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| ONR Technical Assessment Guide  Guidance on Mechanics of Assessment |



ONR Technical Assessment Guide (TAG)

Guidance on Mechanics of Assessment

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# Introduction

1. ONR has established its [Safety Assessment Principles](http://www.onr.org.uk/saps/saps2014.pdf) (SAPs) [1]) which apply to the assessment by ONR specialist inspectors of safety cases for nuclear facilities that may be operated by potential licensees, existing licensees, or other duty-holders. The principles presented in the SAPs are supported by a suite of guides to further assist ONR’s inspectors in their technical assessment work in support of making regulatory judgements and decisions. This technical assessment guide (TAG) is one of these guides.
2. This TAG provides advice on the general approach and considerations when assessing dutyholder’s submissions.

# Purpose and Scope

1. Assessment of dutyholder submissions is a fundamental and major component of ONR’s work. It is therefore appropriate to consider how this should be undertaken, in order to:

* ensure assessment work is appropriately comprehensive and proportionate;
* maximise the effectiveness of available effort;
* promote consistency in the standard of assessment;
* identify potential pitfalls and provide advice on ways to avoid them, and
* ensure appropriate recommendations/conclusions are reached.

1. This guide does not set out the definitive way to conduct assessment. Rather it sets out the purposes of assessment, the principles to be considered and provides reference to other ONR processes relevant to assessment.
2. This TAG is relevant to all of ONR’s purposes. This includes assessment of nuclear safety cases, nuclear security plans, design safety reports, risk assessments and safeguards material accountancy and control plans.

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# Relationship to Licence and Other Relevant Legislation

1. ONR carries out assessment of dutyholder’s submissions across all of its purposes. The list of relevant legislation is therefore extensive, and this section will only provide some examples of relevant legislation. It is neither viewed as comprehensive nor exhaustive.
2. Relevant legislation includes:

* Health and Safety at Work Act 1974 (HSWA) and its Relevant Statutory Provisions
* The Energy Act 2013 and its applicable provisions including:
  + Nuclear Industry Security Regulations (NISR) 2003
  + Carriage of Dangerous Goods Regulations 2009
  + Safeguards Act 2000
  + [Radiation (Emergency Preparedness and Public Information) Regulations (REPPIR)](http://uk.practicallaw.thomsonreuters.com/Document/I2CCA4A5051EB11E984DAE235364AAE9D/View/FullText.html?originationContext=document&transitionType=DocumentItem&vr=3.0&rs=PLUK1.0&contextData=(sc.Search)) 2019

1. All nuclear site Licence Conditions (LC) [2] have the potential to require the licence holder to produce documentation which could be subject to regulatory assessment, including the arrangements for compliance with the licence conditions. Examples of dutyholder submissions that are likely to undergo regulatory assessment could include:

* Arrangements for dealing with any accident or emergency made under LC11 – emergency arrangements.
* Safety case arrangements made under LC14 - safety documentation.
* Periodic and systematic review and reassessment of safety cases sought under LC15 – periodic review.
* Safety case documentation required under LC22 - Modification or experiment on existing plant.
* Safety case documentation required under LC23 – operating rules.
* Decommissioning arrangements or programmes sought under LC35 – decommissioning.

1. NISR 2003 requires the dutyholder to produce documentation for approval.   
   This could include:

* Approval of new or replacement security plans under Regulations 5 and 6 respectively.
* Temporary Security Arrangements and permanent amendments under Regulation 6.
* Temporary Security Plans submitted under Regulation 8.
* Transport Security Statements submitted under Regulation 16.

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# Relationship to SAPs/SyAPs, WENRA Reference Levels and IAEA Safety/Security Standards Addressed

1. Several International Atomic Energy Agency (IAEA) documents (for example, refs. [3], [4] and [5]) place expectations that the regulatory body should review and assess relevant information within the areas of safety and security.
2. IAEA General Safety Requirement (GSR) Part 1 [3] places requirements on national regulatory organisations. It states that the objective of regulatory functions is the verification and assessment of safety in compliance with regulatory requirements. This includes:

* **Requirement 25: Review and assessment of information relevant to safety** - The regulatory body shall review and assess relevant information — whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere — to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization and again over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization.
* **Requirement 26: Graded approach to review and assessment of a facility or an activity (by the regulatory body)** - Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.

1. The Convention on the Physical Protection of Nuclear Material, as reinforced by IAEA Nuclear Security Series 13 [5], places a legally binding obligations on member states including:

* **Fundamental Principle C: Legislative and Regulatory Framework** - The State is responsible for establishing and maintaining a legislative and regulatory framework to govern physical protection. This framework should provide for the establishment of applicable physical protection requirements and include a system of evaluation and licensing or other procedures to grant authorisation.

1. The Western European Nuclear Regulators Association (WENRA) Safety Reference Levels (SRL) [6] note the different regulatory regimes and range of plants and therefore state that they do not go into legal and technical expectations. The SRL’s should be considered, as appropriate, during ONR’s assessment of a dutyholder’s submission.
2. These expectations flow through into the ONR’s Safety Assessment Principles (SAPs) [1] and the Security Assessment Principles (SyAPs) [7] which provide guidance to ONR inspectors on expectations for dutyholder submissions relating to nuclear safety and security. ONR’s SAPs and the SyAPs should be applied to all of ONR’s nuclear safety and security assessment work. These documents are supported by a suite of TAGs which provide more detailed advice to inspectors on standards to be applied during assessment.

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# Advice to Inspectors

## Purpose of Assessment

1. In the context of this guidance, assessment is the act of making a judgement by the consideration of relevant evidence. The purpose of assessment is to allow ONR inspectors to reach an independent and informed judgement on the adequacy of a dutyholder’s submission. Assessment is used to inform ONR whether the dutyholder is, or will be, compliant with relevant legislation and can inform ONR permissioning or approval decisions [8].
2. Assessment is carried out by sampling submitted information, consideration of operational conditions and judging it against applicable standards and guidance. Where relevant this should include the need to demonstrate that risks are reduced, or are capable of being reduced, to As Low As Reasonably Practicable (ALARP) (for submissions relating to HSWA or the Ionising Radiation Regulations 2017 (IRR’s)). Security assessment should include the need to demonstrate that defined outcomes are achieved in accordance with the graded approach.
3. Assessment is normally undertaken by ONR specialist inspectors, but specialist technical support contractors can be used to provide an input to regulatory assessments. Although technical support contractors cannot make regulatory decisions their technical contributions can be used to inform the judgements of inspectors.
4. Regulatory judgements and decisions should be recorded, typically in an assessment report. An ONR assessment report can take many forms and details on the types can be found in ONR guidance on the production of reports [9].

## Principles of Assessment

1. Regulatory assessment should be in line with the expectations of ONR’s enforcement policy statement [10]. This includes proportionality, consistency of approach, targeting of enforcement action, transparency and accountability for the regulator’s actions.
2. Regulatory assessment should also be demonstrably independent from the dutyholder processes which generated the submission. The dutyholder's resources are limited, and the needs of safety or security can conflict with the needs of one or more of the other factors (performance, cost, production, functionality, project duration). In spite of a dutyholder aiming to achieve an adequate standard there remains the risk that safety or security will take a lesser share of the dutyholder's attention or resources than it should. ONR inspectors are therefore deliberately independent of dutyholders and have legal powers to enforce the vires within ONR’s purposes.
3. Potential shortfalls against relevant standards are not always self-evident to dutyholders and organisations might not be aware of up-to-date standards or relevant good practice across the industry. ONR benefits from knowledge across the industry and that perspective can be applied to our assessment work. Further, as organisations can be subject to “groupthink” this can be challenged through independent assessment.
4. Although ONR inspectors are less affected than dutyholders by the pressures that arise these considerations still do have an effect, and we must guard against allowing them to degrade the quality of ONR’s assessments. Time pressures that dutyholders seek to impose on ONR can have a major impact if we allow them to, and although it is sometimes appropriate to allow such pressures to inform the priority that is assigned, it is not appropriate to allow them to influence the scope or depth of assessment that is considered necessary. Equally, ONR is responsible under the regulators code [11] to “carry out their activities in a way that supports those they regulate to comply and grow “. We should therefore undertake assessment in a timely manner.
5. ONR inspectors should always remain objective, and a particular awareness of our objectivity should be maintained. We should be forceful in questioning dutyholders’ positions and requiring evidence to support their claims and arguments. If ONR inspectors become aware of conflicts of interest or loss of objectivity for any reason, they should inform appropriate ONR management such that their suitability for carrying out the assessment can be considered.

## Assessment Approach

### Adequacy of Information Supplied by the Dutyholder

1. Usually, it would be expected that the information provided for assessment has been approved through the dutyholder's due process (e.g., nuclear safety/security committees, independent nuclear safety/security assessment, peer review) and thus appropriately scrutinised and accepted by the dutyholder. In some cases, where timely assessment is required, the ONR assessment may proceed alongside the dutyholder's own due processes for final approval of the submission. However, the final ONR assessment must be based on the dutyholder's approved submission.
2. Normally a great deal of information is potentially available, both within a submission and from its references. A useful means of accelerating an inspector’s understanding of the submission is through the dutyholder presenting its case to the inspector (e.g., at a meeting).
3. The inspector carrying out the assessment needs to consider the presentation of this information and the quality of the submission prior to commencing assessment. Factors to consider include:

* Is it comprehensive, coherent, accurate and consistent?
* If not, is the missing information or assumed prior knowledge already to hand?
* Is it adequately structured?
* If a staged submission, does the information supplied match the scope of the staged submission?
* Is the level of detail sufficient?

1. It is the dutyholder’s responsibility to demonstrate the safety of the plant, the delivery of the appropriate security outcomes, or compliance with relevant legislation, and a poorly presented or structured submission prevents that responsibility being fulfilled. The dutyholder should have reached a properly objective and valid conclusion and this position should be demonstrable via the documentary evidence. An inspector should not be unduly reticent in rejecting a dutyholder’s submission if it has failed to demonstrate these objectives.   
   The specific shortfalls to support the rejection should be indicated by the inspector to the dutyholder. However, inspectors should be aware that the submissions are not written for the regulator but for the dutyholder’s organisation. Prior to any rejection consideration should be given to the target audience and whether the submission meets its intended purpose in that context.
2. Submissions should consist of three elements: claims, argument and evidence.   
   The claims represent the dutyholder’s perception of the objectives to be met, and may be explicitly stated or implicit, in which case they should be self-evident.   
   The evidence is the raw information or data that underpins the ability to show that the requirements are met. The evidence should either be stated in the submission itself or referenced from it. The arguments are what link the evidence to the claims, they do the 'showing' that the claims are met - they 'tell the story'. Caution should be applied when documentation consists either of vast amounts of evidence with very little in the way of argument, or very extensive arguments with little evidence. Further guidance on expectations for the purpose, scope and content of safety cases can be found in the ONR Safety Case TAG [12] and the Safety Directors Forum good practice guide on right first time safety cases [13]. In the case of security plans, where industry has not developed good practice guidance, the dutyholder should be invited to demonstrate how the evidence underpins the claim.

### Sampling

1. It is seldom possible or necessary to assess a submission in its entirety.   
   Sampling is used to limit the areas scrutinised, to limit the total effort to be applied, and to improve the overall efficiency of the assessment process. In general, the inspector should undertake a broad review of the highest-level claims and arguments and then undertake the majority of sampling in areas of high significance, areas of novelty or high uncertainty since weaknesses in these areas is potentially serious. Some samples may also be drawn from lower significance areas in line with the expectations of ONR’s enforcement policy statement (EPS) [10]. If sampling is done carefully, it can be expected to test for weaknesses in the submission as a whole. A powerful technique to apply is "deep thin slice" sampling, where deliberate scrutiny of a number of detailed matters across a narrow field is applied. In spite of the narrow view taken this technique is very good at revealing generic weaknesses.
2. Judgement is necessary both in deciding whether to assess a particular submission at all - significance is the usual criterion here though there can be others - and in the time and hence degree of sampling that should be allocated if it is assessed. However, whatever submissions and samples are assessed, it is important always to apply sufficient rigour to arrive at defensible judgements, since they may well be challenged either at the time or at any time later. Shortage of time may restrict the range of cases or the areas that are sampled but should not restrict the depth and rigour of assessment. As the assessment progresses inspectors need to be alert to avoid unnecessary mission creep but equally, they should be prepared to change their sample as further information becomes available.

### Undertaking Assessment

1. Prior to commencing any assessment, the assessor should:

* understand the reason for their assessment;
* understand the scope of their assessment (eg interfaces with other specialisms or the scope of assessment if there are a series of staged submissions); and
* consider if they are a suitably qualified and experienced person (SQEP) to undertake the agreed scope or if other advice is required.

1. The assessor should record their assessment plan in a unique WIReD assessment record.
2. The reason for the assessment is often linked to ONR making a permissioning decision. The permissioning process enables ONR to apply regulatory control to certain dutyholder undertakings, and to respond to dutyholders who require permission to commence, continue, modify or cease specified activities under relevant legislation. The permissioning plan is recorded in a unique WIReD permissioning record that the project or site inspector responsible for the permissioning decision completes. This plan should identify the background/scope/type of a particular permission/approval being requested and aid any assessment being undertaken to support it.
3. Following completion of assessment, the recommended permissioning decision is recorded and justified in accordance with the requirements of the ONR management system (e.g., through completion of a permissioning decision record or a project assessment report). As such, the output from any assessment must link back to the original reason for the assessment (e.g., the requirement for a permissioning decision). Further guidance on permissioning can be found in reference [8].
4. Inspectors should then commence assessment but avoid passive reading of the dutyholder’s submission. To provide independence and active assessment of the dutyholder’s submission the inspector should initially consider their expectations for the submission. Without reading (much of) the documentation it should be possible to identify relevant good practice (RGP), regulatory requirements and expectations for topics that should be considered and addressed by the submission.
5. Once the inspector has a clear idea of expectations for the submission, the dutyholder's work can be sampled in more detail, but in an active manner and to more purpose. As the submission is sampled in more detail and the inspector’s understanding of the submission increases the inspector should occasionally repeat the above process to ensure they are clear of their expectations of the submission and any RGP. It is good practice to record changes to the assessment plan in the WIReD unique record for the assessment. In this process the implicit assumptions and boundaries in the dutyholder’s submission will be more likely to be revealed where they differ from the inspector's own thoughts. All such assumptions and boundaries revealed in this way should be tested objectively for validity, as should underlying explicit assumptions. If a "deep thin slice" sampling approach has been used, this may require examination of several levels of references to establish the underpinning technical or performance basis of a claim. The references can exist in many formats and levels of authority which the assessor should consider the validity of if key to the substantiation.
6. It is important to recognise that the objective of this process is to have carried out an independent thought process to compare against the dutyholder’s submission. Independent assessment is therefore much more powerful, particularly in revealing omissions, which are of course often not mentioned at all and often represent the most serious of shortcomings. Thus, deliberate attention to independence leads to greater efficiency in that effort is expended in direct relation to impact.

### Queries during the Assessment Process

1. During the assessment process queries will arise that will require clarification from the dutyholder. ONR inspectors should be aware of the process for raising queries on the relevant project, programme or site. In some instances, dutyholders may provide a verbal or written response to the query raised. In other cases, the dutyholder may seek clarification on what the inspector requires to resolve the issue raised.
2. Inspectors should be cautious when supporting documentary evidence is not provided to support claims made. This situation usually occurs during discussions when the assurance is given verbally, and the inspector is expected to take the justifier's word for the matter in question. The inspector should, if key to the judgement, request that the supporting evidence be made available.
3. If no supporting evidence is available, then the assurance may still be accepted providing one or more of the following points can be established:

* the matter is not one that is central to the overall validity of the submission.   
  In other words the case would stand without the assurance, but it provides an additional element of comfort or an increased margin;
* assurance is straightforward with little or no possibility of misunderstanding between the inspector and the justifier;
* the assurance is indeed factual and not in any way dependent on the opinion of the justifier;
* the justifier is personally competent, appropriately informed and empowered to make the assertion - it is not something reiterated from someone else:
* Previous interventions have established that something is in fact the case.

1. When satisfied, the inspector should document the acceptance of the assurance in a formal manner, request that the assurance be recorded in the minutes of the meeting or request the assurance via a written method (letter, email etc) with any necessary supporting information that is available. It is important that the record should name the individual making the assurance, not only to demonstrate a traceable reference in this respect but also to maintain the individual's awareness of formal responsibility as spokesperson for the dutyholder. Such evidence should be uploaded to the WIReD assessment record.
2. If the matter is one that is central to the submission, then it should be made clear that further evidence must be supplied, even, if necessary, by repeating and recording the process that led to the original assertion.
3. A situation that can occur after a legitimate concern has been raised by an inspector and has been accepted, is that a dutyholder will ask for assistance with respect to what needs to be done to satisfy the inspector's concern. Inspectors should adopt a constructive approach with dutyholders, in line with ONR’s enabling regulation approach [14]. However, when providing guidance inspectors should be mindful of the duty to provide advice whilst ensuring that this is not prescriptive, and that any solution is ‘owned’ by the dutyholder.
4. Any guidance should be:

* Clear on legal duties and what is (and is not) required for compliance.
* Constructive, committed, open.
* Encouraging development of fit for purpose solutions which meet legal obligations and represent RGP.

### Areas of Regulatory Concern

1. Where areas of regulatory concern are identified these should be discussed with the project or site inspector responsible for the permissioning decision as early in the assessment process as possible. Considerable interaction with the dutyholder may be required to pursue and influence the improvements required to address the shortfalls identified. In some instances, it may be necessary for the improvement to be in place prior to the permission being granted. In other cases, it may be appropriate to raise regulatory issues so that the dutyholder develops and delivers a suitable action plan. Further information on the management of regulatory issues is provided in reference [15].
2. A dutyholder’s internal assurance team may have intelligence on areas of regulatory concern and can also be used to provide assurance that issues raised have been addressed by the dutyholder.

### Interfaces with Other Assessments

1. The inspector should, where relevant, ensure that interfaces between different specialist assessments do not lead to gaps. Where two specialist inspectors each assume that the other will address points at or near the specialism boundaries there is the potential for assessment gaps to form or for duplication of the assessment to occur. In reality, operations, plants etc do not separate themselves conveniently into the areas that specialist inspectors (and dutyholder’s) separate themselves into, so care is needed to ensure comprehensive coverage of all areas of legitimate concern.
2. Inspectors should therefore identify at the outset of any assessment:

* Any likely interfaces and establish a clear understanding with other inspectors how that interface will be managed.
* Any interfaces with dutyholders and who is the principal point of contact in a given area.
* Any interfaces with other regulators and the need to understand the scope of their legal vires.

## Actual Plant/Operational Condition Compared to Documented Claims

1. It should always be borne in mind that there may be a difference between the implied claims in the submission paperwork and the actual plant/operational configuration or condition. This is because the relationship between the plant/operations and the associated submission is not always as rigid as might be assumed, the justification sometimes representing a claimed state or expectation that may not be fully attained in practice. These considerations apply with regard to design intent and implementation, which may not always be the same; and to operational claims. Appropriate measures should therefore be taken to verify or otherwise test the claims made, preferably by inspection.
2. Inspection in support of assessment should be against specific rather than general plant/operational features. "Deep thin slice" sampling can be used to test the dutyholder's adherence to declared procedures, principles and claims.
3. When a weakness is found it should be pursued in some detail; it is most unlikely to be an isolated case. Whenever sampling is used it should be as part of a predetermined plan, and where time is limited the number of samples should be reduced rather than the depth of each sample. Generally, three or four samples are sufficient for most inspection purposes and should be chosen by the inspector unless there is an overriding reason for the dutyholder to choose them, in which case it must be ensured that there is no possibility of favourable selection occurring. If weaknesses are found then it will probably be necessary to take further samples to ascertain how widespread they are, but the new samples need only be reviewed for the particular weakness rather than in the same detail as the original samples. If the weakness has already been identified by the dutyholder (e.g., in a Security Improvement Schedule (SIS)) then it would be expected that they would have a justification of the adequacy of measures in place or a plan to resolve the shortfall, including compensatory measures in the interim. Where this is the case sufficient sampling should be done to establish the adequacy of the proposed solution.
4. If inspection indicates the procedures or safety/security systems claimed in the documentation are not being implemented, that is a matter for an enforcement decision by the site inspector. Any enforcement decision would be in accordance with ONR’s enforcement management model (EMM) [16].

## Judging Adequacy and Use of RGP

1. It is the responsibility of the inspector carrying out the assessment to judge when and if a submission is adequate. Although it can be assumed that the dutyholder believes a submission to be adequate, the inspector must have in mind a clear and independent image of what adequacy means and must be able to recognise when it has been achieved.
2. Judging adequacy is normally straightforward against prescriptive duties but is more challenging against non-prescriptive requirements (e.g., against the duty to reduce risk ALARP or against other goal-setting standards in legislation or licence conditions). Within ONR we are usually able to make judgments by comparing the dutyholder’s submission against RGP. RGP refers to those good practices that have been previously assessed and judged to meet the requirement in question (whether that be reducing risks ALARP or another goal-setting outcome). There are a number of sources of RGP. For nuclear safety, the key written sources are the SAPs, TAGs and Technical Inspection Guides (TIG). Several TIGs and TAGs also address conventional health and safety, where ONR would also make particular use of guidance published by HSE. The ALARP TAG [17] provides more information . For security, the SyAPs and security TIGs and TAGs are the primary sources of RGP.
3. It should be noted that RGP is not mandatory and is only a starting point for situations that do not fall within the scope of the circumstances under which the RGP has been derived. ONR inspectors must be mindful that a dutyholder is always free to take an alternative approach providing it can still demonstrate the required safety or security goal. More information on the definition of ALARP and the use of RGP in judging compliance with ALARP and other goal-setting requirements can be found in the ALARP TAG [17].
4. The inspector’s report should articulate the degree to which RGP has been met including any proportionate application of their expectations. This should be an explicit statement and not a broad general statement (e.g., the intent of the SAPs/SyAPs has been met). Should the judgement be contentious or not clear cut a useful source of advice is colleagues in the relevant specialism or other ONR working groups (e.g., for safety the ALARP working group or for security the DL forum).
5. Inspectors should be aware that their decision making and judgements on adequacy can be subject to review. ONR’s internal peer review process is defined in reference [18]. ONR’s process for resolving differences of regulatory opinion is defined in reference [19]. Externally an inspector’s judgement could be subject to review by appeal to a judicial review or at an inquiry following an incident. The inspector’s task would be to demonstrate that the assessment carried out was that which would have been done by a reasonable person with appropriate qualifications and experience, exercising discretion as permitted by law. If an inspector can justify the judgement in this context, then the process has gone far enough. Detailed consideration of this can be found in the judge over your shoulder – guide to good decision making [20].

## Record Keeping

1. The need for a comprehensive written record is of paramount importance and should be clear from the above argument. Within ONR the written record could be an assessment report, decision record or project assessment report. Further information on these types of reports can be found in refs. [8] and [9].
2. If an incident occurs, it is likely to be long after the justification and its assessment have been carried out. Even if the inspector had a defensible position at the time, poor record keeping might make this difficult or even impossible to establish.   
   The assessment records need not all be included in the final assessment report or note, but documents used as the basis of assessment and inspector’s decision-making should be referenced within the assessment report. These documents should be made available on WIReD or ONR’s electronic document and record management system (EDRMS). If security classification precludes their storage on WIReD or EDRMS, there should be clear instructions in the WIReD as to how copies of the document can be accessed (typically with reference to the dutyholder’s own storage arrangements).

## Assessment Rating

1. Inspectors should apply an assessment rating to formal permissioning assessments to inform the level of response that should be sought against any identified shortfalls. The assessment rating should be given against the dutyholder’s formal submission. This means that the rating should not take account of regulatory interventions undertaken by ONR inspectors following the formal submission to improve the quality of the submission and/or safety standards. Responses to queries or points of clarification should not be considered improvements to the case and therefore should not form part of the rating process.
2. Significant shortfalls should only be recorded if permissioning was not granted or significant modification was sought to the case during the assessment process. If significant modification was required to the submission during the assessment process to enable permissioning, regulatory follow up should be targeted at the failing in dutyholder’s due process. Conversely, assessment ratings should not be applied to dutyholder’s draft submissions provided for information or early engagement. These documents would likely be incomplete and require improvements as part of the dutyholder’s processes and therefore it is not appropriate to rate these submissions in a draft state. In such cases the rating should again be applied to the submission formally supplied to ONR once it has completed the dutyholder’s due process.
3. To ensure a balanced assessment any best practice within the dutyholder’s submission should be identified as well as any shortfalls.
4. The rating should be in accordance with the ONR guidance for assessment ratings in Appendix 1.

# References

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| --- | --- |
| [1] | ONR, “Safety Assessment Principles (SAPs) for Nuclear Facilities - 2014 Edition (Revision 1),” 2020. |
| [2] | ONR, “Licence Condition Handbook,” 2017. |
| [3] | IAEA, “GSR Part 1 - Govermental, Legal and Regulatory Framework for Safety,” International Atomic Energy Agency (IAEA), Vienna, 2016. |
| [4] | IAEA, “IAEA General Safety Guide (GSG) 13 - Functions and Process of the Regulatory Body for Safety,” IAEA, Vienna, 2018. |
| [5] | IAEA, “Nuclear Security Series No. 13. Nuclear Security Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities (INFCIRC/225/Revision 5),” 2011. |
| [6] | WENRA, “WENRA Safety Reference Levels for Existing Reactors,” 2020. |
| [7] | ONR, “Security Assessment Principles (SyAPs) for the Civil Nuclear Industry,” 2017. |
| [8] | ONR, “NS-PER-GD-001 - The Purpose and use of Permissioning”. |
| [9] | ONR, “NS-TAST-GD-108 - Guidance on the Production of Reports for Permissioning and Assessment,” 2022. |
| [10] | ONR, “Enforcement Policy Statement”. |
| [11] | Department for Business Innovation and Skills, “Regulators Code 2014”. |
| [12] | ONR, “NS-TAST-GD-051 - The Purpose, Scope and Content of Safety Cases”. |
| [13] | Safety Directors Forum, “UK Nuclear Safety Case Forum Guide, Right First Time Safety Cases: How to write a usable safety case,” March 2014. [Online]. Available: https://www.nuclearinst.com/write/MediaUploads/SDF%20documents/Safety%20Case/UK\_Nuclear\_SC\_Forum\_guide\_-\_How\_to\_write\_a\_usable\_Safety\_Case\_-\_March\_2014\_.pdf. |
| [14] | ONR, “Holding Industry to account and influencing improvements in nuclear safety and security – Enabling Regulations in practice,” 2018. |
| [15] | ONR, “ONR-RIO-PROC-001 - Management of Regulatory Issues”. |
| [16] | ONR, “ONR-ENF-GD-006 - Enforcement Management Model”. |
| [17] | ONR, “NS-TAST-GD-005 - ONR Guidance on the Demonstration of ALARP”. |
| [18] | ONR, NS-TAST-PROC-001 - Peer Review and Acceptance of Reports for Permissioning, 2022. |
| [19] | ONR, “NS-INSP-IN-002 - Resolving Differences of Professional Opinion in ONR”. |
| [20] | H.M Government, “Judge over your shoulder,” 9 October 2018. [Online]. Available: https://www.gov.uk/government/publications/judge-over-your-shoulder. |

# Glossary and Abbreviations

ALARP As low as reasonably practicable

DR Decision Record

EDRMS Electronic document and records management system

EMM Enforcement Management Model

EPS Enforcement Policy Statement

HSWA Health and Safety at Work Act

IAEA International Atomic Energy Agency

IRRs Ionising Radiation Regulations

LC Licence Condition

NISR Nuclear Industry Security Regulations

ONR Office for Nuclear Regulation

REPPIR Radiation (Emergency Preparedness and Public Information) Regulations

RGP Relevant Good Practice

SAPs Safety Assessment Principles

SIS Security Improvement Schedule

SP SharePoint (Microsoft) – Record management system for WIReD

SQEP Suitably Qualified and Experienced Person

SRL Safety Reference Level

SyAPs Security Assessment Principles

TAG Technical Assessment Guide

TIG Technical Inspection Guide

WENRA Western European Nuclear Regulators Association

WIReD Well Informed Regulatory Decisions (ONR management tool)

# Appendix 1 – Assessment Ratings Guide

To use this guide, inspectors should identify applicable indicators from the list based on their assessment findings. Then select an appropriate rating which is the best fit, overall.

The majority of licensees and duty holders should be operating predominantly with a rating of Green.

| Indicative Assessment Findings | Rating | ONR Response |
| --- | --- | --- |
| * Relevant good practice generally met, or minor shortfalls identified, when compared with appropriate benchmarks. * There may be some opportunities for improvement to reduce risks to ALARP or enhance security measures. * There may be some examples of standards being used as a reference at national/international level. * Relatively minor, if any, deficiencies in the technical quality of the safety case or security plan when judged in terms of being intelligible, complete, valid, evidential, robust, integrated, balanced, and forward looking. * No regulatory intervention and guidance needed with relatively minor, if any, issues being raised for clarification. * Relatively minor, if any, deficiencies in safety case compliance arrangements or their implementation under LC13, LC14, LC15 and LC23. * Relatively minor if any deficiencies in security plan compliance arrangements under NISR 2003. * Safety case, periodic review or security plan submitted on time or slightly late. * There may be some examples of best practice which have been observed and recorded. | **Green** | **No Formal Action**   * Provide feedback on the rating and key points to be recorded in the Assessment Report. * If appropriate, provide regulatory advice on how to address any identified areas for improvement. * Expect the licensee/duty holder to address any identified improvements and manage resolution via their internal management controls. * If safety case or periodic safety review supports a permissioning decision recommend issuing consent/approval/agreement. * If security plan supports a permissioning decision recommend issuing approval. * Make a Level 4 Regulatory Issues Database entry, if necessary, to monitor licensee/duty holder progress. * Record any examples of best practice in the Assessment Report and acknowledge these to the licensee/duty holder. * Record advice given regarding continuous improvement and best practice. |
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| * Significant shortfall against relevant good practice or established standards when compared with appropriate benchmarks. * Significant or systematic failure in the technical quality of the safety case or security plan when judged in terms of being intelligible, complete, valid, evidential, robust, integrated, balanced, and forward looking. * Significant regulatory intervention and guidance needed with many technical issues being raised requiring regulatory follow-up. * Significant or systematic failure in safety case compliance arrangements or their implementation under LC13, LC14, LC15 and LC23. * Significant gaps in dutyholder ability to demonstrate achievement of security outcomes. * Significant or systematic failure in security plan compliance arrangements or their implementation under NISR 2003. * Safety case, periodic review or security plan improvements submitted well past agreed time. | **Amber** | **Seek Improvement**   * Provide feedback on the rating and key points from the assessment to be recorded in the AR. * Identify and discuss any significant shortfalls with the licensee/duty holder, at an appropriate level. * Review the shortfall(s) against the ONR Enforcement Management Model (ref. [16]). * If the safety case supports a permissioning decision, consider withholding consent/approval/agreement. * If the security plan supports a permissioning decision, consider withholding approval. * Make a Regulatory Issues Database entry at Level 3 or above to log any enforcement communication and to track progress. * Follow-up and close out the Regulatory Issue when complete. |
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| * Major non-compliance with defined or established standards necessary to ensure nuclear safety or security. * Major inadequacies in the safety case or security plan which require prompt regulatory intervention. * Persistent need for regulatory intervention and guidance with multiple issues requiring frequent regulatory contact. * Major shortfall in safety or security requirements revealed as a result of a periodic review of the safety case or security plan, an incident on the site, or any examination, inspection, maintenance or test of any part of a plant indicating that the safe operation or safe condition of the plant may be affected so giving rise to a significant and discernible risk gap to members of the public or workers under the EMM. * Submission of safety case, periodic review or security plan severely delayed, when the intent of the submission is to justify continued operation when a major shortfall in safety or security requirements has been revealed.   Failure to deliver safety case or security improvements and commitments previously identified in ONR enforcement communications. | **Red** | **Demand Improvement**   * Provide feedback on the rating and key points from the assessment to be recorded in the AR. * Raise the identified shortfall(s) with the relevant licensee/duty holder leadership and note the potential for enforcement action. * Draw the matter to the attention of the relevant Programme Delivery Lead. * Review the shortfall(s) against the ONR Enforcement Management Model (ref. [16]). * If safety case or periodic safety review supports a permissioning decision withhold consent/approval/agreement. * If security submission supports a permissioning decision withhold approval. * If safety case or periodic safety review is intended to support continued operation issue a direction under LC31 to shutdown plant, operation or process. * Make a Regulatory Issues Database entry at Level 1 or 2 to log the enforcement communication and to track progress. * Consider if a holding to account, or similar meeting, with the licensee/duty holder is appropriate.   Follow-up and close out the Regulatory Issue when complete. |