Office for Nuclear Regulation

New Reactors Division – Generic Design Assessment

Step 4 Assessment of Management for Safety and Quality Assurance for the UK HPR1000 Reactor

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EXECUTIVE SUMMARY

This report presents the findings of my assessment of the Management for Safety and Quality Assurance (MSQA) arrangements which controlled the development and production of the safety case for the generic UK HPR1000 design, undertaken as part of the Office for Nuclear Regulation's (ONR) Generic Design Assessment (GDA). My assessment was carried out using the Pre-Construction Safety Report (PCSR) and supporting documentation submitted by the Requesting Party (RP).

The objective of my assessment was to make a judgement on whether the MSQA arrangements developed and deployed by the RP, as detailed in the PCSR, were adequate for the development and production of the safety case for the UK HPR1000 design in a way which was acceptably safe and secure (subject to site specific assessment and licensing), as an input into ONR's overall decision on whether to grant a Design Acceptance Confirmation (DAC).

The scope of my GDA assessment was to review the adequacy of the RP's MSQA arrangements developed and implemented for producing the UK HPR1000 safety case and design. My GDA Step 4 assessment built upon the work undertaken in GDA Steps 2 and 3 and enabled a judgement to be made on the adequacy of the MSQA information contained within the PCSR and supporting documentation and its effective implementation.

My assessment focussed on the following aspects related to the generic UK HPR1000 reactor design and safety case:

- The further development and implementation of the RP's MSQA general arrangements and the resolution of shortfalls identified in GDA Step 3.
- The management system arrangements for the use of operating experience in the UK HPR design and safety case.
- The management of requirements, assumptions and commitments.
- The design control process.
- The control of changes to the UK HPR1000 design.
- The consolidation of the safety case's supporting MSQA documents.

The conclusions from my assessment are that:

- I am satisfied that the RP's MSQA arrangements, which were used to control the development of the UK HPR1000 PCSR and supporting documentation, were adequate in terms of ONR's expectations. ONR's expectations are detailed in its GDA Technical Guidance document ONR-GDA-GD-007 and include relevant good practice, technical assessment guides and management system standards.
- I considered that the RP's MSQA arrangements provided sufficient quality management controls in the production of the UK HPR1000 PCSR to ensure that it would be produced to an adequate and consistent standard.

These conclusions are based upon the following factors:

- My technical assessments, both general and in-depth (on a sampling basis) of the RP's MSQA arrangements detailed in the generic UK HPR1000 safety case documentation, and the implementation of the same.
- Interactions with the RP including inspections of its MSQA arrangements, the review of a sample of the RP's MSQA arrangements and the assessment of the responses to the MSQA related Regulatory Queries (RQs) and Regulatory Observations (ROs) raised during the GDA.

Overall, based on my assessment, undertaken in accordance with ONR's procedures, the MSQA details contained within the PCSR and supporting documentation submitted as part of the GDA process, presented an adequate 'MSQA safety case' for the generic UK HPR1000 design.

I therefore recommend that, from a MSQA perspective, a DAC may be granted.

LIST OF ABBREVIATIONS

ALARP	As Low As Reasonably Practicable
CGN	China General Nuclear Power Corporation Ltd.
DAC	Design Acceptance Confirmation
DL	Document List
DMC	Design Modification Committee
FCG3	Fangchenggang Nuclear Power Plant Unit 3
GDA	Generic Design Assessment
GNI	General Nuclear International Ltd.
GNSL	General Nuclear System Ltd.
HF	Human Factors
HOW2	(ONR) Business Management System
IAEA	International Atomic Energy Agency
ISO	International Organisation for Standardisation
MDSL	Master Document Submission List
MSQA	Management for Safety and Quality Assurance
NPP	Nuclear Power Plant
ONR	Office for Nuclear Regulation
OpEx	Operational Experience
PCER	Pre-construction Environment Report
PCSR	Pre-construction Safety Report
PTI	Project Technical Inspector
QA	Quality Assurance
RO	Regulatory Observation
RP	Requesting Party
RQ	Regulatory Query
TAG	Technical Assessment Guide
TIG	Technical Inspection Guide
SoDA	Statement of Design Acceptability
WENRA	Western European Nuclear Regulators ‘Association

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1 INTRODUCTION

1.1 Background

1. This report presents my assessment conducted as part of the Office for Nuclear Regulation (ONR) Generic Design Assessment (GDA) for the generic UK HPR1000 design within the topic of Management for Safety and Quality Assurance (MSQA).

2. The UK HPR1000 is a pressurised water reactor (PWR) design proposed for deployment in the UK. General Nuclear System Ltd (GNSL) is a UK-registered company that was established to implement the GDA on the UK HPR1000 design on behalf of three joint requesting parties (RP), i.e., China General Nuclear Power Corporation (CGN), EDF SA and General Nuclear International Ltd (GNI). The roles of the requesting parties within GDA are detailed in Chapter 20 of the PCSR (Ref. 1); this was captured in Section 7.1 of ONR's GDA Step 3 summary report (Ref. 2).

3. GDA is a process undertaken jointly by the ONR and the Environment Agency. Information on the GDA process is provided in a series of documents published on the joint regulators 'website (www.onr.org.uk/new-reactors/index.htm). The outcome from the GDA process sought by the RP is a Design Acceptance Confirmation (DAC) from ONR and a Statement of Design Acceptability (SoDA) from the Environment Agency.

4. The GDA for the generic UK HPR1000 design followed a stepwise approach in a claims-argument-evidence hierarchy which commenced in 2017. Major technical interactions started in Step 2 which focussed on an examination of the main claims made by the RP for the UK HPR1000. In Step 3, the arguments which underpin those claims were examined. The Step 2 reports for individual technical areas, and the summary reports for Steps 2 and 3 are published on the joint regulators 'website. The objective of Step 4 was to complete an in-depth assessment of the evidence presented by the RP to support and form the basis of the safety and security cases.

5. The full range of items that formed part of my assessment is provided in ONR's GDA Guidance to Requesting Parties (Ref. 3). These include:

   - Consideration of issues identified during the earlier Step 2 and 3 assessments.
   - Judging the design control arrangements against the Safety Assessment Principles (SAPs) (Ref. 4).
   - Reviewing details of the RP's design controls and quality control arrangements to secure compliance with the design intent.
   - Assessing arrangements for ensuring and assuring that safety claims and assumptions will be realised in the final as-built design.
   - Resolution of identified nuclear safety issues or identifying paths for resolution.

6. The purpose of this report is therefore to summarise my assessment of the MSQA topic which provides an input to the ONR decision on whether to grant a DAC, or otherwise. This assessment was focused on the submissions made by the RP throughout GDA, including those provided in response to the MSQA-related Regulatory Queries (RQs) and Regulatory Observations (ROs) raised. ROs issued to the RP are published on the GDA's joint regulators' website, together with the corresponding resolution plans.

1.2 Scope of this Report

7. This report presents the findings of my assessment of the MSQA for the generic UK HPR1000 design undertaken as part of GDA. I carried out my assessment using the Pre-construction Safety Report (PCSR) Chapter 20 (Ref. 1) and supporting documentation submitted by the RP. My assessment was focussed on considering

whether the MSQA arrangements for the development of the generic safety case were adequate for producing the generic UK HPR1000 safety case and design, in line with the objectives for GDA.

1.3 Methodology

8. The methodology for my assessment follows ONR's guidance on the mechanics of assessment, NS-TAST-GD-096 (Ref. 5).

9. My assessment was undertaken in accordance with the requirements of ONR's How2 Business Management System (BMS). ONR's SAPs (Ref. 4), together with supporting Technical Assessment Guides (TAGs) (Ref. 5), and international MSQA standards were used as the basis for my assessment. Further details are provided in Section 2. The outputs from my assessment are consistent with ONR's GDA Guidance to RPs (Ref. 3).

2 ASSESSMENT STRATEGY

10. This section details my strategy for assessing the RP's MSQA arrangements used to produce the UK HPR1000 design and safety case, which includes the scope of my assessment and the standards and criteria that were applied.

2.1 Assessment Scope

11. A detailed description of my approach to this assessment can be found in ONR-GDA-UKHPR1000-AP-19-019, Revision 1 (Ref. 6).

12. ONR's assessment of the RP's MSQA arrangements during GDA Step 3 of GDA concluded that the arrangements were adequate for that stage of the GDA project (Ref. 7). Shortfalls in MSQA arrangements at the process level were identified at the end of GDA Step 3, the more significant of these being detailed in RO-UKHPR1000-0004 and RO-UKHPR1000-0024 (Ref 8).

13. My GDA Step 4 assessment covered:

- The further development and implementation of the RP's MSQA general arrangements during GDA Step 4.
- The adequate resolution of the shortfalls identified in GDA Step 3 (Ref. 7), which were:
  - Project oversight and control arrangements of the RP for the GDA process.
- Work planning, including the production of adequate specifications and improved communication between General Nuclear System Limited and CGN.
  - The management of safety case requirements, assumptions, and commitments.
  - The UK HPR1000 design submission control process.
  - The control of changes to the UK HPR1000 design.
- The Master Document Submission List (MDSL).
- The utilisation of Operating Experience (OpEx) for the design.
- Consolidation of the MSQA arrangements which controlled the development and production of the safety case for the UK HPR1000 reactor design, arrangements referenced in PCSR Chapter 20 (Ref. 1).

2.2 Sampling Strategy

14. In line with ONR's guidance (Ref. 9), I chose a sample of the RP's submissions to undertake my assessment. Some aspects were identified as requiring further development at the end of GDA Step 3 and are listed above. My assessment strategy was also influenced by my previous experience of similar arrangements for other nuclear facilities.

2.3 Out of Scope Items

15. There were no out-of-scope items in this GDA topic.

2.4 Standards and Criteria

16. The relevant standards and criteria adopted within this assessment were principally the SAPs (Ref. 4) and ONR TAGs (Ref. 5) and Technical Inspection Guides (TIGs) (Ref. 10), international standards (Refs 10 and 11), and relevant good practice informed from existing practices adopted on nuclear licensed sites in Great Britain. The key SAPs and any relevant TIGs and TAGs, national and international standards and guidance are detailed within this section.

2.4.1 Safety Assessment Principles

17. The SAPs (Ref. 4) constitute the regulatory principles against which ONR judge the adequacy of safety cases. The SAPs applicable to MSQA are included within Annex 1 of this report.

18. The key SAPs applied within my assessment were SAPs MS-1, MS-2, MS-3 and MS-4.

2.4.2 Technical Assessment Guides and Technical Inspection Guides

19. The following TAGs and TIGs were used as part of this assessment:

- NS-TAST-GD-049, 'Organisational Capabilities' (Ref. 5).
- NS-TAST-GD-051, 'The Purpose, Scope and Content of Safety Cases' (Ref. 5); and
- NS-INSP-GD-017, 'Licence condition (LC) 17- Management Systems' (Ref. 10).

2.4.3 Standards and Guidance

20. The following standards and guidance were used as part of this assessment:

- 'IAEA Safety Standard GSR Part 2 – Leadership and Management for Safety (2016)' (Ref. 11).
- ISO 9001:2015 - 'Quality Management Systems – Requirements' (Ref. 12); and
- ISO10005:2018 – 'Quality Management Systems - Guidelines for Quality Plans' (Ref. 12).

2.5 Use of Technical Support Contractors

21. I did not utilise any technical support contractors (TSC) to assist with my assessment.

2.6 Integration with Other Assessment Topics

22. GDA requires the submission of an adequate, coherent, and holistic generic safety case. Regulatory assessment of MSQA is by its nature a cross-cutting topic. I engaged

routinely with all other ONR assessment topic inspectors, individually or collectively. I have worked particularly closely with the ONR GDA Project Technical Inspector (PTI).

23. In GDA ONR's MSQA assessment is undertaken jointly with the Environment Agency. Throughout this report, when I refer to "the regulators", I imply the joint ONR / Environment Agency MSQA assessment team.

24. I worked closely with the ONR PTI to provide and receive support in the close out of ROs and to assess the adequacy of the RP's responses, from a MSQA perspective, on:

- design change control;
- management of safety case commitments;
- management of safety case requirements and assumptions; and
- consolidation of the safety case.

3 REQUESTING PARTY'S SAFETY CASE

3.1 Introduction to the Generic UK HPR1000 Design

25. The generic UK HPR1000 design is described in detail in the PCSR. It is a three-loop PWR designed by CGN using the Chinese Hualong technology. The generic UK HPR1000 design has evolved from reactors which have been constructed and operated in China since the late 1980s, including the M310 design used at Daya Bay and Ling'ao (Units 1 and 2), the CPR1000, the CPR1000^{+} and the more recent ACPR1000. The first two units of CGN's HPR1000 Fangchenggang Nuclear Power Plant (NPP) Units 3 (FCG3) and 4, are under construction in China and Unit 3 is the reference plant for the generic UK HPR1000 design. The design is claimed to have a lifetime of at least 60 years and has a nominal electric output of 1,180 MW.

26. The reactor core contains zirconium clad uranium dioxide (UO_2) fuel assemblies and reactivity is controlled by a combination of control rods, soluble boron in the coolant and burnable poisons within the fuel. The core is contained within a steel reactor pressure vessel which is connected to the key primary circuit components, including the reactor coolant pumps, steam generators, pressuriser and associated piping, in the three-loop configuration. The design also includes a number of auxiliary systems that allow normal operation of the plant, as well as active and passive safety systems to provide protection in the case of faults, all contained within a number of dedicated buildings.

27. The reactor building houses the reactor and primary circuit and is based on a double-walled containment with a large free volume. Three separate safeguard buildings surround the reactor building and house key safety systems and the main control room. The fuel building is also adjacent to the reactor and contains the fuel handling and short-term storage facilities. Finally, the nuclear auxiliary building contains a number of systems that support operation of the reactor. In combination with the diesel, personnel access and equipment access buildings, these constitute the nuclear island for the generic UK HPR1000 design.

3.2 The Generic UK HPR1000 Safety Case

28. In this section I present an overview of the MSQA arrangements which controlled the development and production of the safety case for the generic UK HPR1000 reactor design provided by the RP during GDA. Details of the technical content of the documentation and my assessment of its adequacy are reported in the subsequent sections of my report.

29. The UK HPR1000 PCSR Chapter 20, 'MSQA and Safety Case Management' (Ref. 1) provides:

- An overview of the project, safety case and design arrangements used by the RP to manage the production of the UK HPR1000 safety case and design documentation.
- Details of:
  - The leadership and management for safety arrangements for providing direction, governance and overseeing of safety related decisions. It also explained the organisational capacity and capability arrangements for the project.
  - The project arrangements for the control of technical work including work planning and the timely delivery of the GDA submissions.
  - The management system arrangements used by the RP to produce the safety case and the reference design.
  - The GDA documentation hierarchy.

4 ONR ASSESSMENT

4.1 Structure of Assessment Undertaken

30. At the end of GDA Step 3 ONR concluded that the RP's organization and documented MSQA arrangements "had matured" and met, in general terms, ONR's expectations for that stage of the project, as per ONR's guidance and the international standards referenced in Section 2.

31. During GDA Step 4, I was able to assess the effectiveness of the RP's MSQA arrangements based on 'outputs', for instance: design submissions, responses to ROs and RQs (Refs.8 and 13), and the implementation of these arrangements using feedback from ONR's and the Environment Agency's inspectors/assessors and the RP's internal assurance.

32. I carried out my assessment of the RP's MSQA arrangements in accordance with my MSQA Step 4 assessment plan (Ref. 6), by:

- Conducting reviews of the RP's MSQA procedures and instructions.
- Conducting regular MSQA engagements with the RP.
- Obtaining feedback from ONR's and the Environment Agency's inspectors/assessors on the quality of submissions.
- Leading and/or participating in targeted MSQA workshops / inspections of the RP's processes:
  - CGN, January 2020 (Ref. 14). This inspection covered CGN's main design submission control process.
  - EDF, January 2020 (Ref. 15). This inspection covered:
    - Progress against the GDA Step 3 MSQA inspection findings.
    - EDF's role in the UKHPR1000 GDA project.
    - EDF's engagement in key GDA forums.
    - EDF's view on project progress to date.
    - Preparation for site specific phase and engagement with prospective licensee.
    - Technical and project risks.
  - GNSL, July 2020 (Ref. 16). This inspection covered:
    - GNSL's organizational capability.
    - Transition strategy to the licensee.
    - Work planning arrangements for the delivery of GDA submissions.

    - Quality control of submissions.
    - Design management – design modifications, configuration management, RP's Technical Committee, holistic design review.
    - Safety case management – commitments and requirements.
    - GNSL's use of OpEx in GDA.
    - PCSR / Pre-construction Environment Report (PCER) alignment.
    - Control of the MDSL.
- CGN, November 2020 (Ref. 17). This inspection covered:
    - CGN's organizational capability deployed to deliver GDA.
    - Project management.
    - Work planning
    - Documented management system.
    - Quality Assurance (QA) audits.
    - Transfer of design.
    - Design interfaces.
    - Quality control of submissions.
    - Design management – design modifications, configuration management, RP's Technical Committee, holistic design review.
    - Safety case management – commitments and requirements.
    - CGN's use of OpEx in GDA.
    - Arrangements for the formal consolidation into the safety case submissions of information provided in response to RQs and ROs.
- EDF, March 2021 (Ref. 18). This inspection covered:
    - Organizational changes and capability.
    - GDA project programme.
    - Work planning.
    - Follow up of interface issues raised at previous inspection.

33. Throughout GDA Step 4 I used the information obtained during the above inspections / workshops to inform my ongoing judgements on the effectiveness of the RP's arrangements and to initiate improvement actions with the RP, raising RQs and ROs where appropriate.

34. The following table lists the topics assessed and signposts the assessments of the MSQA shortfalls identified by ONR at the end of GDA Step 3:

Table 1: MSQA-based Topics Assessed during Step 4 of GDA

Report Section	Section Title	GDA Step 3 shortfalls addressed in Step 4 (see Ref. 7)
Section 4.2	Development and implementation of the RP's MSQA general arrangements.	• RP's project oversight and control arrangements for the GDA process. • RP's work planning.
Section 4.3	MSQA arrangements developed in support of the close out of RO-UKHPR1000-0044, 'Identification and use of operational experience in the UK HPR1000 generic design and safety case'.	N/A

Report Section	Section Title	GDA Step 3 shortfalls addressed in Step 4 (see Ref. 7)
Section 4.4	MSQA arrangements developed in support of the close out of RO-UKHPR1000-0004, 'Development of a suitable and sufficient safety case'.	• RP's management of safety case requirements, assumptions, and commitments.
Section 4.5	Design submission control process.	• RP's work planning. • UK HPR1000 design submission control process.
Section 4.6	MSQA arrangements developed in support of the close out of RO-UKHPR1000-0024, 'Control of changes to the UK HPR1000 design'.	• RP's control of changes to the UK HPR1000 design.
Section 4.7	Consolidation of safety case documentation (PCSR Chapter 20).	N/A

4.2 Development and Implementation of the RP's MSQA General Arrangements.

35. At the end of GDA Step 3, ONR concluded that PSCR Chapter 20 (Ref. 1) and the higher-level MSQA documents (Refs. 19 and 20), which provide an overview of the GDA project's organisation and quality assurance arrangements, were adequate for that stage of the project.

36. As part of my GDA Step 4 assessment, I reviewed these high-level documents, which had been subject to minor amendments, against the requirements of the relevant international MSQA standards detailed in Section 2.4.3 and concluded that they remained adequate.

37. The rest of this section details my assessment of the further development and implementation of the RP's MSQA general arrangements in the key areas of:

- Organizational capability.
- Project oversight, work planning and co-ordination.
- Quality planning.
- Transfer of design, safety case, environmental and security information to the licensee.
- MDSL.
- RP's internal assurance of the adequacy of its MSQA arrangements

Organizational Capability

38. I carried out assessments of the RP's organizational capability against the relevant standards, SAPs (Ref. 4), TAGs (Ref. 5) and TIG (Ref. 10) as part of the of my workshops / inspections (listed in Section 4.1).

39. The overall organisational structure of the RP did not change during GDA Step 4. However, new roles and functions were identified as being required, for instance:

- During GDA Step 4, the RP's organizational capability was further enhanced by the appointment of the Human Factors (HF) Manager within the GDA Project Office. This is a cross-cutting role, intended to strengthen HF integration and coordination between the safety case group and design group.
- During GDA Step 4, the RP further drew on the support of TSCs for training and coaching in UK regulatory expectations and report writing. Internal resource competences were subject to re-assessment by the RP and, where necessary, additional training was provided.
- GDA Step 4 scheduled training was delivered by UK TSCs, who provided UK context courses on safety case management, development, traceability and evidence. Training in the use of OpEx to support ALARP arguments was also provided. It was stated that 350 team members participated in the courses.
- At the CGN workshop / inspection carried out in November 2020 (Ref. 17), I reviewed the training material for the 'Use of OpEx information to support the UK HPR1000 GDA' course and viewed the associated training records on CGN's database. The course material set out the purpose of OpEx and its importance in supporting ALARP arguments.

40. I have concluded, based on the above, that organizational capability enhancements were appropriate, and met the organizational capability requirements of the ONR SAPs, relevant international standards (see Section 2.4) and ONR Guide NS-TAST-GD-049, 'Organisational Capabilities' (Ref. 5).

Project Oversight, Work Planning and Co-ordination

41. ONR's GDA MSQA Step 3 note (Ref. 7) highlighted project oversight, work planning and co-ordination as shortfalls which the RP had to address. Throughout the GDA Step 4 engagements I paid particular attention to the effectiveness of these aspects within the RP.

42. At the regulators 'workshop engagement with EDF in January 2020' (Ref. 14), EDF highlighted ongoing concerns relating to their interfaces with, and the flow of information between, EDF and CGN. The regulators held a follow-up inspection on EDF in March 2021 (Ref. 18) to assess the resolution of these concerns. I noted that sufficient improvements in the EDF / CGN interfaces had been achieved, mostly in terms of cross-cutting process activities. The regulators were satisfied that the interfaces were adequate in terms of the key activities undertaken by EDF in support of the project, e.g., for the technical review of CGN submissions

43. I have concluded that the RP had made the necessary improvements in project oversight, work planning and co-ordination, recommended by ONR during GDA Step 3, based on the following:

- The RP's work planning and co-ordination improved. This was in part achieved through the implementation of cross-cutting processes, such as design change control, and the co-ordination of the resolution of RQs and ROs.
- The effective functioning of project level committees, such as the Technical and Design Modification Committee (DMC), which had representation from CGN, EDF SA and GNSL; this was evidenced by the quality of modification submissions' records examined, and records of technical decision-making in committee minutes.
- The project capability enhancements detailed above.
- The improvements in the submissions' quality (in terms of editorial and technical content) and timeliness of delivery.

Quality Planning

44. I assessed the adequacy of the RP's quality planning. The RP used project and work task level quality plans to control the quality related activities associated with design submissions.

45. I reviewed GNSL's delivery quality plan (Ref. 21). This quality plan covered the key cross-project activities and management arrangements associated with the delivery of the UK HPR1000 GDA. I found that the quality plan was sufficiently comprehensive and considered the quality plan to be adequate against the requirements of the relevant international standard, ISO 10005 (Ref. 12).

46. I viewed the quality plan on various occasions throughout the GDA Step 4. I found that the quality plan was being appropriately "signed off" as the quality related activities listed were being completed.

47. The RP produced task level quality plans which detailed the steps important to the successful completion of individual design topic submissions. These were used to ensure the consistent delivery of design submissions of an adequate quality and provide records of the completion of cross-project quality related activities.

48. I was satisfied that the RP's quality planning for the GDA Step 4 work was adequate.

Transfer of Design, Safety Case, Environmental and Security Information to a Future Licensee

49. At the inspection / workshop of GNSL (Ref. 16) the regulators reviewed the RP's the arrangements being developed to facilitate the transfer of design, safety case, environmental and security information to a future licensee.

50. The RP's arrangements for transition planning were developed during GDA Step 4. I examined these arrangements in terms of facilitating the knowledge transfer of the safety case to the licensee and I considered them to be adequate. The RP added a section to the PCSR (Chapter 20 Section 20.4.4.7), (Ref. 1) to provide an overview of these transition planning arrangements.

51. To ensure that sufficient knowledge of the UK HPR1000 generic design and safety, environmental and security cases is communicated to the licensee, GNSL also produced topic summary reports for each technical discipline to provide overviews of GNSL knowledge and assist in the transfer of GDA information. This includes GDA safety case and design documents, regulator engagement, commitments for the site-specific phase, outstanding technical risks, lessons learned, and experience feedback.

52. GNSL has also developed document distribution arrangements to respond to Intellectual Property requests on GDA documents from the licensee.

53. Agreement of the handover package of information with a Licensee is listed as an activity within the RP's GDA Project Delivery Quality Plan (Ref. 21).

54. I considered that the RP was making adequate arrangements to facilitate the transfer of design, safety case, environmental and security information to the licensee.

Master Document Submission List

55. I assessed the RP's arrangements for the control of the MDSL (Ref. 22). The MDSL is a "live" document that allows ONR to understand and reference precisely what constitutes the latest versions of the GDA submissions, and ultimately, when / if a DAC is granted, what exactly they cover. At the end of GDA the MDSL will contain the

totality of the GDA submission that has been submitted to the regulators, e.g.: safety case head document and its references, Generic Security Report and its references, and environmental submission and its references. The importance of the early deployment of adequate arrangements for the control of the MDSL and the overall Document List (DL) by the RP is emphasised in ONR-GDA-GD-007, 'New Nuclear Power Plants: Generic Design Assessment Technical Guidance' (Ref. 9).

56. The RP's arrangements for the control of the MDSL and DL are set out in HPR-GDA-PROC-006, Rev. 2, 'Document List and Master Document Submission List Arrangements' (Ref. 23). I assessed these arrangements and considered them to be adequate.

57. I assessed the implementation of MDSL and DL arrangements at the workshop with the RP in July 2020 (Ref. 16):

- GNSL was responsible for sending ONR the MDSL, the DL and the Integrated Delivery Plan. The CGN schedule engineer was responsible for establishing and maintaining the CGN submitted document list. I assessed the relevant CGN procedure for managing submissions to ONR and considered the arrangements to be adequate.
- The MDSL spreadsheet detailed the live totality of submissions and their latest revision. Each document was assigned a unique control reference known as the primary key. The flow of document configuration information from the various source files used to compile the MDSL and the DL was demonstrated. I considered these arrangements to be adequate.
- GNSL stated that they carried out a check of the contents of the MDSL at the end of each GDA Step. This activity was shown as a quality plan step (Ref. 21), prior to completion of the PCSR at the end of GDA Step 4.

58. I concluded that the RP's control of the MDSL and DL was adequate when compared against the expectations in ONR-GDA-GD-007, 'New Nuclear Power Plants: Generic Design Assessment Technical Guidance' (Ref. 9) and the document control requirements detailed in the relevant international standards (Section 2.4.3). However, when carrying out a safety case consolidation exercise I noted that not all supporting MSQA documents referenced in the PCSR Chapter 20, MSQA, had been listed in the MDSL. This issue was later resolved - see Section 4.7.

RP's Internal Assurance of the Adequacy of its MSQA Arrangements

59. I assessed the adequacy of the RP's quality assurance audits and reviews. These were important internal project oversight activities.

60. GNSL is a project organisation which will disband at the conclusion of the UK HPR1000 GDA. As such, the RP had not considered it appropriate to seek independent certification of GNSL's quality management system. However, a UK TSC was tasked with carrying out an independent audit of GNSL in 2019 and no significant findings were reported. I considered that this arrangement was appropriate for this organization.

61. CGN maintains independent certification of its quality management system as evidenced by their third-party certificate, which I viewed as part of my assessment. The certificate had been awarded by a suitably accredited certification body. The scope of certification covered the type of design work carried out by CGN for GDA.

62. I reviewed the RP's internal and external audit findings and the findings of the project QA Management Review for 2019 to the regulators at the workshops in July and November 2020 (Refs. 16 and 17).

63. I reviewed the findings from a scheduled audit carried out on CGN. From the audit scope and findings, I concluded that an effective audit had been carried out. The corrective and preventive actions were identified and resolved.

64. I noted that several audit findings related to design personnel not always following the procedures. CGN personnel working on GDA must follow GDA project specific arrangements to meet UK expectations, as these may differ from their usual working arrangements (for FCG3 for instance). In such changing circumstances strict adherence to procedures is especially important.

65. The RP responded to my concern (Ref. 24) on procedural adherence within CGN. Their responses included details of:

- The nature / criteria of non-conformances found during the 2020 audit programme and CGN's awareness of the quality implications of the same.
- The preventive actions implemented in response to the nature / criteria of the non-conformances, which I considered to be appropriate and proportionate.
- CGN's quality policy and expectations.
- The CGN code of conduct, which includes procedural adherence, and was stated to be posted throughout their buildings.
- CGN's promotion of compliance with procedures with measures to avoid non-compliance such as enhanced submissions checking and the use of software platforms for design checks and acceptance.

66. The most common cause of non-conformances had been the lack of understanding of the specific, additional UK HPR1000 arrangements. This had been addressed through the enhanced awareness and procedures training. I was satisfied that the quality improvements detailed were appropriate and adequate.

67. I concluded from the findings of the audits and from the routine QA management review, that the RP's QA monitoring arrangements were adequate in terms of the relevant MSQA international standards (see Section 2.4.3).

68. Early in GDA Step 4 it was evident from feedback from the regulators' assessment teams that the quality of the submissions did not always meet their expectations.

69. The quality shortcomings mostly related to the "assessability" of the submissions, i.e., clarity of the text, lack of referencing, and lack of clear links between submission narrative and conclusions.

70. The RP took early actions to address these shortfalls. For instance, they used the services of TSCs to coach RP designers and authors, and to check submissions for assessabilty prior to their issuing to the regulators.

71. ONR, the Environment Agency and the RP monitored further reported quality issues. Following the improvements implemented by the RP the situation improved and quality issues have remained low since. I concluded that shortfalls in submissions' assessability had been resolved by the middle of 2020.

4.2.1 Strengths

72. The RP maintained and improved its MSQA arrangements throughout GDA Step 4.

73. The RP was responsive to regulatory feedback on observed shortfalls and implementing the necessary improvements.

74. The RP's MSQA arrangements and process records were readily accessible to the regulators.

75. There was good evidence of effective RP's oversight and audit of its MSQA arrangements.

4.2.2 Outcomes

76. I was able to carry out an effective assessment of the RP's MSQA arrangements and of the effectiveness of their deployment.

77. The GDA Step 3 shortfalls relating to project oversight, work planning and control arrangements of the RP, and the MDSL had been resolved.

78. The overall quality of the RP's submissions met GDA Step 4 quality expectations.

4.2.3 Conclusion

79. Based on the outcome of my assessment of the RP's general MSQA arrangements, I have concluded that:

- The PCSR Chapter 20, 'MSQA and Safety Case Management' (Ref. 1) provided an adequate overview of the project's organizations, roles and responsibilities, the overarching MSQA arrangements, and a route map to the project's processes. This met the expectations in the SAPs and other relevant ONR guidance and international standards detailed in Section 2.4.
- The RP's general MSQA arrangements, that I assessed and have detailed in this section, met the requirements of the national and international standards and ONR's SAPs and guidance listed in Section 2.4.

4.3 MSQA Arrangements Developed in Support of the Close-out of RO-UKHPR1000-0044

80. At the end of GDA Step 3 ONR identified OpEx as a topic for further regulatory assessment during GDA Step 4. As the RP's safety case submissions for GDA Step 4 were received and assessed by the regulators early in 2020, it was apparent to the regulators' assessors that there were shortfalls in the RP's use of OpEx.

81. ONR's assessments across several topic areas such as chemistry, radiological protection, human factors, and decommissioning, had revealed several shortfalls which required corrective actions by the RP. These topic areas typically place a greater emphasis on using OpEx as a source of supporting evidence to make a robust demonstration of safety. Some of the gaps identified included:

- Insufficient evidence of a systematic approach being applied to gather and use OpEx to support the demonstration of ALARP.
- A narrow selection of OpEx, often limited to the CGN's experience only.
- Insufficient justification being provided to support the RP's conclusions on the applicability of the OpEx considered and the links (i.e., referencing) to the safety case claims and arguments which the OpEx directly supported.

82. To address these concerns ONR raised RO-UKHPR1000-0044 on 'Identification and Use of Operational Experience (OpEx) in the UK HPR1000 Generic Design and Safety Case' (Ref. 8).

83. I supported ONR's assessment of the RP's response to this RO by:

- Assessing and reporting on the RP's progress in addressing the RO actions as part of the MSQA workshops (Refs. 16 and 17) and at routine MSQA meetings with the RP.

- Reviewing the RP's OpEx procedure (Ref. 25), which was amended in response to RO-UKHPR1000-0044. The amended procedure addressed the relevant ONR expectations detailed in SAP MS-4 (Ref. 4).
- Assessing the implementation of the methodology detailed in the updated procedure (Ref. 25).

84. ONR assessed a sample of the RP's OpEx reports produced in accordance with its revised OpEx procedure and were satisfied that these reports adequately demonstrated the application of the RP's arrangements for the control and use of OpEx in the generic safety case. On this basis RO-UKHPR1000-0044 was closed. Further details of the work done by ONR to close RO-UKHPR1000-0044 can be found in ONR's GDA Step 4 assessment report ONR-NR-AR-21-007 Rev. 0, 'UK HPR1000 - GDA Step 4 Cross Cutting Assessment Report' (Ref 26).

4.3.1 Strengths

85. The RP developed and deployed a procedure for the use of OpEx in safety case production which met ONR's expectation.

4.3.2 Outcomes

86. The RP was able to demonstrate the adequate application of their improved OpEx process.

4.3.3 Conclusion

87. Based on the outcome of my assessment of the RP's OpEx arrangements, which were improved in response to RO-UKHPR1000-0044, I concluded that the RP had developed and was deploying adequate arrangements for the use of OpEx for the UK HPR1000 safety case and addressed the MSQA shortfall from GDA Step 3.

4.4 MSQA Arrangements Developed in Support of the Close-out of RO-UKHPR1000-0004

88. At the end of the UK HPR1000 Step 2 GDA ONR raised RO-UKHPR1000-0004 – 'Development of a Suitable and Sufficient Safety Case' (Ref. 8). Action 4 of this RO was raised because ONR had identified potential shortfalls in the RP's management of safety case requirements, assumptions, and commitments.

89. ONR's GDA technical guidance (Ref 9) details that a key output of the safety case is the ability to transfer the requirements, assumptions and commitments made within the safety case documentation into the as built plant and operating regimes. While the building and operating a new NPP will be the responsibility of the licensee, ONR requires the GDA RP to put in place effective processes to ensure that the requirements, assumptions, and commitments made within the GDA safety case documentation are identified, traceable, and readily transferrable to the licensee.

90. ONR's GDA guidance to RPs (Ref. 3) requires the RP to submit such arrangements in Step 4 of GDA. However, lessons learned from previous GDAs, captured in ONR's GDA technical guidance (Ref. 9), have highlighted that this process should be developed and deployed early in GDA, as it has proven difficult and time consuming to develop adequate arrangements in the latter stages. This was not wholly achieved for the UK HPR1000 GDA. Consequently, much late effort was expended by the RP to retrospectively deploy demonstrably adequate requirements and assumptions processes in the PCSR and its supporting level 2 and 3 references.

91. ONR's GDA technical guidance (Ref. 9) also details the importance of the cross-cutting input from the MSQA inspector in assessing the adequacy of the RP's requirements, assumptions, and commitments arrangements. I have worked jointly with the Environment Agency's MSQA Topic Lead and ONR's PTI in this regard.

92. Sufficient progress was made with regard to the RP's arrangements for the management of safety case commitments, in particular the control of commitments to be addressed post-GDA. These arrangements are detailed in the RP's procedure GH-40M-20 (Ref. 27). This procedure was updated in response to regulatory feedback provided at workshops / inspections, and I considered it to be adequate when compared against the international standards detailed in Section 2.4.3.

93. The RP carried out a significant amount of work during GDA Step 4 to develop and demonstrate its methodologies and arrangements for managing requirements (which included assumptions). In response to RO-UKHPR1000-0004 the RP produced a requirements management summary report (Ref. 28) detailing its proposed approach to requirements management, and a procedure, GH-40M-026 (Ref. 29) setting out the process for implementing the summary report's approach. The summary report and procedure were updated to address regulators' comments and feedback.

94. I assessed progress with the ongoing development, refinement, and deployment of these arrangements at the regulatory workshops with the RP (Refs.16 and 17) and at routine progress meetings between the RP and ONR.

95. I reviewed the requirements and assumptions 'management arrangements' (Ref. 29) and considered that the process detailed was adequate when compared against the international standards detailed in Section 2.4.3.

96. Further details of the work done by ONR to close Action 4 of RO-UKHPR1000-0004, including a description of ONR's assessment of the effectiveness of the requirements management process, can be found in ONR's GDA Step 4 assessment report covering cross-cutting topics, ONR-NR-AR-21-007 (Ref. 26).

97. The RP's understanding of ONR's expectations for the management of requirements, assumptions and commitments had improved as a result of the regulatory engagements throughout GDA Step 4.

98. For the purposes of assessing the RP's MSQA arrangements, I am satisfied that the RP has developed adequate arrangements for the management of requirements, assumptions, and commitments.

4.4.1 Outcomes

99. The RP engaged with ONR in a positive manner to develop and improve their GDA commitments process, and their safety case requirements management process as detailed in Refs. 27 and 29.

4.4.2 Conclusion

100. Based on the outcome of my assessment of the RP's arrangements for the management of requirements, assumptions, and commitments I concluded that the RP had produced arrangements which met the requirements of the relevant international MSQA standards (see Section 2.4.3) and addressed the MSQA shortfall from GDA Step 3.

101. ONR's conclusions on the demonstration of the adequacy of these arrangements by the RP, against ONR's expectations set out in the GDA technical guidance (Ref. 9),

are reported in ONR's GDA Step 4 assessment report covering cross-cutting topics (Ref. 26).

4.5 Design Submissions Control Process

4.5.1 Assessment

102. I assessed this process in depth as it is the RP's main design quality assurance and control process for safety case and design submissions. I addressed the adequacy of this process at a workshop with the RP at the CGN's offices in Shenzhen, China, in January 2020 (Ref. 14). I looked at the interfaces of this process with other RP's safety case delivery processes (e.g., modifications and design change control, requirements management, consolidation of the safety case, etc.) at the workshops with the RP (Refs. 16 and 17). At the CGN workshop I focused my assessment activities on:

- Design process controls and design work planning.
- Clarifying and understanding design terminologies used by RP.
- Testing the application of the design controls using structural integrity (SI) examples.
- Understanding how the RP applied a graded approach based on nuclear safety when determining design control requirements.
- The adequacy and retrievability of design control records.

103. The RP's overarching procedure for the design process was PJ-30E-001 Rev. E (Ref. 30). The procedure provided a high-level overview of the design process and references to the supporting procedures. The design activities detailed aligned with the requirements of ISO 9001:2015, clause 8.3. (Ref. 12), namely:

- Design scheduling and quality planning.
- Design inputs.
- Design Review.
- Design internal verification.
- Design approval.
- Independent design verification / validation.

104. I reviewed the RP's supporting procedures for the design control activities referenced from PJ-30E-001 and examined associated design control records related to the SI Topic.

105. CGN used a computer system called the Design Management Platform. This system functioned as a work control system for routing / assigning design control tasks and for recording their outcomes. I examined information on the system. I considered that its functionality was adequate, based on the completeness of the records and the ease by which records were retrieved.

106. I examined the 'technical organisational measures' for the SI topic. Technical organisational measures are an output of the design planning stage and were, essentially, design quality plans. A technical organisational measure had been produced for each design package, in accordance with procedure PJ-30E-001. The SI technical organisational measures detailed the design activities required, resource allocation and the checking, verification, and validation controls to be applied.

107. The graded approach to work is a requirement of IAEA GSR Part 2, 'Leadership and Management for Safety' (Ref. 11). A graded approach had been followed by the RP in determining the extent / level of design controls required at the planning stage in accordance with PJ-30E-001 and its supporting procedures.

108. I examined the design input records for the reactor pressure vessel.

109. I examined the RP's verification plan for the SI topic, which had been produced in accordance with procedure PJ-30E-001 and supporting procedures. The verification plan detailed the required verification method (document review) and the parties responsible.

110. I examined the RP's design review arrangements. These aligned with the requirements of ISO 9001:2015, Clause 8.3.4 (Ref. 12), namely, to evaluate the ability of the results of the design to meet the input requirements.

111. Supported by ONR's SI team, I examined the RP's design review records for the defect tolerance assessment for the reactor pressure vessel shell. The design review sheet was obtained from the Design Management Platform. It showed that the review had been carried out by six appropriate persons within the RP (e.g., the senior mechanical analyst, the department's chief engineer, etc.) and review comments and actions were recorded.

4.5.2 Strengths

112. The Design Management Platform ensured that the required design control requirements (planning, development, verification, approval, and staged reviews) were carried out in accordance with the RP's design control procedures and the records were readily retrievable.

4.5.3 Outcomes

113. The key outcomes from this assessment and inspection were as follows:

- I was able to carry out an effective inspection of the RP's main design control process.
- The ONR inspection team were able to clarify and understand the terminologies used by the RP. For instance, it was clear that design "checking" was the equivalent of "internal verification" prior to internal approval (as per previous versions of ISO 9001), and that "verification" was equivalent to the "external independent verification", carried out by EDF for this project.
- I was able to gain assurance of the effectiveness of the RP's design control process.

4.5.4 Conclusion

114. Based on the outcome of my assessment of the RP's design submissions control process, I have concluded that:

- The RP's design submissions control process, as detailed in procedure PJ-30E-001 and its supporting procedures, and implemented through the Design Management Platform, aligned with the design control requirements of MSQA standard ISO 9001:2015 (Ref. 12).
- The RP's design submissions process control arrangements deployed were adequate, based on the samples of design records examined.

4.6 MSQA Arrangements Developed in Support of the Close-out of RO-UKHPR1000-0024

4.6.1 Assessment

115. During the GDA Step 3 the regulators found that the GNSL's design change control procedures were not consistent with CGN's internal procedures. The regulators also found that GNSL's arrangements were only being applied to design changes arising directly from GDA.

116. Design changes arising from FCG3, the UK HPR1000 reference design, were sentenced differently and, consequently, were not considered by GNSL's Modifications Committee. The regulators raised concerns regarding this approach and informed the RP that it was our expectation that all design changes should be treated consistently, in accordance with the RP's procedures, regardless of their source / origin.

117. During the MSQA workshops in China in October 2019 (Ref. 31), the regulators were informed that new design changes had arisen, both from GDA and from FCG3, and that these continued to be reviewed and approved using different approaches. Furthermore, the regulators were informed that the RP had developed an updated modification control procedure that differed from that previously discussed with the regulators. Upon review, the regulators found that the procedure contained inconsistencies and determined that the procedure had not been wholly implemented.

118. The regulators emphasised that they needed to have confidence that the RP had robust arrangements for design change control. The evidence provided from the trialling of these arrangements during Step 3 did not provide this confidence.

119. RO-UKHPR1000-0024 (Ref. 8) was subsequently raised, detailing these shortfalls, and identifying actions to be taken by the RP to address ONR's expectations for controlling design changes. This RO required the RP review their arrangements for design changes, ensuring consistency between CGN and GNSL arrangements, and to provide an implementation plan for these amended arrangements, which would include enhances staff training and oversight of their work.

120. The RP provided a RO resolution plan (Ref. 8) which, along with supporting procedures and records, formed the basis of my assessment, which is summarised in the following paragraphs.

121. For my assessment I reviewed the design control procedures submitted by the RP, that had been amended in response to RO-UKHPR1000-0024 (Ref. 8), and details of the implementation plan and associated records.

122. With regards to amending the CGN and GNSL arrangements:

- The RP amended and submitted three design control procedures to address the action (Refs. 32, 33 and 34).
- I reviewed the amended design change control procedures against the expectations of relevant ONR SAPs (Ref. 4) and relevant international management system standards (Refs. 11and 12) (see Section 2.4.3).

123. I was satisfied that the control of design arrangements had been reviewed and suitably amended by the RP to address RO-UKHPR1000-0024.A1.

124. With regards to the implementation of the amended arrangements:

- In April 2021 the RP provide details of the progress made to address the resolution plan activities (Ref. 35).

- Evidence was provided to show that staff awareness briefings had been carried out. This consisted of copies of briefing attendance records.
- The DMC had retrospectively reviewed those design changes not previously considered by this committee.
- I reviewed minutes of the Technical Committee Meeting and concluded that it was adequately performing its design change oversight role.
- I reviewed reports of the quarterly checks of CGN's implementation of the design modification process, and the internal RP audits of GNSL's and CGN's modification control processes and considered them to be adequate.

125. As part of ONR's MSQA workshop with the RP in October 2020 (Ref. 17) I carried out an assessment of the effectiveness of the implementation of the enhanced design change control arrangements deployed by the RP in closing RO-UKHPR1000-0024.

126. The RP described their design modification process, whereby changes are made to the design after each update of the design baseline (Design Reference Points DR1, DR2, DR3, etc.). This process was detailed in their design change control procedure GH-40M-012 (Ref. 34) which had been updated to address RO-UKHPR1000-0024. It was a gated process whereby modifications were categorised in terms of safety and environmental risk and subjected to an appropriate level of scrutiny depending on the categorisation.

127. To assess the deployment of the enhanced design change process the regulators selected recent design modifications in advance of the workshop and asked the RP to demonstrate the application of their design change process, including the categorization of design modifications, to these examples.

128. For each of these design modifications, I examined the various process control sheets / records by sampling. This included, for instance, various technical change note process control sheets and the minutes of the DMC.

129. The regulators found that the RP's arrangements for managing recommendations made by the DMC, and the project's responses to them were not clear.

130. The regulators requested that the RP consider how recommendations from the DMC were captured, considered by CGN and actioned. The RP incorporated the details of this process within the design change procedure GH-40E-012 (Ref. 34) and its supporting technical change notes 'forms.

131. The RP provided feedback and evidence that this shortfall had been addressed at the April 2021 MSQA meeting (Ref. 35) and I was satisfied that this shortfall had been adequately addressed.

4.6.2 Strengths

132. The RP was receptive to the regulators 'findings relating to their design change control process and took the necessary actions to ensure that the process arrangements were updated to meet the regulators 'expectations.

4.6.3 Outcomes

133. The RP demonstrated that they had implemented the agreed improvements detailed in their responses to RO-UKHPR1000-0024 and that ONR could take assurance in the adequacy and effectiveness of the RP's design change process.

4.6.4 Conclusion

134. Based on the outcomes of my assessments of the RP's design change process I concluded that:

- The RP's design change management arrangements and the agreed improvement actions put forward in response to RO-UKHPR1000-0024, had been effectively implemented.
- The design change process deployed by the RP met the requirements of the relevant international standards and ONR guidance and addressed the MSQA shortfall from GDA Step 3 relating to the control of design changes.

4.7 Consolidation of Safety Cases Supporting MSQA Documents

4.7.1 Assessment

135. As discussed in the previous sections, throughout GDA Step 4 I identified and reported shortfalls in the RP's MSQA arrangements that affected the production and updating of MSQA documents and the implementation of the revised arrangements. I tracked the updates to the MSQA arrangements and assessed their adequacy. The more safety significant updates are detailed in the above topic assessment sections.

136. To assess the overall consolidation of the MSQA aspects of the safety case, headed by Chapter 20 of the PCSR, I selected examples of reported document shortfalls (see below) and checked them to confirm:

- That the associated MSQA arrangements had been appropriately updated and issued by the RP.
- That the updated documents were listed on the MDSL.

137. I raised RQ-UKHPR1000-0727 (Ref. 13) to seek clarification on how responses to design modifications submitted to ONR would be addressed. To address this RQ the RP had to update its modifications procedure GH-40M-012 (Ref. 34) to detail how my comments on submitted modifications would be addressed. The RP updated GH-40M-012 (Ref. 34) and I considered that the changes were adequate. This procedure was further updated in response to regulator feedback and each time the document was issued accordingly.

138. At the workshop / inspection of CGN in November 2020 (Ref. 17) the ONR PTI discussed with the RP potential shortfalls in its arrangements for the management of commitments; particularly post-GDA commitments. The PTI requested that the RP address these shortfalls by updating their management of commitments procedure GH-40M-020 Rev. C. The RP updated the procedure and issued GH-40M-020 Rev. D (Ref. 27) in February 2021. The updates were assessed by the PTI and considered adequate, and the updated document was issued by the RP.

139. When I checked the MDSL to confirm that updated MSQA documents were being captured in the MDSL I found that this was generally not the case. I raised RQ-UKHPR1000-1741, 'Management System Procedures referenced in the Safety Case Chapter 20, MSQA, not referenced in the MDSL' (Ref. 13), which asked the RP why this was the case and to propose adequate corrective actions.

140. The RP responded that this was an oversight on their part and that all MSQA arrangements, including GNSL/CGN/EDF procedures, which are directly referenced in the PCSR would be included in the MDSL. They also confirmed that prior to the MDSL being formally issued a review will be undertaken, based on PCSR v2, to ensure that

all the RP's authored documents directly referenced in the PCSR are included in the MDSL. I was satisfied by this response.

4.7.2 Strengths

141. In updating its MSQA arrangements I gained assurance that the RP was applying adequate document change control arrangements in accordance with the international MSQA standards listed in Section 2.4.3.

4.7.3 Outcomes

142. My safety case consolidation checks highlighted that the MSQA process control documents had been overlooked by the RP when updating the MDSL.

4.7.4 Conclusion

143. In terms of the consolidation of the Safety Case Documents for Chapter 20, MSQA, I was satisfied that the supporting MSQA documents were controlled and updated in an adequate manner throughout GDA Step 4, as per the international MSQA standards listed in Section 2.4.3.

144. I was further satisfied that the RP had taken actions to ensure that referenced MSQA were being included in the MDSL as they were updated.

4.8 Comparison with Standards, Guidance and Relevant Good Practice

145. The standards, guidance, and relevant good practice I used for my assessment are referenced, in context, throughout this report. In addition to my professional experience on the topic of MSQA as applied to the development of nuclear safety cases and their associated designs, I used the standards and guides detailed in Section 2.3 of this report to assess the RP's MSQA arrangements for the GDA project.

146. Throughout my assessment, I made extensive use of:

- The international MSQA standards IAEA Safety Standard GSR Part 2 – Leadership and Management for Safety (2016) (Ref. 11).
- ISO 9001: 2015, Quality Management Systems – Requirements (Ref. 12), and
- ONR's SAPs on Leadership and Management for Safety - MS 1, 2, 3 and 4 (see Annex 1).

147. Drawing on my professional experience and the above standards and ONR principles, I have been able to draw the overarching conclusions on the RP's MSQA arrangements for the development of the UK HPR1000 safety case and design, which are detailed in the following section.

5 CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

148. This report presents the findings of my MSQA assessment of the generic UK HPR1000 design as part of the GDA process. Based on my assessment, undertaken on a sampling basis, I have concluded the following:

- The PCSR Chapter 20, 'MSQA and Safety Case Management' (Ref. 1) provided an adequate overview of the project's organizations, roles and responsibilities, the overarching MSQA arrangements, and a route map to the project's processes. This met the expectations in the SAPs and other relevant ONR guidance and international standards detailed in Section 2.4.

- The RP's general MSQA arrangements met the requirements of the national and international standards and ONR's SAPs and guidance listed in Section 2.4.
- That the RP had developed adequate arrangements for the use of OpEx for the UK HPR1000 safety case.
- That the RP's arrangements for the management of requirements, assumptions, and commitments met the requirements of the relevant international MSQA standards (see Section 2.4.3).
- That the RP's design submissions process control arrangements deployed were adequate and met the requirements of the relevant international standards and ONR guidance listed in Section 2.4.
- The design change process deployed by the RP was adequate and met the requirements of the relevant international standards and ONR guidance listed in Section 2.4.
- The MSQA Safety Case Documents for PCSR Chapter 20 were controlled and updated in an adequate manner throughout GDA Step 4 and that referenced MSQA documents were being included in the MDSL as they were updated.

149. Overall, based on my sample assessment of the safety case for the generic UK HPR1000 design undertaken in accordance with ONR's procedures, I am satisfied that MSQA arrangements detailed within the PCSR Chapter 20 and supporting documentation is adequate. On this basis, I am content that a DAC should be granted for the generic UK HPR1000 design from a MSQA perspective.

5.2 Recommendations

150. Based upon my assessment detailed in this report, I recommend that:

- **Recommendation 1:** From a MSQA perspective, ONR should grant a DAC for the generic UK HPR1000 design.

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Annex 1

Relevant Safety Assessment Principles Considered During the Assessment

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SAP No.	SAP Title	Description
MS.1	Leadership and management for safety - Leadership	Directors, managers and leaders at all levels should focus the organisation on achieving and sustaining high standards of safety and on delivering the characteristics of a high reliability organisation.
MS.2	Leadership and management for safety - Capable organisation	The organisation should have the capability to secure and maintain the safety of its undertakings.
MS.3	Leadership and management for safety - Decision making	Decisions made at all levels in the organisation affecting safety should be informed, rational, objective, transparent and prudent.
MS.4	Leadership and management for safety - Learning	Lessons should be learned from internal and external sources to continually improve leadership, organisational capability, the management system, safety decision making and safety performance.