressed. Each RO can have several associated Actions. ROs will be published on the Joint Regulators website.
 - Regulatory Issue – an RI is raised when the Regulator(s) identifies a serious regulatory shortfall which is potentially significant enough to prevent provision of a DAC, and requires action and new work for it to be addressed. Each RI can have several associated Actions. RIs will be published on the Joint Regulators website.
- 27 It is possible that a question raised as an RQ could escalate to an RO or to an RI.

Public input

- 28 The regulators intend that their GDA processes should operate in a transparent and open way. In this regard the regulators:

- expect that the Safety, Security and Environment submissions provided for GDA will be made available to the public by the Requesting Party, with the exclusion of sensitive nuclear information and commercially confidential information;
- expect that the Requesting Party will invite and respond to comments they receive from the public during the GDA process;
- will consider the public comments made, together with any response from the Requesting Party, during their assessment of the design;
- will monitor the process and publish their views on the main issues raised; and
- will make arrangements for more general public and stakeholder engagement during GDA.

Overall timescale

29 Indicative timetables are shown in Figures 1 and 2 for Phase 1 (GDA) and Phase 2 (site specific licensing and permitting) of the regulators processes for permitting the construction of new nuclear power stations. However, the length of each step will be highly dependent on many factors, such as:

- content, quality and timeliness of the submissions;
- completeness of the design at the start of GDA;
- introduction of design changes during the assessment processes;
- significance of assessment issues which arise;
- responsiveness of Requesting Parties to issues and questions;
- availability of resources to the regulators;
- ability to draw on information from overseas nuclear regulators;
- number of designs being assessed in parallel; and
- experience of the regulators with similar designs.

30 The regulators will agree a bespoke timetable with the Requesting Party, which will be kept under review as the assessment work progresses.

GDA Outputs

31 The regulators will make regular public statements on their progress during the GDA process, and at key stages will publish reports on their interim findings.

32 On completion of the GDA, the regulators will issue reports on their findings along with the supporting technical assessment reports. If the design is judged to be satisfactory, the regulators will issue the following:

- ONR - Design Acceptance Confirmation (DAC);
- Environment Agency - Statement of Design Acceptability (SoDA).

33 Where the regulators judge that there are significant, unacceptable shortfalls in the design or the Requesting Party submissions, then no DAC or SoDA will be issued. It would be a matter for the Requesting Party to decide whether to propose additional work to address the shortfalls, which may allow the regulators to issue a DAC or SoDA at some future date.

34 If the regulators' assessments are largely complete and the generic design is found to be generally acceptable but some nuclear safety, security or environmental issues remain, or

where shortfalls in information have been identified, then the outstanding issues may be identified as GDA Issues, for which the Requesting Party will be required to provide credible resolution plans. If the regulators are satisfied with the resolution plans then they may be able to issue an Interim Design Assessment Confirmation (iDAC) and an Interim Statement of Design Acceptability (iSoDA).

35 GDA Issues and are defined as follows:

- 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.

36 The timescales for the close-out of any GDA Issue will depend on the programmes identified in the Requesting Party's resolution plans. During the close-out stage:

- the Requesting Party will submit additional information in response to all the GDA Issues; and
- the regulators will undertake sufficient assessment to be able to judge whether this additional information adequately addresses all the GDA Issues.

37 Following the satisfactory completion of the GDA Issue close-out stage, the regulators may then be able to issue a final DAC and SoDA.

4 PHASE 2 - SITE-SPECIFIC ASSESSMENT

- 38 Where applications are made for site-specific permissions (nuclear site licence, environmental permits, and security plan approval) the regulators will follow their existing procedures. Where these site-specific applications are based on a design that has undergone GDA, the regulators will take full account of the work that they have already carried out and the advice that they have provided. Figure 2 outlines how the site licensing and permitting processes can fit together. In setting timescales for applications, applicants should take account of other relevant consenting issues for nuclear sites, for example the Development Consent Order.
- 39 Following a GDA, ONR's subsequent licensing assessment would centre primarily on site-specific issues that have an impact on the safety of the station and matters relating to the organisational structure and capabilities of the potential licensee. Similarly, the principles of the conceptual security arrangements would be developed into a construction site security plan, and the nuclear site security plan. These will each require ONR's approval before the start of construction, and before nuclear material is brought to the site, respectively.
- 40 The Environment Agency's consideration of site-specific applications will take full account of the detailed design of the proposed station, including any changes since GDA, and will generally focus on local impacts associated with the permissions sought and the suitability of the potential operator.
- 41 Part of the link from GDA to site-specific assessment is assured by identification of GDA Assessment Findings. The findings, which will be published at the end of GDA, are primarily concerned with the provision of additional evidence, after GDA, to confirm certain safety, security or environmental aspects as the project progresses through the detailed design, construction and commissioning stages. The site operator will need to address all the Assessment Findings from the GDA process
- 42 Typical cases that could lead to the identification of GDA Assessment Findings are:
- Areas in the Requesting Party's submissions where the regulators require additional confirmatory analysis, but are content that the work can be undertaken during the detailed design, construction and commissioning stages.
 - Conditions linked to major verification and validation commitments given by the Requesting Party in its submissions that cannot be completed until the construction / commissioning phase.

5 REFERENCES

More information on the GDA process can be found on the regulators' joint website at www.hse.gov.uk/newreactors/index.htm. See also the Environment Agency website www.environment-agency.gov.uk and the ONR website www.hse.gov.uk/nuclear.

- 1 *New Nuclear Reactors: Generic Design Assessment Guidance to Requesting Parties* ONR June 2013 www.hse.gov.uk/newreactors/*****.pdf
- 2 *Guidance on the Security Assessment of Generic New Nuclear Reactor Designs* ONR (CNS) Technical Assessment Guide CNS-TAST-GD-007 Revision 0 2013 (pending publication)
- 3 *The management of Sensitive Nuclear Information during the Generic Design Assessment of Nuclear Technologies* ONR's CNS February 2008 www.hse.gov.uk/nuclear/ocns/ocnsinfomanage.pdf
- 4 *Process and Information Document for Generic Assessment of Candidate Nuclear Power Plant Designs*. Version 2, Environment Agency, March 2013. <https://brand.environment-agency.gov.uk/mb/Ndy3V>

6 CONTACTS

The regulators' Joint Programme Office administers both the GDA process and subsequent site-specific licensing and permissioning, and can be contacted at Joint Programme Office, Nuclear Reactor Generic Design Assessment, 4N.G Redgrave Court, Merton Road, Bootle, Merseyside, L20 7HS or at new.reactor.build@hse.gsi.gov.uk.

This document is available online at <http://www.hse.gov.uk/newreactors/ngn01.pdf>.

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Figure 1 – Indicative timetable: Generic Design Assessment

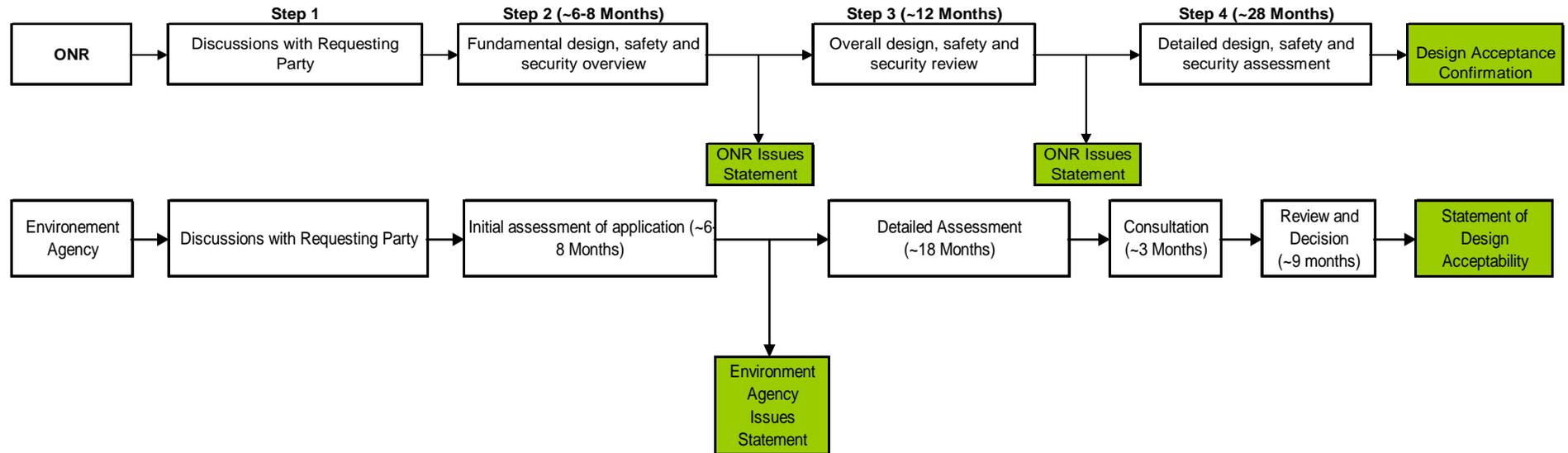


Figure 2 – site assessment: licensing and permitting

