



ONR GUIDE			
LC14 SAFETY DOCUMENTATION			
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1 INTRODUCTION

- 1.1 This update of the guide encompasses the relevant expectations of the Safety Case Principles in the published ONR Safety Assessment Principles [ref 7.1] and the lessons from experience encapsulated in the ONR 'Right First Time Safety Case' concept (see Annex 1) and the Nimrod Review [7.4].

2 PURPOSE AND SCOPE

- 2.1 This guide has been prepared to facilitate a consistent approach to Licence Condition (LC) 14 compliance inspections and to provide assistance to inspectors carrying out interactions with licensees on safety cases.
- 2.2 The guide is focused on the whole process to deliver fit for purpose, 'right first time' safety cases. Guidance on the purpose, scope and content of safety cases is provided in NS-TAST-GD-051 [7.2].
- 2.3 This guide does not indicate when or to what extent LC14 compliance inspections should be carried out. These are matters to be covered in programme intervention plans. However, the guide is intended to inform all types of LC14 interventions, from a compliance inspection by an individual inspector to more expansive or longer running inspections. The guidance can be used in part or whole as appropriate.

3 LICENCE CONDITION 14: SAFETY DOCUMENTATION

- 3.1 LC14.1 Without prejudice to any other requirements of the conditions attached to this licence condition the licensee shall make and implement adequate arrangements for the production and assessment of safety cases consisting of documentation to justify safety during the design, construction, manufacture, commissioning, operation and decommissioning phases of the installation.
- 3.2 LC14.2 The licensee shall submit to ONR for approval part or such parts of the aforesaid arrangements as ONR may specify.
- 3.3 LC14.3 The licensee shall ensure that once approved no alteration or amendment is made to the approved arrangements unless ONR has approved such alteration or amendment.
- 3.4 LC14.4 The licensee shall furnish to ONR copies of any such documentation as ONR may specify.

4 PURPOSE OF LICENCE CONDITION 14

- 4.1 The fundamental purpose of LC14 is to ensure the licensee has effective measures in place to deliver good quality, fit for purpose safety cases. LC14 (2) to (4) provide specific powers that ONR may use to approve the licensee's arrangements (in whole or part) and to specify copies of documents to be furnished to ONR.
- 4.2 LC14 is focused on the whole process (i.e. the arrangements) for delivering safety cases during any phase of a facility's life cycle. Other licence conditions have more explicit requirements on what needs to be produced and why, namely:
- LC 23 (Operating Rules), specifically 23(1), requires a licensee to produce an adequate safety case in respect of any operation that may affect safety;
 - LC19 (Construction or Installation of New Facility);
 - LC20 (Modification to Design of Facility under Construction);

- LC21 (Commissioning);
- LC22 (Modification or Experiment on Existing Facility); and
- LC35 (Decommissioning)

4.3 In addition, LC15 (Periodic Review) requires a licensee to make and implement adequate arrangements for the periodic review and reassessment of safety cases.

5 GUIDANCE ON ARRANGEMENTS FOR LC14

5.1 The licensee should have satisfactory arrangements to address all the requirements of LC14 including compliance with the regulatory powers in LC14.2, 14.3 and 14.4 should they be applied. If LC14.2 is applied, the arrangements should ensure that no changes are made to approved sections without seeking further approval from ONR. The arrangements should be readily available, up to date and controlled under a management system compliant with the requirements of LC17 (Management Systems).

5.2 The arrangements should have clear references to the related Licence Conditions (see 4.2 above). This suite of arrangements should include a system for classification by safety significance based on hazard which takes due recognition of the work being inadequately conceived or executed. There should be a review process for each classification commensurate with the safety significance.

5.3 The arrangements should:

- ensure that the impact of any new or revised safety case on all other relevant safety cases is visible, documented, monitored and controlled;
- require suitably qualified and experienced persons (SQEP) to undertake relevant roles or activities;
- ensure that contractors used for safety case work are appropriate and the individuals involved are SQEP (including criteria for selecting contractors and assessing their competence before, during and after completion of the work);
- include sufficient and robust steps for checking and review of safety cases that are commensurate with safety significance;
- include an endorsement and approval process for safety documentation that is commensurate with safety significance;
- ensure the licensee maintains and controls safety case supporting documentation and it is readily retrievable;
- ensure the responsibility for ownership of safety cases is defined clearly at all times in the facility life cycle.

5.4 In addition, the arrangements should encompass the interface process between the licensee and ONR. The licensee needs to ensure sufficient time is included in programmes where ONR assessment of safety submissions is required or anticipated. Interfaces with other regulators (as necessary) should also be identified.

5.5 It is not sufficient for the licensee simply to have a suite of documented arrangements and procedures. The whole process for delivering safety cases needs to be well defined, demonstrably robust and reliable. In addition, the process needs to be continually monitored to ensure it remains robust. See ONR SAP SC.1 [7.1].

5.6 ONR SAP SC.1 states that "the process for producing safety cases should be designed and operated commensurate with the hazard, using the concepts applied to high reliability engineered systems." Therefore, the different elements of the whole safety case process should be defined clearly, including their purpose and key

features, and the potential weaknesses or failure modes. The defences or barriers in place to mitigate against the potential failures or weaknesses should be identified.

- 5.7 Figure 1 illustrates typical elements in the whole safety case process but ONR is not prescribing a set model. It is up to each licensee to define its safety case process and be able to demonstrate this meets ONR's expectations.
- 5.8 However, there are important elements in the whole process that should be present in all LC14 arrangements. To achieve high reliability, there should be some form of diversity within the safety case process. This should include safety case review by SQEP people who are independent of those involved in its production. The independent review function(s) should consider the adequacy of previous steps in the safety case process, not just the technical content of the safety case itself. For example, if significant issues with the safety case are raised at the independent review stage, this raises questions about the adequacy of the process not just the technical content of that safety case. The arrangements should ensure that process deficiencies are sought out, investigated and fixed, not just the specific technical issues. Otherwise, quality problems could occur with subsequent safety cases (and may not be detected).
- 5.9 Specific measures and checks should be in place to guard against known 'common cause failures' of safety case processes (e.g. resource constraints, programme pressures, commercial drivers and incentive schemes). These factors can result in poor quality or incomplete safety cases and inadequate identification or management of risks.
- 5.10 The consideration of options and development of an appropriate strategy are important initial elements to achieving a successful safety case, including demonstrating risks are ALARP. Therefore, the arrangements should include optioneering and development of the safety case strategy as formal elements of the process (rather than an ad-hoc or optional step). The extent of work involved will be dependent on the nature of specific safety cases.
- 5.11 SAP SC.2 states that "the safety case process should produce safety cases that facilitate safe operation". Therefore, the arrangements for LC14 need to ensure that key users of the safety case are engaged in the process and their needs are taken into account. Key users include operations and maintenance staff and those managers accountable for safety.
- 5.12 There should be a formally appointed Process Owner (PO) for the LC14 arrangements, with responsibility for the whole safety case process. The PO role should ensure the process is continually monitored, reviewed and improved.

6 GUIDANCE ON INSPECTION OF ARRANGEMENTS AND THEIR IMPLEMENTATION

- 6.1 Licensees' safety cases should be 'right first time'. If ONR identifies significant issues with a safety case that has completed due process within the licensee, this is indicative of underlying problems with the LC14 arrangements and/or their implementation. Inspectors should be aware of the licensee's history regarding safety cases prior to carrying out LC14 inspections (discuss this with ONR specialist inspectors, who have undertaken assessment of licensee's safety submissions). Any notable or persistent shortcomings should inform the scope and depth of the intervention plan.
- 6.2 The licensee should have a head document that defines the whole safety case process, the different elements and their purpose and key roles (e.g. Process Owner).

Some licensees call this type of document the Safety Case Manual or Process Manual. This document should also identify key potential failure modes and defences within the process, in line with SAP SC.1 (see 5.6).

- 6.3 The different elements of the whole safety case combine to provide the necessary defence in depth to ensure it is robust and reliable. Therefore, each element needs to be effective. If there is over-reliance on the later elements in the process (e.g. independent review and Nuclear Safety Committee (NSC)), this is an indicator of underlying problems. The number and significance of issues raised by independent review and/or the NSC provide useful information for LC14 inspections. This information can be obtained by reading NSC minutes and samples of independent review reports.
- 6.4 Typically, safety case documents are 'approved' within the licensee's process as individual documents (i.e. each one is subject to measures such as quality check, verification and independent review). This might include a summary safety report or NSC paper that encompasses the full safety case. However, what can be missed with this approach is a 'fit for purpose' test of the complete case. Inspectors should explore how the licensee ensures safety cases are fit for purpose. For example, is anyone in the licensee responsible for taking an overview of the whole safety case, or at least sampling parts of it, to confirm it fits together and is accessible and usable? Are key users of the safety case asked to undertake user tests? ONR assessments of licensees' safety cases often reveal issues relating to clarity and accessibility that the licensee should have identified.
- 6.5 The licensee should take steps to make sure the safety case process is effective and robust. It is not sufficient to assume the process is sound. Inspectors should examine how the licensee monitors, reviews and improves the process. For example, look for quality measures for individual safety cases and early warning indicators of potential problems or pressure points likely to have an adverse effect on the safety case process (e.g. lack of SQEP resources, significant time or funding constraints, unrealistic milestones, continual changes to the safety case strategy or scope, major external drivers on the licensee).
- 6.6 Monitoring should include the application of additional oversight and specific checks during times of high stress (e.g. tight deadlines, intense commercial or operational pressure) to ensure the safety case process is not undermined and remains robust. Where significant safety case quality issues arise, there should be a review of the underlying causes of the problems and appropriate corrective actions. The licensee's objective should be to fix the process not just address specific issues with an individual safety case.
- 6.7 Significant issues raised by ONR are another source of information for a licensee to monitor the safety case process. A poor quality safety case should not be able to pass all the way through the licensee's process before it reaches ONR. Therefore, the licensee should consider the implications of ONR issues in terms of improving the process.
- 6.8 User aids should be one of the outputs from the safety case process (i.e. considered to be an integral part or important adjunct to the process). Accessibility and usability of safety cases can be improved by use of specific aids aligned to the needs of particular groups. For example: visual representation of the facility/plant with the key safety case requirements and safety features; operating procedures or instructions with a clear safety case origin/basis; defence in depth information (with a clear distinction between engineered safety features and reliance on procedural controls); safety case guides or 'route maps' for managers and engineering staff. Inspectors should look for them and talk to users (e.g. operations staff) about their suitability. Ask if users have been

involved in developing the aids. This can be done as part of an intervention on LC14 but it's also something inspectors can combine with other visits to facilities. It is important to bear in mind that these types of aid need to fit the needs of the target users, not ONR.

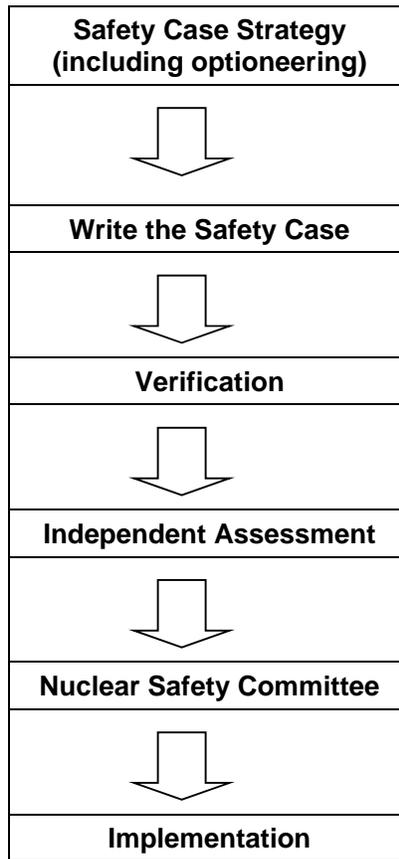
- 6.9 There should be links between the safety case process and the licensee's operating experience and learning process(es), to ensure that relevant information on events and near misses is fed back into safety cases (extant and under development). This provides a reality check for safety cases (testing assumptions, claims and supporting analyses etc.).
- 6.10 A robust safety case process is dependent upon a good safety culture. It is essential that the different steps in the process are seen to be important defences that help ensure safety and not as obstacles that need to be overcome (especially when the pressure is on). Culturally, undermining or short-cutting steps in the safety case process is akin to defeating plant interlocks because they 'get in the way of progress'. Experience shows that significant problems with safety cases can occur when the process is put under severe pressure. Inspectors should talk to people with roles in the process and licensee senior managers and consider the following types of question:
- Is there a recognition of the importance of maintaining a robust safety case process?
 - Is there a willingness to delay the programme if problems arise with the safety case?
 - Do people feel free to raise doubts or concerns and are they heeded?
 - Do senior managers 'walk the talk' regarding safety over production?
 - Can the licensee provide any relevant examples in response to these questions?
- 6.11 LC 14 applies to the licensee, not just to a licensed site. Activities undertaken by a licensee in connection with LC 14 at locations away from site (e.g. corporate headquarters, technical centre, design office) are subject to the requirements of the arrangements. Inspectors may need to examine compliance with the arrangements (e.g. interview staff, examine documentation) at these other locations.
- 6.12 Licensees often use contractors or agency staff in the production or review of safety cases. Inspectors should establish where, how and to what extent the licensee uses contractors. This can be done before an inspection (to help develop the plan) or explored during the inspection. The licensee needs to be able to demonstrate that LC 14 arrangements encompass the use of contractors (as necessary) and that Intelligent Customer requirements are being met [7.3]. If an inspection is going to include a visit to contractors' offices, the licensee should be informed.
- 6.13 For a comprehensive LC14 intervention, inspectors should consider working through the whole safety case process with more focus on people and the roles they perform, not just the documented arrangements. For example, talk to the Process Owner, safety case authors, verifiers, independent reviewers, NSC members (including independents) and Safety Case Owners. Use the specific areas for attention and common problems (above) to guide the discussions.
- 6.14 The licensee should have specific training for key roles in the safety case process (e.g. Safety Case Owner, authors and verifiers, independent reviewers). This is distinct from any training or SQEP status in technical topic areas. Safety case process roles have their own responsibilities and competence requirements.
- 6.15 There are important lessons from the Nimrod Review [7.4] with respect to both safety case process and content. NS-TAST-GD-051 [7.2] includes an annex with key lessons

from Nimrod. In the context of LC14, it is important to recognise that MOD appeared to have in place a robust safety case process, including independent assessment. However, the process was undermined by organisational and cultural issues, not least an assumption of safety. This was compounded by a failure to involve operations staff (flight crew and maintenance staff) in the production and review of the safety case. In addition, there had been relevant operating experience (notably a precursor event) that had not been fed back into the safety case. Inspectors should establish if the licensee has reviewed and strengthened the safety case process in the light of the lessons from Nimrod.

- 6.16 Inspectors are encouraged to read the relevant sections of the Nimrod Review for themselves to understand the extent of the issues and the wider relevance. The safety case aspects are covered in Chapters 9 to 11 and 22 of the report. It is a well structured and readable document, with good summaries at the start of each chapter. See the link in 7.4 to access the report.
- 6.17 Basic guidance to aid planning for LC14 inspections is given in Annex 2. Inspectors should use the links into the relevant parts of the guide to understand the context of the basic steps and the more specific factors to consider.

7 FURTHER READING

- 7.1 Safety Assessment Principles for Nuclear Facilities, 2014.
- 7.2 ONR HOW2 – Nuclear Safety Technical Assessment Guide – The Purpose, Scope and Content of Nuclear Safety Cases, NS-TAST-GD-051 Revision 4, July 2016.
- 7.3 ONR HOW2 – Nuclear Safety Technical Assessment Guide – Licensee Core and Intelligent Customer Capability, NS-TAST-GD-049, Revision 5, April 2016.
- 7.4 The Nimrod Review: an independent review into the broader issues surrounding the loss of the RAF Nimrod MR2 aircraft XV230 in Afghanistan in 2006, Charles Haddon Cave QC, October 2009. <http://www.official-documents.gov.uk/document/hc0809/hc10/1025/1025.pdf>

FIGURE 1 – TYPICAL ELEMENTS OF A SAFETY CASE PROCESS**Notes:**

1. This is not seeking to prescribe a specific process design; it reflects the different elements that should appear within the whole process.
2. This does not preclude licensees from having additional steps in the process.
3. 'Independent Assessment' encompasses a range of terms and activities such as Peer Review and Independent Nuclear Safety Assessment (INSA).
4. Project steps such as identify/assign safety case manager, authors etc. are not shown here.

ANNEX 1 – RIGHT FIRST TIME SAFETY CASE CONCEPT (RFTSC)

ONR has developed the Right First Time Safety Case (RFTSC) concept to put more focus on the whole process within licensees for producing safety cases, rather than the technical content or methodologies. RFTSC is based primarily on ONR Safety Assessment Principle SC.1 (robust safety case process) but encompasses SC.2 (usable safety cases) and SC.5 (balanced safety cases).

The RFTSC approach is intended to address the underlying reasons for poor quality safety cases (i.e. deal with the causes not the symptoms). The objective is to achieve more reliable and robust safety case processes in licensees that deliver consistently good quality, balanced and usable safety cases.

One of the aims of RFTSC is that licensees will have a better definition and understanding of the whole safety case process and the factors that can jeopardise the quality of safety cases. Therefore, the safety case process can be better managed and defended against these pressures/risks.

ONR has benchmarked RFTSC against the lessons from the Nimrod review. This has confirmed that the RFTSC approach, focusing on SAPs SC1, SC2 and SC5, encompasses the key types of weaknesses in a safety case process highlighted in the Nimrod review.

The concept has been applied in specific RFTSC interventions with a number of licensees.

ANNEX 2 – BASIC GUIDANCE FOR PLANNING INSPECTIONS

Basic points to consider for LC14 inspections (intended to be used to help develop inspection plans with links to relevant parts of the guidance for more specific factors to consider):

Points to Consider	Relevant part(s) of Guidance
Do the arrangements cover all the clauses of LC14?	Para 5.1
Is there a head document that defines the whole safety case process, key roles and requirements?	Para 5.6, 6.2
Do the LC14 and/or related arrangements include a system for classification of safety cases?	Para 5.2
Do the arrangements encompass the development of safety case strategy and optioneering	Para 5.10
Are there clear SQEP requirements for the key roles in the arrangements (including competence of contractors)?	Para 5.3, 6.2, 6.12
Is there a formally appointed Process Owner for the LC14 arrangements and safety case process?	Para 5.12, 6.2
Are the requirements and responsibilities for ownership of safety cases defined clearly?	Para 5.3, 6.14
Do the arrangements ensure the key users of safety cases are engaged in the process and the outputs meet their needs?	Para 5.11, 6.8
Are the users familiar with the relevant safety cases and key requirements?	Para 6.8
Does the licensee test that safety cases are fit for purpose and usable?	Para 6.4
Does the licensee undertake monitoring of the safety case and continual improvement to ensure it is robust?	Para 6.5 to 6.7, 6.10
Has the licensee taken into account the lessons from the Nimrod Review?	Para 6.15