

PROJECT ASSESSMENT REPORT

Report Identifier:	ONR-Policy-all-PAR-11-001
Revision:	2
Project:	Implementation of the Nuclear Safety Directive 2009/71/Euratom in relation to Great Britain
Site:	All sites
Title:	Variation of licence conditions 17 and 36 to implement the Nuclear Safety Directive 2009/71/Euratom in relation to Great Britain
Licence Instrument No.: (if applicable)	Variation to all Nuclear site licences
Nuclear Site Licence No.:	As above
Licence Condition:	Licence condition 17 and 36
TRIM Ref:	2011/428358

Document Acceptance and Approval for Issue / Publication

Role	Name	Position	Signature	Date
Author	[REDACTED]	Policy Advisor – ONR 7		June 2011
Reviewer	[REDACTED]	Head of Policy - ONR 7		July 2011
Accepted by	Dr M Weightman	HM Chief Inspector of Nuclear Installations		July 2011
Approval for publication	Dr M Weightman	HM Chief Inspector of Nuclear Installations		July 2011

Revision History

Revision	Date	Author(s)	Reviewed By	Accepted By	Description Of Change
1	July 2011	[REDACTED]	[REDACTED]	Dr M Weightman	Contributions from ONR colleagues
2	August 2011	[REDACTED]	[REDACTED]	Dr M Weightman	Prepared for publication

Circulation (latest issue)

Organisation	Name	Date
Office for Nuclear Regulation	All staff	August 2011

NOT PROTECTIVELY MARKED

Office for Nuclear Regulation

An agency of HSE

Redgrave Court Merton Road Bootle Merseyside L20 7HS

www.hse.gov.uk/nuclear

Implementation of the Nuclear Safety Directive 2009/71/Euratom in relation to Great Britain

Project Assessment Report: ONR-Policy-all-PAR-11-001

Revision 2

August 2011

© *Crown copyright*. If you wish to reuse this information visit [www.hse.gov.uk/copyright](http://www.hse.gov.uk/copyright.htm).htm for details.

You may reuse this information (excluding logos) free of charge in any format or medium, under the terms of the Open Government Licence. To view the licence visit www.nationalarchives.gov.uk/doc/open-government-licence/, write to the Information Policy Team, The National Archives, Kew, London TW9 4DU, or email psi@nationalarchives.gsi.gov.uk.

Some images and illustrations may not be owned by the Crown so cannot be reproduced without permission of the copyright owner. Enquiries should be sent to copyright@hse.gsi.gov.uk.

TABLE OF CONTENTS

1	TITLE	2
2	PERMISSION REQUESTED	2
3	BACKGROUND	2
4	WORK CARRIED OUT BY ONR IN CONSIDERATION OF THIS REQUIREMENT	2
	4.1 Consultation	3
5	MATTERS ARISING FROM ONR'S WORK	3
6	CONCLUSIONS	3
7	RECOMMENDATION	4
8	ANNEX A: TEMPLATE VARIATION FOR LICENCE CONDITION 17 AND 36	6
9	ANNEX B: REVISED GUIDANCE NOTE	8

1 TITLE

1. Variation of licence conditions 17 and 36 to implement the Nuclear Safety Directive (NSD) 2009/71/Euratom in relation to Great Britain.

2 PERMISSION REQUESTED

2. This Project Assessment Report (PAR) has not been generated in response to a permissioning request. It sets out the process followed in the Office for Nuclear Regulation (ONR) in implementing the Nuclear Safety Directive (NSD) 2009/71/Euratom in relation to Great Britain.

3 BACKGROUND

3. Council Directive (2009/71/Euratom) establishing a Community Framework for the Nuclear Safety of Nuclear Installations was agreed at the European Environmental Council on 25 June 2009. All EU Member States were required to fully implement the provisions of the NSD by 22 July 2011.

4. Close consultation with the Department for Energy and Climate Change (DECC) ensured a separate but parallel approach to implementation, with ONR, as an agency of the Health and Safety Executive (HSE), addressing the requirements as they relate to Great Britain, and DECC ensuring implementation of the Directive in the wider UK.

5. In Great Britain, most of the provisions of the NSD are implemented by the current nuclear safety regime, in particular through the Nuclear Installations Act 1965 and the standard set of 36 licence conditions attached to nuclear site licences. However the amendments to licence condition 17 and 36, which are attached to the template variation at Annex A ensure that the obligation to fully implement the Directive in relation to Great Britain is met.

4 WORK CARRIED OUT BY ONR IN CONSIDERATION OF THIS REQUIREMENT

6. An analysis of the Nuclear Safety Directive (NSD) by policy and legal advisers resulted in the production of a table which identified that limited changes were necessary to ensure the NSD was fully implemented in relation to Great Britain.

7. Further legal advice, and inputs by ONR operational colleagues, were used to develop an approach to address the implementation gaps identified in that table. A paper from HSE's Nuclear Directorate (ONR's predecessor organisation), setting out the broad approach, was agreed by the Health and Safety Executive's Senior Management Team (SMT) and Board in October 2010. The Chair of the HSE subsequently wrote to the responsible DECC Minister to confirm the HSE approach.

8. Further work on detailed implementation options, that also met the Government's broad policy objective of doing the minimum necessary to implement EC Directives, continued through late 2010 and into 2011. This work resulted in a proposal to implement the Directive requirements by amending licence conditions 17 and 36.

4.1 Consultation

9. ONR's proposed approach to implement the NSD had been shared with DECC colleagues. It was also discussed informally with industry representatives at a DECC meeting early in 2011. Subsequent confirmation by legal advisers of the necessity of the proposed approach satisfied industry that the amendments proposed by ONR were the minimum necessary to meet implementation and avoid the risk of a successful legal challenge by the EC.

10. Further informal exchanges with industry, ahead of formal consultation, enabled ONR to produce an impact assessment, and demonstrated the need for the formal consultation to have explanatory material outlining the changes, and their effects, in more detail, particularly in respect of the minimal change to ONR's regulatory behaviour.

12. Her Majesty's Chief Inspector of Nuclear Installations (HMCNI) wrote to all nuclear site licence holders on the 12 May 2011 with the proposed amendments to licence conditions 17 and 36. This letter contained the explanatory note referred to above. The consultation package was made available the same day on the ONR website together with an Impact Assessment (IA). The consultation also featured in the ONR bulletin (which has a membership of over 6000 external stakeholders). At close of the consultation (30 June 2011) 20 responses had been received primarily from industry.

5 MATTERS ARISING FROM ONR'S WORK

13. In light of comments received some small changes were made to the amended licence condition 17 in the consultation package. A change was made to address consistency in terminology between licence condition 17(1) and licence condition 36(2) (and licence conditions generally) in the use of the word 'safety'; and words were inserted to ensure that the flexibility afforded to approval of "such part or parts" of the management systems in 17(3) were also applied to quality the management arrangements in the 17(3) text.

14. The explanatory note referred to at paragraph 10. above was updated to reflect ONR's intention to translate that explanatory material into ONR guidance material e.g. technical assessment guides; technical inspection guides; and notes for inspectors; and provide industry with the opportunity to contribute to this process. Similar opportunities will also be provided to controlling bodies (e.g. the Nuclear Decommissioning Authority (NDA)).

6 CONCLUSIONS

15. The template variation and replacement licence conditions attached at Annex A) were drafted and cleared by legal advisers (Treasury Solicitors); and reflect the minimum changes necessary to fully implement the NSD in relation to Great Britain and avoid the risk of successful legal challenge by the European Commission.

16. Variations for all licensed sites were signed by HMCNI on the 21 July 2011, and came into force on the 22 July 2011, the deadline for implementation. Once signed, documents were scanned and emailed to each licensed site, and hardcopies despatched thereafter, with copies being sent to DECC, the Environment Agency (EA) and Nuclear Decommissioning Authority (NDA)

in line with ONR practice. Copies of the amended licence conditions were also made available to the Defence Nuclear Safety Regulator (DNSR)¹.

7 RECOMMENDATION

17. The recommendation that variations under Section 4(3) of the Nuclear Installations Act be granted to amend all existing nuclear site licences was accepted and variations signed on the 21 July 2011.

¹ The Defence Nuclear Safety Regulator promulgates Authorisation Conditions (AC), with nearly identical wording to the Licence Conditions, to set out the regulatory requirements in the defence nuclear programmes where licensing is not applied.

TABLE OF ANNEXES

- a) Template variation for licence condition 17 and 36**
- b) Revised Guidance note**

8 ANNEX A: TEMPLATE VARIATION FOR LICENCE CONDITION 17 AND 36

SITE LICENCE NO: [NUMBER]

VARIATION: [NUMBER]

NUCLEAR INSTALLATIONS ACT 1965 (AS AMENDED)

VARIATION

of Nuclear Site licence [SITE LICENCE NO.]

[NAME OF LICENSEE]

[NAME OF SITE]

The Office for Nuclear Regulation (an agency in the Health and Safety Executive), in exercise of its powers under section 4(3) of the Nuclear Installations Act 1965 (as amended), hereby varies the conditions attached to Nuclear Site Licence No. [NUMBER] granted to [LICENSEE] in respect of the site of [SITE NAME] on [DATE OF LICENCE] as follows:

1. There shall be substituted:
 - (a) for Condition 17 of Schedule 2 to the said Nuclear Site Licence, the Condition 17 annexed hereto; and
 - (b) for Condition 36 of Schedule 2 to that Licence, the Condition 36 annexed hereto.
2. This Variation comes into force on 22 July 2011.

For and on behalf of the Office for Nuclear Regulation
(an agency in the Health and Safety Executive)

Dr M Weightman

HM Chief Inspector of Nuclear Installations

A person authorised to act in that behalf

Dated: 21st July 2011

ANNEX – VARIATION OF CONDITIONS 17 AND 36 OF SCHEDULE 2

CONDITION 17 MANAGEMENT SYSTEMS

- (1) Without prejudice to any other requirements of the conditions attached to this licence, the licensee shall establish and implement management systems which give due priority to safety.
- (2) The licensee shall, within its management systems, make and implement adequate quality management arrangements in respect of all matters which may affect safety.
- (3) The licensee shall submit to the Executive for **approval** such part or parts of the aforesaid management systems or part or parts of the aforesaid quality management arrangements as the Executive may **specify**.
- (4) The licensee shall ensure that once **approved** no alteration or amendment is made to the **approved** management systems or **approved** quality management arrangements unless the Executive has **approved** the alteration or amendment.
- (5) The licensee shall furnish to the Executive such copies of records or documents made in connection with the aforesaid quality management arrangements as the Executive may **specify**.

CONDITION 36 ORGANISATIONAL CAPABILITY

- (1) The licensee shall provide and maintain adequate financial and human resources to ensure the safe operation of the licensed site.
- (2) Without prejudice to the requirements of paragraph (1), the licensee shall make and implement adequate arrangements to control any change to its organisational structure or resources which may affect safety.
- (3) The licensee shall submit to the Executive for **approval** such part or parts of the aforesaid arrangements as the Executive may **specify**.
- (4) The licensee shall ensure that once **approved** no alteration or amendment is made to the **approved** arrangements unless the Executive has **approved** such alteration or amendment.
- (5) The aforesaid arrangements shall provide for the classification of changes to the organisational structure or resources according to their safety significance. The arrangements shall include a requirement for the provision of adequate documentation to justify the safety of any proposed change and shall where appropriate provide for the submission of such documentation to the Executive.
- (6) The licensee shall if so **directed** by the Executive halt the change to its organisational structure or resources and the licensee shall not recommence such change without the **consent** of the Executive.

9 ANNEX B: REVISED GUIDANCE NOTE

Nuclear Safety Directive 2009/71/Euratom

Note on changes to licence condition 17 and 36.

Summary

1. This note sets out the details of, and the basis for, the proposed amendments to licence conditions 17 and 36. The changes are necessary to ensure that the Nuclear Safety Directive (NSD) has been fully transposed in Great Britain, and to better reflect current industry terminology (licence condition 17). In making these changes, the Office of Nuclear Regulation anticipates minimal costs and does not expect any resulting changes in current industry practice or in regulatory behaviour. **ONR will consider how best to embody the changes described in this document into revisions of ONR's suite of guidance, including Technical Assessment Guides; Technical Inspection Guides and Notes for Inspectors, and will provide nuclear site licence holders and controlling bodies with the opportunity to contribute to that work.**

Licence condition 17

2. The purpose of the existing licence condition 17 is to require the licensee to set out the managerial and procedural arrangements that will be used to initiate, control and monitor those actions which may affect safety. This includes all procedures and arrangements made by the licensee to comply with all licence conditions.

3. HSE/ONR's views on what the licensee's quality assurance arrangements should be to meet the requirements of the existing licence condition 17 are set out in T/INS/017 – Quality Assurance which can be found at:- http://www.hse.gov.uk/foi/internalops/nsd/tech_insp_guides/tins017.pdf

The proposed changes

4. Article 6(4) of the Nuclear Safety Directive 2009/71/Euratom (NSD) requires that licensees establish and implement management systems that give due priority to nuclear safety, and that the Regulator subject these to regular verification.

5. The revised version of Licence condition 17 requires licensees expressly to “establish and implement management systems that give due priority to safety”. The term “safety” is used here rather than “nuclear safety” as this is consistent with the current practice in the existing licence conditions.

6. The requirement for licensees to make adequate “quality assurance” arrangements for all matters which may affect safety will also be amended so that it refers to “quality management” arrangements. This terminology brings the language of the licence condition more in line with that employed in modern standards (e.g. IAEA) and used across the industry. This change is not required to implement the NSD, but, ONR consider it sensible to make it at this time. It is our view that this change in terminology does not affect the substance of the existing obligations to make and implement adequate quality assurance arrangements.

Effects of the proposed changes

7. At present, a broad assessment of licensee's management systems is carried out by ONR during its routine assessment and inspection activities. Inspectors will, as they do now, continue to monitor the licensee's safety management systems and the effectiveness of the quality assurance/management arrangements particularly as they relate to other licence conditions. ONR will be able to approve 'such part or parts' of both the management systems and quality management arrangements that ONR specifies. This would be limited and targeted. ONR therefore considers that, in practice, there will be **no change** in substance to what is currently required by T/INS/017 – Quality Assurance.

Licence condition 36

8. Article 6(5) of the NSD requires a licensee to provide and maintain adequate financial and human resources to ensure it can fulfil its obligations in respect of nuclear safety. The purpose of the existing licence condition 36 is to ensure that the licensee has adequate arrangements in place to control any change to its organisational structure or resources which could affect safety. It is proposed therefore to amend licence condition 36 to encompass the licensee's responsibility to have and maintain adequate financial and human resources.

The proposed changes

9. The amended licence condition 36 will place licensees under an express duty to provide and maintain adequate financial and human resources. With regard to *financial resources*, the amended licence condition 36 places an express duty on the licensee to provide and maintain adequate financial resources. As regards the need to provide and maintain adequate *human resources*, ONR considers that licensees will already comply with this new requirement by virtue of their Nuclear Baseline.

Effects of the proposed changes

10. At present, before granting a nuclear site licence, and periodically thereafter, the licence applicant/holder needs to satisfy ONR that they will have/have an adequate management structure, safety management arrangements and resources to discharge the obligations associated with operating a nuclear site and complying with all licence conditions.

11. Ensuring finances are in place and maintained throughout the lifetime of a nuclear installation is an integral part of the nuclear safety regime, and therefore an implicit aspect of the licensee's ability to demonstrate nuclear safety. The amendment to licence condition 36 makes this requirement explicit. However, ONR anticipates that minimal changes will be required to current practice amongst licensees.

12. On a day-to-day basis, compliance with legal duties to maintain an appropriate level of nuclear safety is likely to be sufficient evidence of compliance with the licence condition regarding the licensee's existing financial resources.

13. As regards the requirement to maintain financial resources, ONR's view is that the licensee should be able to clearly demonstrate that they:

- (a) know what their ongoing safety needs are;
- (b) have assessed what financial resources are necessary to continue to meet those needs;

(c) have and are maintaining, or have in place arrangements to obtain, the necessary financial resources; and

(d) have relevant records which are being retained in accordance with licence condition 6.

14. Informal consultation carried out within the nuclear industry has indicated that most licensees already meet the above expectations – including taking steps to ensure they have the resources to meet future safety needs - and should be readily able to provide relevant financial documentation if requested by ONR, (see para 15 below). ONR does not anticipate licensees needing to make significant changes to the way in which they currently operate.

15. Examples of evidence that licensees may have available for these purposes will include: safety cases; safety management prospectuses; annual financial accounts, plans for construction and key financial decision points; investment plans; lifetime Plans (LTP); and the Nuclear Baseline. Other documents may of course be used to demonstrate compliance with the requirements of the revised licence condition 36.

16. If ONR is satisfied that the licensee is adequately maintaining its plant, and has a valid and acceptable safety case and Nuclear Baseline then we do not anticipate needing to routinely request such financial information. If ONR needs to make such a request, it may need to draw on the expertise of external financial advisers, in addition to seeking suitable assurances from Government, and the costs of such engagement would be recovered from the licensee. Whilst it is not possible to estimate the frequency of such requests ONR anticipate that they will be rare. Costs associated with gaining such advice will be kept to the minimum necessary.

17. Where the licensee's budget is controlled by another body (such as the NDA), financial (and other resourcing) arrangements are likely to be set out in the management contracts between the licensee and the controlling body (e.g. the lifetime plan or LTP). ONR anticipates that the controlling body will co-operate with the licensee in ensuring the adequacy of the resources needed for safety, and the coherence between the regulatory requirements of the ONR and the controlling body. The licensee however remains responsible for nuclear safety under the terms of its nuclear site licences and the conditions attached to it.

Amendment of Licensee's Documentation

18. While licensees are expected to comply with the new requirements from 22 July 2011, ONR will not expect all documentary changes to be made by that date. ONR will expect any relevant changes to be made in the course of normal business/updating.