

REGULATORY OBSERVATION	
REGULATOR TO COMPLETE	
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TRIM Ref:	2018/255957
Related RQ / RO No. and TRIM Ref: (if any):	RQ-UKHPR1000-0111 RQ-UKHPR1000-0136 RQ-UKHPR1000-0148
Observation title:	Development of a Suitable and Sufficient Safety Case
Lead technical topic:	Related technical topic(s):
6. Cross Cutting	<ol style="list-style-type: none"> 1. Chemistry 2. Civil Engineering 3. Control & Instrumentation 4. Conventional Fire Safety 5. Conventional Health & Safety 7. Electrical Engineering 8. External Hazards 9. Fault Studies 10. Fuel & Core 11. Human Factors 12. Internal Hazards 13. Management of Safety Quality Assurance 14. Mechanical Engineering 15. Probabilistic Safety Analysis 16. Radiological Protection 17. RadWaste, Decommissioning & Spent Fuel Management 18. Security 19. Severe Accident Analysis 20. Structural Integrity
<i>Regulatory Observation</i>	
<u>Background</u>	
<p>Production of an adequate safety case, as defined in the Safety Assessment Principles (SAPs) [1], is a legal requirement in the UK for licensees of nuclear power plants. For GDA, the "Guidance to Requesting Parties" [7] requires the production and submission to ONR of relevant aspects of the safety case for the design undertaking the GDA, as this forms the basis for ONR's assessment.</p> <p>An adequate safety case should be complete, coherent, cogent and consistent. A vital aspect of how a safety case is produced and presented is that it should be readily understood by all stakeholders, in particular by those who have responsibility for safety. These attributes should mean that it will be easy to implement, easy to comply with and therefore more likely to be worked to. This should in turn enable the safety case to be kept up to date and ultimately, to drive an overall improvement in safety.</p> <p>Production of a safety case can be complex and time consuming. It therefore requires forethought to be given right through the safety case production and development process to ensure that the right people are involved at the right time, with a clear vision for what the safety case is trying to achieve. In addition, the UK regulatory regime places a particular requirement on the duty holder (in this case, the Requesting Party) to demonstrate</p>	

that they have reduced risks So Far As Is Reasonably Practicable (SFAIRP). This has impacts on the safety case, in terms of how it is presented, its content and how it may be produced.

Interactions with the RP, General Nuclear Systems (GNS) to date, including RQ-UKHPR1000-0111 [8] which requested that GNS outlines its arrangements for managing the development of the safety case, have not provided ONR with sufficient confidence that the RP has developed and is implementing suitable and sufficient procedures and controls to ensure that the UK HPR1000 safety case will meet regulatory expectations.

Consequently, this RO is seeking to address the development and delivery of a safety case for UK HPR1000 which meets UK requirements and expectations. A fundamental part of achieving this is to have a clear understanding of the strategy, objectives, scope and plan for development of the safety case.

Relevant Legislation, Standards and Guidance

A documented safety case is a requirement of the Licence Conditions (LC) associated with holding a nuclear site licence, particularly LCs 23 [5] and 14 [6]. Safety documentation is also required under other legislation, such as relevant statutory provisions of the Health and Safety at Work etc Act 1974 (e.g. the Management of Health and Safety at Work Regulations 1999 and the Ionising Radiations Regulations 2017). Safety cases are also considered in IAEA [2] and WENRA standards and guidance [3].

The SAPs contain specific principles relating to safety cases (SC1-8) [1] which are further expanded in TAG NS-TAST-GD-051 [4].

Regulatory Expectations

Overall, ONR expects to be provided with evidence to demonstrate that GNS has adequate processes and controls in place to ensure that a suitable and sufficient safety case for UK HPR1000 will be produced and developed throughout GDA. ONR considers that such a safety case is vital to ensuring that GDA can be meaningfully progressed to expected timescales. In order to provide confidence that this can be achieved ONR considers that a strategy, programme and suitable arrangements to implement them are key inputs to timely delivery of a high quality, comprehensive safety case, which is essential for the completion of GDA. The RP is expected to have suitable organisational arrangements in place to control the development of the safety case, with appropriate oversight being provided by individuals with sufficient expertise and authority to ensure that its strategy and plans are implemented by safety case authors. In addition ONR is seeking assurance that the safety case will be suitable for implementation as part of an operating regime, in particular how any assumptions, requirements or commitments identified in the safety case are captured and transferred to the future licensee. Where reasonably practicable, the RP should ensure the involvement of future operators in developing this safety case in order to ensure its operational considerations are included and the safety case will be of practical use during the site specific phase. These expectations are derived from the Guidance to Requesting Parties [7].

When comparing the above requirements and expectations to the current position of the RP, the main concerns over the development of the safety case for UK HPR1000 can be summarised as:

- The current status of the planning and arrangements to develop the safety case do not appear to align with ONR expectations for progress through GDA;
- The overall objectives, strategy and scope of the safety case have not been adequately demonstrated;
- It is unclear how the integration of the different aspects of the safety case will be managed to ensure a coherent, consistent and proportionate safety demonstration will be provided;
- The architecture of the safety case is unclear, in that the hierarchy of submissions, their structure and interactions do not appear to have been fully considered, nor how the currently identified submissions will develop the safety case;
- There does not appear to be sufficient organisational control over the production and development of the safety case. Importantly, there does not appear to be designated individual(s) with sufficient authority to influence the development of the safety case as it is being produced.
- The approach being adopted to ensure that the safety case can effectively be put into practice appears to be underdeveloped.

In essence, the current development of the safety case at present appears to be reactive, rather than proactive, and there is a need to demonstrate to ONR a more rigorous and considered level of planning and control over development of the safety case moving forward. These concerns mean that ONR requires

additional confidence that the RP has adequate arrangements in place to enable progress throughout step 3 and 4 of GDA.

In response to this RO, GNS is requested to provide responses to a number of interrelated actions that cover strategy, programme, organisation and the management of commitments, assumptions and requirements.

References

- [1] Safety Assessment Principles for Nuclear Facilities, 2014 Edition, Revision 0, ONR, November 2014
- [2] IAEA General Safety Requirements, GSR Part 4, 2009, "Safety Assessment for Facilities and Activities"
- [3] Issue N of WENRA's report on reactor Reference Safety Levels
- [4] ONR's Technical Assessment Guide (TAG): NS-TAST-GD-051 The purpose, scope and content of nuclear safety cases http://www.onr.org.uk/operational/tech_asst_guides/ns-tast-gd-051.pdf
- [5] ONR's TIG: NS-INSP-GD-023 Licence Condition 23 – Operating rules http://www.onr.org.uk/operational/tech_insp_guides/ns-insp-gd-023.pdf
- [6] ONR's Technical Inspection Guide (TIG): NS-INSP-GD-014 Licence Condition 14 - Safety documentation http://www.onr.org.uk/operational/tech_insp_guides/ns-insp-gd-014.pdf
- [7] ONR-GDA-GD-001 Revision 3, New nuclear reactors: Generic Design Assessment Guidance to Requesting Parties, September 2016
- [8] Safety Case Queries Arising from Cross-Cutting Workshop on 17 May 2018, RQ-UKHPR1000-0111, May 2018, TRIM Ref. 2018/177198

Regulatory Observation Actions

RO-UKHPR1000-0004.A1 – Safety Case Development Strategy

In response to this Regulatory Observation Action, GNS should:

- Provide a demonstration of the adequacy of the approach that will be taken to produce and develop the UK HPR1000 safety case throughout GDA. This should provide an adequate description of what the safety case is expected to contain and the approach that is being taken to manage and produce this. The information provided should enable ONR to judge whether a suitable and sufficient safety case will be produced and continually developed throughout GDA, which is likely to meet UK regulatory expectations and facilitates the production of a subsequent site specific safety case by the future licensee.
- ONR considers that the response to this Action should include information on:
 - The documented safety case strategy, associated processes and approach, which provide information on the objectives, scope and purpose for the overall UK HPR1000 safety case and how this will be cascaded into individual documents;
 - The integration of the overall strategy with any secondary strategies, such as those which may be produced at a topic, system or process level;
 - Clear identification and definition of technical and safety case interfaces, and a description of how they are being managed;
 - The definition of the architecture / hierarchy of safety case documentation, demonstrating how the different levels and types of safety case documentation and the arguments and evidence contained therein, will be produced and linked together to cover the full scope, interactions and content of the safety case;
 - How learning from previous safety case experience has been incorporated in the above strategy, including UK context matters; and
 - How progress will be measured, reviewed and controlled and how the success of the outputs will be measured.

Resolution required by 'to be determined by General Nuclear System Resolution Plan'

RO-UKHPR1000-0004.A2 – Safety Case Delivery Programme

In response to this Regulatory Observation Action, GNS should:

- Provide a programme for delivery of the UK HPR1000 safety case as identified in the strategy defined under Action 1. This plan should include sufficient detail to demonstrate that the strategy identified in

Action 1, will be enacted.

- ONR considers that the response to this Action should include information on:
 - A definition of the main safety case tasks required to be completed during GDA (including any tasks already completed or ongoing), and identification of any interface with future (post GDA) tasks;
 - Identification of the various reports (e.g. PCSR, topic reports, basis of safety case, support studies, etc) which will be produced with clear presentation of their hierarchy and interfaces;
 - The timeline for production of the deliverables, including any review period and their submission date to ONR (if applicable);
 - Any specific constraints or assumptions which may impact on the programme;
 - Any dependencies between technical areas, topics or documentation; and
 - The process to control and update the programme, including when this will be submitted to ONR at regular intervals throughout GDA as new information becomes available and changes occur.
- The programme should cover both steps 3 and 4 of GDA.

Resolution required by 'to be determined by General Nuclear System Resolution Plan'

RO-UKHPR1000-0004.A3 – Safety Case Development Organisation

In response to this Regulatory Observation Action, GNS should:

- Provide a demonstration of the adequacy of the organisation that is in place to produce and develop the UK HPR1000 safety case throughout GDA.
- ONR considers that the response to this Action should include information on:
 - The organisational arrangement, roles and associated responsibilities and authorities related with the production of the UK HPR1000 safety case;
 - The arrangements for ensuring management oversight of the development of the safety case by an individual/individuals with authority and influence to ensure the effective implementation of the strategy and programme.
 - The arrangements to ensure that suitably qualified and experienced safety case professionals are used to provide advice on and support writing of the safety case;
 - Any training undertaken / planned to inform safety case authors or other individuals who have a role in producing the safety case;
 - Any independent or peer review activities and processes that may be employed;
 - How any third party inputs will be specified, controlled, managed and intergrated; and
 - How involvement of personnel with relevant plant and operating experience will be achieved, including consideration of the full lifecycle including construction, commissioning, operations and decommissioning.

Resolution required by 'to be determined by General Nuclear System Resolution Plan'

RO-UKHPR1000-0004.A4 – Capturing Assumptions, Requirements and Commitments from the Safety Case

In response to this Regulatory Observation Action, GNS should:

- Provide a demonstration of the adequacy of the approach that is being adopted to ensure that safety related assumptions, requirements and commitments identified within the safety case are appropriately captured and managed throughout GDA, and are supplied to the future licensee.
- ONR considers that the response to this Action should include information on:
 - Details of the method that is adopted for clearly identifying any safety related assumptions, requirements and commitments in the text of the safety case, including how they are:
 - recognised;
 - uniquely identified and tracked;
 - collated and catalogued;
 - graded based on safety significance;
 - consolidated into a single consistent set, applied throughout the safety case;
 - updated and managed throughout GDA
 - Any training given / planned to the safety case authors, or others involved in the safety case production process;

Protective Marking (if required)

- How they will be effectively transferred to the future licensee to be included in operating rules, manuals, procedures, training requirements, commissioning tests, etc., as appropriate, including identification of, and mapping to, any documentation with may be produced after GDA (such as in construction and commissioning documentation).

Resolution required by 'to be determined by General Nuclear System Resolution Plan'

REQUESTING PARTY TO COMPLETE

Actual Acknowledgement date:

RP stated Resolution Plan agreement date: