



Office for  
Nuclear Regulation

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# **Applicants Guide 2016**

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# Why change?



# Why change?

- Last revised 2001
- RMT team transferred from DfT to ONR
- Alignment of some regulatory processes

*Regulatory standards have not changed*

Emphasis in AG is now on how to put together a design safety case, and not to restate the regulations

# Applicants Guide 2016

## Aspects covered

- Structure and content of submissions
  - desirable qualities of safety cases
  - tiered approach
  - route map
- Validations
- Renewals and Extensions to approvals
  - design reviews
- Modifications
- Approval process

# Design Review

- Not a new requirement.....

*“However, before applying for a second renewal (a maximum of 6 years), the applicant must have subjected the DSR and all supporting evidence to a Design Review. Such a Design Review shall have been conducted by a competent person within (or independent of) the applicants organisation.” AG 2001*

4.2 *“Applications for renewal should include the documentation to justify safety (ie the safety case) over the renewal period, and a periodic design review report.”*

AG 2016

# Design Review

*“In either case the periodic design review report will be an important focus of the ONR assessment of the submission, and facilitate this assessment. It should lead to an earlier response and lower charges, if applicable. The periodic design review should be systematic and comprehensive, but also proportionate in depth taking account of the potential hazards.”*

AG gives a list of 12 criteria to consider in a design review, plus *“any other aspects considered relevant by the reviewer”*.

# Periodic Design Review Report

- For minor changes
  - periodic design review report (PDRR) could be an addendum to the existing design safety report (which has only minor updates)
- For major changes (or cumulative minor changes)
  - a new, consolidated design safety report (plus a PDRR)

PDRR must detail and explain any changes made

Changes need to be justified (in PDRR or revised DSR)

Safety case and its implementation  
must remain clear

# Modifications

- Modification categorisation clarified
- Statutory requirement that higher hazard designs are approved by Competent Authority, and hence the same for modifications that affect the design
  - unlike nuclear safety (discretionary)
- Two criteria for categorisation
  - impact on safety provisions
  - significance of that impact
    - non-compliant if inadequately conceived or executed



# Categories of Modifications

Impact on Safety Provisions	Significant	Category of Modification
YES	YES	A
YES	NO	B
NO	YES	B
NO	NO	C

- Category A or B
  - require CA approval
- Category C
  - no impact on safety provisions or compliance with regs, therefore self-approved

*For Category A/B, ONR review may take into account an applicant's process of independent safety assessment*

# Modifications

## some points to consider

- Category C
  - discuss proposed categorisation with ONR if uncertain
  - send copies of self-approval documentation to ONR
- Cumulative effects of A-C modifications at design review
- Amendments and concessions
  - treat as modifications
  - aggregate manufacturing concessions into a modification

# Discussion

- Any comments by end of this week
- Should be on ONR website in a few weeks
- Comments received so far
  - Table 2 (timescales) is indicative
  - Dropped requirements from old AG:
    - put in what you need to make the safety case

Any Questions?