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| ONR Procedure  Management of Regulatory Issues |



ONR Procedure

Management of Regulatory Issues

**Process Owner**: Director of Regulation - Technical Directorate

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Table 1 - Revision commentary

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| --- | --- |
| Issue No. | Description of Update(s) |
| 6 | Revision to reflect new WIReD Regulatory Issues Database (RID).  Update to definition to reflect Safeguards international obligations.  Updates to recording information on the RID, governance and Appendix 1.  Document reformatted into an ONR Procedure and new Unique Doc. ID given. |
| 6.1 | Format update and review date extended. |
| 6.2 | Minor update to extend the review date by 6 months to allow time to discuss ownership of process following recent organisational changes within ONR. |
| 6.3 | General editorial updates to improve alignment with WIReD Issues guidance, organisational changes and ONR purposes review. |

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# Introduction

## Background

1. In May 2004, an explosion at the ICL Plastics Factory in Maryhill, Glasgow resulted in 9 deaths with a further 33 people injured, 15 of them seriously. This incident was to have significant implications for safety regulators.
2. The subsequent independent inquiry chaired by Lord Gill concluded that the explosion, caused by the ignition of Liquefied Petroleum Gas (LPG) that had escaped from a poorly maintained and inaccessible section of pipework, was an “avoidable disaster”. Lord Gill also concluded that the Health and Safety Executive (HSE) had “failed in its duty to effectively manage the regulatory issues that led to the explosion”; in particular, he criticised the lack of consistency in the HSE’s approach to the identification and management of regulatory issues and, the failure to use regulatory issues to inform its intervention strategy for the ICL factory. As a consequence, HSE failed to appreciate the significance of the buried pipework (from which the LPG had escaped), failed to pursue follow-up visits promptly and, failed to apply appropriate caution in the acceptance of a compromise that focused on addressing the more easily accessible areas of the LPG system.
3. As part of ONR’s response to the Gill Report, the Regulatory Issues Database (RID) was created. The RID, now integrated into ONR’s WIReD system (WIReD), provides the mechanism to record and monitor progress against the follow-up actions required to address issues identified by ONR inspectors. This is supported by a systematic regulatory issue’s management and governance process, to be adhered to consistently by all ONR inspectors, irrespective of purpose or specialism.
4. This procedure is not exhaustive and nor can it cater for all scenarios. It is intended to provide a framework for the management and recording of information in Regulatory Issues, with the intent of driving consistency. However, if you have an example which doesn’t meet the expectations set out within this procedure, this should be discussed with the relevant Head of Profession and recorded in the Regulatory Issue.

## Definitions

Table 2 – Table of Definitions

| Term/Acronym | Description |
| --- | --- |
| Management Group | Within this document, the term ‘management group’ is used generically to include any governance forum with assigned responsibility for managing regulatory issues. These include:   * Regulatory Leadership Team (Regulatory Directorate level governance) * Directorate Board * Sub-Directorate Board * Directorate Management Group * Intervention Management Group * Issues Review Group |
| Regulatory Issue | Any matter relating to ONR’s purposes (nuclear safety, nuclear site health and safety, nuclear security, nuclear safeguards and transport of radioactive material) that has the potential to degrade safety or security, or challenge regulatory compliance, an agreed regulatory strategy or an international obligation.  Within this document the term ‘safety’ relates to all aspects of safety including Health, Conventional, Nuclear, Radiological, Chemo-toxic, Fire and Transport. The term ‘nuclear security’ refers to all matters related to Civil Nuclear Security, Protective Security and Cyber Security - including Protective Security (incorporating physical security, personnel security, emergency preparedness and response, sabotage target analysis and review, and transport security) and Cyber Security and Information Assurance (incorporating resilience and regulation of the supply chain (List N). |
| WIReD terminology from User Guide | * Tab – a section of the application accessed from the titles below the business process flow. Each tab has a number of fields of or for information grouped in blocks. * Block – a group of fields, some, but not all, blocks have a title. * Field – typically a box that either displays a piece of information or into which information can be entered. Each field has a title/name and a field i.d. (which is sometimes quite different to the name as it is fixed when the field was created during development whereas the name can be updated over time). |

# Management of Regulatory Issues within ONR

1. A regulatory issue can arise at any point during any regulatory activity be it site inspection, permissioning or conducting a formal technical assessment. It is important to note that the identified regulatory shortfall is the dutyholder’s responsibility to address: It is important that, in discussions concerning the raising of a regulatory issue, the dutyholder understands the nature of the shortfall in the context of the regulatory expectation and, agree the actions necessary to ensure the shortfall is resolved to ONR’s satisfaction.
2. ONR’s inspectors are required to record and manage all regulatory issues through to closure using WIReD. This includes routine issues identified and managed by ONR inspectors, through to high level strategic issues and those that may have long resolution timescales (e.g. COMAH 15 revision plan items) that we wish to maintain regulatory visibility of.
3. Information entered into WIReD by ONR staff should provide a full auditable trail of the issue; this includes the actions placed on dutyholders, reference to any associated enforcement, reference to all relevant correspondence, monitoring of progress including a history of interactions between ONR and the dutyholder relating to the resolution of this issue (including key decisions and agreements) and the basis for closure. WIReD provides this functionality and further guidance is included within the [WIReD user guide](https://how2.prod.onr.gov.uk/CtrlWebIsapi.dll/E538D0862C0349D38E47A34E4CE73A08.cwl?__id=webFile.save&doc=93FF3DF9FE504B3DADAF43D4291B2C7E&dpt=1&save=1) [1]. It is important to appreciate that WIReD is ONR’s principal knowledge management mechanism and each Issue should be appropriately linked and/or cross referenced to source documentation within either WIReD or CM9 / SharePoint. Whilst WIReD provides improved integration, automation and visibility for the dutyholders, it is not a replacement for inspector’s verbal communications with the dutyholders to discuss regulatory issues.
4. WIReD provides assurance to the ONR Board, the Senior Leadership Team (SLT) and Regulatory Leadership Team (RLT) that inspectors and management groups are effectively managing and tracking their regulatory issues and any associated enforcement actions to satisfactory closure.

## Issue Level

1. ONR uses a graded approach for the management of regulatory issues: the level assigned provides two key functions:

* To indicate its significance.
* To assign an appropriate level of management scrutiny and governance.

1. The level assigned also reflects the level of oversight ONR expects the issue to receive within the dutyholder’s organisation.
2. The following guidance is provided to promote consistency of approach across ONR irrespective of specialism or purposes. Although the inspector will set the level initially, it is the role of the management group to ensure that an appropriate level is assigned and recorded within WIReD.

### Assigning an Issue Level

1. The issue level is a numerical indicator (Level 1 to 4) where Level 1 is assigned to those issues requiring the highest level of ONR management attention and Level 4 the least. In general, the level assigned to a regulatory issue follows the following guidance:

**Level 1**: This is the highest level of importance and should be reserved for issues that merit oversight by CNI and/or Senior Director of Regulation (SDoR) and RLT. Examples include:

* The potential cessation of dutyholder operations.
* An issue leading to a formal investigation, triggering ministerial reporting criteria or where the most significant enforcement action (Prosecution) might be applied.
* Identification of an intolerable risk likely to result in significant public and/or political interest requiring strategic ONR oversight.
* Failure of the UK to meet international safeguard’s obligations that provide a basis for possible escalation or formal sanction by IAEA and/or NCA partners.

**Level 2**: This level applies to those significant issues that do not merit oversight by CNI and/or SDoR but nonetheless merits oversight by the relevant Director of Regulation. Examples include:

* An issue where an Improvement or Enforcement Notice, Specification or Direction (or similar enforcement) might be applied.
* A matter that justifies the withholding of a permission.
* A matter associated with an ONR inspection/assessment rating of ‘Red’ (Demand Improvement), or
* Significant failure to maintain arrangements for nuclear materials accountancy and control.

**Level 3**: This level applies to routine regulatory matters that require oversight by the relevant Head of Regulation. This would generally apply to compliance shortfalls identified and/or resulting in an inspection/assessment rating of ‘Amber’ (Seek Improvement). When raising a Level 3 Issue, consider using the enforcement management model (EMM), which will determine the appropriate enforcement outcome, if any is required.

**Level 4**: This level applies to those matters identified by inspectors that do not merit proactive management by the Head of Regulation. Typically, these are matters arising from ONR interventions that we wish to track with dutyholders where minor shortfalls/improvements have been identified. Level 4 issues do not require formal enforcement communication.

1. The ‘Regulatory Issues Level Guidance Chart’ at Appendix 3 provides additional guidance to inspectors when assigning an initial level to a regulatory issue.
2. The level assigned to a regulatory issue may be increased (escalated – except Level 1 issues) or reduced (de-escalated – except Level 4 issues) at the discretion of the appropriate management group to reflect dutyholder performance in addressing the issue. In such circumstances and where issues relate to specialist topics the relevant Head of Profession may be consulted. This is discussed in more detail under ‘Issues Management (Governance)’ at Section 3.

## Recording Information on WIReD

1. To ensure that ONR records the management of regulatory issues to an appropriate quality and consistent with the demonstration of their proper control, the following data entry requirements against each of the WIReD data fields within the different top level tabs should be met (examples of accepted practice and unacceptable practice are provided at Appendix 1).
2. The below sub-sections reflect the preferred method for recording information within WIReD, however, it is recognised that this may differ slightly for transport purposes and for qualifying nuclear facilities with limited operation (QNFLO) in safeguards. This is largely driven by the capability and capacity of some relatively small transport dutyholders. It is considered disproportionate to raise individual issues for multiple shortfalls. Instead, an issue is often raised following a compliance inspection and individual shortfalls and associated details are recorded as Actions (see Appendix 2).

### Issue Name

1. The Name field should indicate clearly and concisely what the issue is addressing, in a short title. Sufficient keywords should be included to enable discrimination of the issue from other similar issues entered on WIReD.
2. Where practicable, the Name should identify the facility or area to which it applies.
3. Consideration should also be given to wording the issue Name in such a way as to support the broader ONR governance requirement. For example, trending, supporting the review and development of ONR guidance and supporting the review and development of ONR regulatory strategy.

### Owner

* + 1. The inspector responsible for monitoring the dutyholder’s progress in responding to the issue **must** be selected as the Owner. This system will default to the person raising the issue in WIReD.

### Dutyholder and Site

1. A Site, Dutyholder and Dutyholder contact **must** be assigned for each issue from the drop-down menu provided. A site Area/Group should be selected were relevant.

### Issue

1. The Issue field should be kept as short as practicable but provide sufficient information to enable the dutyholder and any fully trained inspector to understand the plant, procedure and people context, the regulatory shortfall, and the significance of the matter.
2. The issue **must** be worded in a way that can be subsequently closed out. Where practicable, the text should identify the facility or area to which it applies.

### Source of the Issue

1. The Type is the nature of the regulatory activity from which the issue arose, e.g., intervention, assessment, enforcement. This should be selected from the drop-down menu.
2. The Reference is the document that provides ONR’s record of the activities and judgements that resulted in the raising of the issue. Examples include Intervention Records from inspections, Contact Records from Meetings or Assessment Report. Good practice is to provide the unique ONR Reference and its associated reference within WIReD or CM9 / SharePoint. When referencing a WIReD source, the link should also be provided, see below.

### Links

1. Inspectors should use the Links tab in WIReD to link the regulatory issue to relevant incidents, inspections, permissioning and assessments. Links should also be added for any other associated or relevant regulatory issues.

### Actions

1. Actions must meet the SMART requirement to enable each action to be closed. The actions must collectively provide the evidence to enable the issue to be closed.
2. To meet the SMART requirement, actions **must** meet the following criteria:

* **Specific**: The actions must specify the activity that the dutyholder needs to deliver to enable the action to be closed.
* **Measurable**: They need to clearly identify the evidence that is necessary to demonstrate that the required activity has been delivered and enable the action to be closed.
* **Achievable**: The actions placed on the dutyholder must be proportionate to the significance of the issue with regards scope and timescales and, within the capability of the dutyholder to reasonably deliver.
* **Relevant**: The actions must contribute directly to closing the issue and result in the dutyholder achieving the required regulatory standards (addressing the shortfall in regulatory expectation).
* **Time-based**: Each action should have an appropriate date by which that action should be closed. Collectively these dates should enable the issue to be closed within the agreed timescale.

1. It is important to discuss any corrective actions and their timetable with the dutyholder to ensure that they are appropriate and achievable. It is also important to gain assurance of the licensee’s/dutyholder’s commitment to address the actions agreed and to ensure they understand the regulatory implications should they fail to be progressed adequately.
2. Actions arising from a Level 1, 2 or 3 regulatory issues should be confirmed in writing via the appropriate ‘Enforcement communication’ (letter or email).
3. It is permissible to modify or refine the specified actions and/or their associated dates in WIReD in light of changing circumstances. In these instances, the issue owner **must** ensure that a record is made via the Progress tab providing the justification for any changes.
4. Where significant changes are proposed to the original action(s), the issue owner should agree these with the relevant management group (for L1-L3 issues); any agreement should be recorded via the Progress tab.
5. It is recommended to assign a numeric label to the Action within the Name field to support subsequent referencing within the Progress tab (refer to Appendix 1).

### Review Frequency

1. WIReD provides the capability to set the frequency of Inspector Reviews in their oversight of dutyholder progress in resolving the issue, and the frequency of Governance Reviews conducted by the Head of Regulation and management group. These are discussed in more detail below:

#### Inspector Review Frequency

1. A review frequency must be allocated to each Issue when it is raised. In the context of WIReD this is the maximum time period (in months) between formal reviews, conducted by the issue owner, of the licensee’s/dutyholder’s progress in addressing the actions agreed to close out the issue. These reviews are termed Inspector Reviews within the Progress tab and Regulatory issue progress block.
2. The Inspector Review frequency should not normally be longer than three months. However, there may be instances where issues are raised which identify actions that may not be closed out for a significant period of time. In these instances, the appropriate management group has the discretion to approve the setting of a review frequency greater than the three-month limit.

#### Governance Review Frequency

1. The Head of Regulation is accountable for setting a frequency, in months, between their formal review of the licensee’s/dutyholder’s progress in addressing the actions agreed to close out the issue and, to review the activities and decisions undertaken by the individual inspectors or the appropriate management group. Refer to Section 3 for details.

### Directorate and Sub-Directorate

1. The directorate and sub-directorate accountable for oversight of the issue, **must** be entered on creation of the issue.

### Progress

1. The Progress tab provides a record of all activities and decisions associated with the regulatory oversight of the issue. This should be updated on a regular basis, for example following progress review meetings with the dutyholder, following receipt of written updates, or to record decisions made by the management group. These updates must make reference to the relevant Source records (e.g., Intervention Records, Contact Records, Assessment Reports, minutes of meetings) or other correspondence in WIReD or CM9 / SharePoint.
2. The ‘Progress’ tab should also be used to record the reason for changes to the due date, actions list (including changes to target dates) and the ‘Progress RAG Status’ (discussed later in Section 3).
3. The ‘Actions’ pane should not be used for recording progress.
4. If an issue stalls or becomes difficult to manage, the issue owner should bring the issue to the attention of the relevant Head of Regulation as soon as practicable. In this instance, inspectors should adjust the RAG Rating via a progress update and explain the basis and what action is required from the dutyholder, for the benefit of the Head of Regulation’s escalation of the issue.
5. The information provided within the Progress tab provides the audit trail of the management group’s oversight of the regulatory issue which may be called upon in any subsequent investigation or via an FOI request. Consequently, amendments to this data are recorded in the WIReD system’s audit history.
6. The database provides for four types of progress history inputs:

* Discrete activities/updates such as ‘Receipt of Action Plan from ABC’ or an MS Teams call from Y20 Facility Manager’. In these types of instances, the Inspector Review and Governance Review ‘toggles’ would be set to ‘No’ and the inspector would enter their name and any relevant Source record and a brief description relating to the relevance of the document or information received from the dutyholder and their future intent (refer to Appendix 1).
* Inspector Reviews: This is an overall review of the issue by the inspector; the review should include a review of action progress, and should capture feedback from dutyholder engagements, where appropriate, to allow a judgement to be made on the dutyholder’s progress with the issue. If deemed to be insufficient, the inspector should consider changing the RAG rating. The inspector should also consider if the inspector review frequency and issue level remain appropriate. To facilitate an Inspector Review, the toggle should be set to ‘Yes’ (the Name field can be left blank, it will be auto populated in this instance). To complete the inspector review, the three fields; Inspector review frequency adequate, Governance review frequency adequate and Issue level adequate must be completed to release the ‘padlock’ on the Confirm Review Complete switch.
* Governance Reviews: These are the reviews conducted by the Head of Regulation (or delegated Management Review Lead) and can be either ad hoc reviews conducted in direct response to an issue or the formal schedule of sub-directorate board/management group meetings. In these instances, the Governance Review ‘toggle’ would be set to ‘Yes’. Once the details of the review, including any basis for endorsement, has been entered, the review pane provides the capability for the Head of Regulation to either confirm or change the RAG rating, review periodicity, and the Level assigned. To complete a review, the three boxes referred to in the Inspector Review paragraph should be completed. Where appropriate this pane also provides the capability to endorse issues at Level 3 and above in response to:
  + An initial request for endorsement at the proposed level.
  + A request for endorsement to ‘Close’ the issue.
  + A proposal to change the level assigned to an issue.
  + They also have the option to highlight if this review was significant (discussed below).
* Dutyholder updates: These are provided directly by the dutyholder through the dutyholder portal and enables the provision of updates and the setting of the dutyholder RAG rating.

1. The Inspector and Governance Review blocks provide the capability to indicate if a particular entry is ‘significant’. Good practice is to ‘toggle’ a review as significant if any of the following conditions apply:

* The review provides the basis for either closing an action or extending the target date identified against an action.
* The review provides the basis for endorsing an Issue at Level 1 or 2, including escalating an Issue up to Level 1 or 2.
* The review provides the basis for endorsing a proposal to reduce the level assigned to an issue for from either a Level 1 or 2 to a Level 3.
* The review provides the basis for a change in RAG rating from Green to Amber or Amber to Red.
* The review provides the justification and endorsement for closing an issue at Level 3 or above.

1. When completing any reviews, the inspector and governance review team must consider sharing the progress update on the portal (via the toggle switch); the default position should be to share progress, although this is at the discretion of the inspector or the governance review team. WIReD will provide a prompt for this field.

### Document References

1. The entries made on WIReD should provide a complete auditable record of the issue. Issue owners should attach copies of significant correspondence and other relevant information, that report interactions between ONR and the dutyholder, in the Documents tab. Alternatively, CM9 / SharePoint references should be included in the Summary tab as Source of the Issue or Progress tab.

### Basis of Issue Closure

1. To demonstrate a complete auditable record of the management of the regulatory issue from being raised through to closure.
2. Inspectors should ensure that each action is closed out with appropriate evidence referenced, along with the inspector’s judgement on the adequacy of the evidence in the action Close out comment.
3. The basis on which the whole issue has been closed must be recorded in the Closure statement on the Close tab. This entry should be as short as practicable but give sufficient information to enable any other warranted inspector to understand the justification for closing the issue and include reference to any evidence supporting the basis for closure.
4. For issues with one action, the entry in the issue Closure statement is likely to mirror the Close out comment for the action. For issues with more than one action, the Closure statement should be a holistic view of the evidence that has been provided to close out the actions, and hence the issue.

# Issues Management (Governance)

## Progress Review

1. All issues must be regularly reviewed through the appropriate management group’s governance arrangements. The reviews should be conducted in accordance with the responsibilities of the individual management group and apply the management hierarchy set out in paragraph 12. For issues at Level 3 and above, the initial governance review (endorsement of the issue) and subsequent reviews should seek to:

* Agree the issue’s title and scope.
* Agree that the issue has been assigned the right level.
* Advise on the adequacy and appropriateness of the action plan to resolve the issue within a reasonable timescale.
* Ensure inspector reviews are being completed within the frequency agreed and action due dates have not slipped.
* Confirm at appropriate intervals (and at least three monthly) that the issue is being appropriately managed, and that relevant interactions and evidence are being recorded within WIReD.
* Confirm the ONR RAG status.
* Agree to the closure of issues where the action plan has been completed.

1. For issues at Level 3 and above, the initial endorsement governance review RI progress entry will be automatically created but will still need to be completed to formally endorse and open the issue.
2. For Level 4 issues, where formal endorsement is not required, an initial governance review will still have to be conducted and completed in WIReD to confirm review frequencies and start the reminder timers.
3. In addition, Sub-Directorate management groups must have arrangements for monitoring the adequate management of Level 4 issues falling within their remits; it is expected that these reviews are undertaken on an at least a three-monthly basis. Management reviews should understand what L4 issues have been raised and closed in the period and sample the adequacy of the entries.
4. In addition to the regular review of progress by issue owners with dutyholder staff, Heads of Regulation should make arrangements for regular engagement with the dutyholder, at an appropriate level, to review overall performance in progressing and closing regulatory issues.
5. It will be for each management group to decide which protective marking should be applied to their regulatory issues and how these should be recorded. Care should be taken to ensure that the cumulative content of the information does not warrant a higher protective marking for the issue, particularly as information is added during the lifetime of the issue. While the system is capable of holding regulatory issues protectively marked up to OFFICIAL-SENSITIVE: SNI users should, where practicable, minimise the sensitivity of information entered into the system, using oblique language, and referring to more sensitive information held elsewhere. For example, Naval Nuclear Propulsion Plant Information (NNPPI) caveated material **must** **not** be held in WIReD. Further guidance may be found in the NISR 2003 Classification Policy [2].

## Changing the Level Assigned to a Regulatory Issue

1. There may be circumstances where inadequate progress towards closure of an issue reaches a point where greater regulatory attention is warranted (refer to paragraph 12). In such circumstances the relevant inspector or management group may increase the issue Level in order to leverage improvement by raising the visibility of the issue within ONR and the dutyholder organisation. When the level assigned to an issue is raised, the dutyholder must be informed by the relevant enforcement communication commensurate with the new level. Changes to issues levels in WIReD are implemented by inspector/governance reviews in the Progress tab.
2. It is also at the discretion of the relevant management group to lower issue levels. This applies when an issue has been partially resolved (reducing its significance) or where emergent information indicates that the issue is not as significant as first thought. This is particularly relevant to long term significant regulatory issues where the improvement activities undertaken by the dutyholder demonstrate:

* An improved understanding of the technical issues associated with the regulatory issue.
* The dutyholder is demonstrably progressing to a position of improved compliance with the regulatory expectation.
* There is a demonstrable reduction in the risk gap.
* For Level 1 Issues being raised or de-escalated a letter will be sent to the appropriate CEO/MD from either the CNI or Senior Director of Regulation, drafted by the relevant directorate. This will reinforce the significance with which ONR views Level 1 issues. The letter will also give the CNI or Senior Director of Regulation the opportunity to discuss the matter with dutyholder CEOs/MD’s.

1. A commentary to explain changes to the issue Level is to be provided in the WIReD Progress tab.
2. Changes to the Level of regulatory issues may necessitate either additional or a reduction in resource allocation, particularly where issues relate to specialist areas. Such changes should be considered during management reviews and communicated to the respective Head(s) of Profession as soon as possible to ensure adequate and appropriate resources allocation.

## RAG Rating

1. WIReD provides a set of Red/Amber/Green (RAG) ratings to support the management of regulatory issues within ONR. There are three types of RAG ratings used within WIReD:

* Time (automatically assigned)
* Progress - ONR view (manually assigned)
* Progress – Dutyholder view (manually assigned)

### RAG rating – Time

1. WIReD will automatically apply a ‘Time RAG’ rating, which is intended to flag the attention of users that an event due date is approaching or has passed. Events monitored by the Time RAG rating include:

* Action due date(s)
* Inspector Review(progress) due date
* Governance Review due date
* However, Inspectors should note that WIReD’s current coding only triggers a Time RAG Red rating when the final action due date is overdue.

1. The review date is used as an ONR management indicator to confirm that ONR’s oversight of regulatory issues is being conducted in a manner to secure the timely improvement of safety, security and safeguards outcomes. Consequently, the ‘Time RAG’ should not reach Red due to overdue inspector or governance reviews. Where the Time RAG is Red as a result of overdue actions, it is good practice to provide a written note in the Progress tab, explaining the significance of the overdue work and regulatory response.
2. ‘Time RAG’ rating definitions are provided in the WIReD User Guide – Issues [1].

### RAG rating - Progress (ONR and Dutyholder)

1. The ONR RAG indicates how ONR perceive the dutyholder’s performance in addressing the close out of each issue. The issue owner is responsible for allocating an initial RAG rating when first entering data onto WIReD and for updating the RAG rating following each progress review.
2. The Dutyholder RAG provides the means by which the dutyholder can record their own perception of their progress in addressing the satisfactory close out of the issue. This information is recorded in WIReD by inspectors using information supplied by the dutyholder (or via the dutyholder via the portal). Where there is a discrepancy between the ‘ONR and the Dutyholder RAG’ status, the issue should be reviewed and investigated by the Head of Regulation.
3. The RAG ratings should be used by management groups to manage the issue’s progress to closure and to indicate when corrective action or escalation may be necessary. For issues at Level 3 or above, the RAG ratings are to be reviewed and updated at each management group meeting by the issue owner. A commentary to explain changes to RAG ratings is to be provided in WIReD Progress tab.
4. RAG rating definitions are provided at Table 3.

Table 3 - RAG Rating Definitions – Progress [ONR and Dutyholder]

|  |  |
| --- | --- |
| Definition for RAG Ratings | RAG rating |
| **Progressing Satisfactorily**  Issue management and control is adequate, the closure of the Issue is progressing in line with the agreed action plan. | Green |
| **Under Threat**  Weaknesses are observed in the management and control of the Issue. Improvements need to be made to ensure the Issue is closed on time. | Amber |
| **Unsatisfactory**  Issue management and control are inadequate to an extent that the Issue will not (likely) be closed on time. | Red |

# Responsibilities

2. This section provides an overview of the responsibilities associated with the management and oversight of regulatory issues.

## Owner

1. All regulatory issues have a designated inspector as owner. In general, this will be the inspector who identifies and raises the issue: Ownership may be passed to another inspector if they are considered the most appropriate person to oversee the resolution of the issue. For example, an issue raised by a specialist inspector during an assessment or thematic intervention may be owned by the relevant site/project inspector due to their regular interactions on site. The issue owner is responsible for:

* Identifying potential shortfalls during the course of inspections, assessments or other interventions and agreeing the need for some form of remedial or corrective action(s) with the dutyholder.
* Proposing an initial ‘level’ to be assigned to the regulatory issue based on their assessment of the significance of the ‘shortfall’ and the level of oversight within ONR.
* Entering the draft details of issues onto WIReD.
* Agreeing action wording and timescales with the dutyholder.
* Drawing proposed new Level 1, 2 and 3 issues to the attention of the Head of Regulation, for endorsement at the appropriate management group forum (refer to paragraph 12). Level 1 and 2 issues will require a supporting enforcement decision record.
* Agreeing an action plan with the dutyholder that will address the issue within an appropriate timescale [closure date].
* Setting an appropriate due date for the next formal review of progress with the dutyholder.
* Leading discussions with licensees/dutyholders at an appropriate level and frequency to:
  + share information held on WIReD.
  + monitor progress.
  + determine an appropriate ONR RAG rating.
* Obtain dutyholder comments where views on progress differ.
* Ensuring that progress is recorded on WIReD by updating the Progress tab and ensuring that the due dates are managed.
* Recording any change made to the action plan and the justification for that change.
* Reporting progress to Head of Regulation and management groups, making recommendations for escalation/de-escalation as appropriate and updating RID entries if changes are agreed.
* Recommending any additional/reduction in resource for onward communication to the respective Head(s) of Regulation.
* Closing the issue when suitable evidence has been obtained that the shortfall has been satisfactorily addressed (for issues at Level 3 or above, agreement to close the issue will need to be endorsed by the appropriate management group).
* Changing the RI owner in WIReD where responsibility for the RI is transferred to a different inspector.

1. In the case of proposed Level 1, 2 or 3 issues arising from routine inspections, Head of Regulation endorsement is implicit in their sign off of the associated Intervention Record.

## Head of Regulation

1. The Head of Regulation is responsible for:

* Establishing suitable governance arrangements for regulatory issues, including the endorsement of the initial Level proposed by the inspector.
* The oversight of enforcement communications relevant to Level 1-3 issues.
* Overseeing the quality of the data entered into WIReD.
* Communicating with the relevant Head of Profession where additional / a reduction of resource is required in the context of managing a regulatory issue.
* Regularly reviewing due dates and assessing whether sufficient justification has been recorded where action plans have changed.
* Reporting to the SDoR and relevant Director of Regulation on progress with Level 1 and 2 issues.
* Engaging with dutyholders on their performance in closing regulatory issues.
* Ensuring the management of regulatory issues fully aligns with relevant regulatory strategies.

## Head of Profession

1. The Head of Profession is responsible for:

* The timely allocation of specialist resource against Directorate demand in order to effectively manage the issue.
* Tier 1 oversight to ensure consistent application of regulatory judgements across regulatory Directorates.

## Director of Regulation

1. The Director of Regulation is responsible for:

* Ensuring the right level of oversight is maintained by Head of Regulation and management groups.
* Overseeing the management of Level 1 and 2 issues and reviewing the regulatory response proposed by Head of Regulations and management groups.
* Contributing to RLT’s oversight of Level 1 issues (including those owned by other Directorates) and advising the CNI.

## Senior Director of Regulation

1. The Senior Director of Regulation is responsible for overseeing the management of Level 1 issues at RLT meetings.

## Directorate Delivery Support (DDS)

1. Where there is such a role within a directorate, DDS teams are able to provide support with some of the administration associated with WIReD (e.g., supporting issues governance meetings). This will vary between directorates and should be agreed.

## Process Owner

1. The process owner is responsible for periodic audit and review of the health of implementation of this procedure across Regulatory Directorate.

## Dutyholder

1. The dutyholder is accountable for completing the actions required to close out a regulatory issue within the agreed timescale.
2. Inspectors should satisfy themselves that the dutyholder has the necessary arrangements and resources in place to progress regulatory issues and that they receive the necessary management oversight commensurate to the level assigned.

# 

# Appendix 1: WIReD Data Entries – Examples of Accepted Practice

Below are a series of examples of what represents acceptable and unacceptable practice for recording data within the followings ‘fields’ in WIReD:

**Name**:

Acceptable:

Corporate arrangements for the examination, inspection, maintenance and testing of safety systems do not meet the requirements of LC28(1).

Legionella risk posed by the Y15 Cooling Tower.

No documented process for the conduct of Security Vulnerability Assessments.

Integrity of spreadsheets used to calculate data used at physical inventory takes (PITs) is compromised / cannot be assured.

Unacceptable:

Fire Dampers.

LLETP.

**Issue**:

Acceptable:

During an SBI conducted on 6 Aug 24, it was identified that the site has significant stocks of reject fuel and components with no route for their disposal.

ABC must address the issue of not having 24/7 monitoring of the network that is capable of initiating an appropriate response to meet the expectations of CPS Outcome 3 or otherwise justify their approach.

A routine inspection of operational records conducted on 7 Apr 24 identified that the quality of records did not meet the requirements of LC25(1). Specifically records inspected exhibited missing signatures, missing data entries and data entries crossed out and overwritten without supporting annotation or signature.

Unacceptable:

The condition of the crane has been identified to be in need of refurbishment.

**Actions**:

Acceptable:

|  |  |
| --- | --- |
| Name: | Action 1- ABC to provide ONR with a Nuclear Baseline Document consistent with RGP |
| Due Date: | 13/5/2025 |
| Action Detail: | ABC to provide ONR with a Nuclear Baseline Document, consistent with RGP (NS-TAST-GD-065 Principle 9) and the minutes from the associated NSC Meeting at which the document was submitted for consideration. |
| Name: | Action 2 - Update Asbestos management arrangements |
| RI Action | ABC to review and update their asbestos management arrangements |
| Due Date: | 30/3/2025 |
| Action Detail: | ABC to review and update their asbestos management arrangements to meet legislative/ACOP requirements by 30 Mar 25. |

|  |  |
| --- | --- |
| Name: | Action 1: ABC to provide a plan with delivery schedule |
| Due Date: | 15/09/2023 |
| Action Detail: | ABC must produce a plan with delivery schedule to ONR by 1 August 2023 as to how they are going to address the shortfall relating to the lack of network segmentation. |
| Name: | Action 2 – Implementation of network segmentation plan. |
| Due Date: | 10/01/2025 |
| Action Detail: | ABC are to address shortfalls and deliver against the agreed action plan and details as set out in the email dated 9 November 2023 [refer to WIReD documents tab of this issue]. ABC must produce by 10 January 2025 an independent assurance report to confirm the network segmentation shortfalls have been addressed. |

Unacceptable:

|  |  |
| --- | --- |
| Name: | External hazards |
| RI Action | ABC to improve arrangements |
| Due Date: | [BLANK] |
| Action Detail: | ABC should improve their arrangements for considering external hazards in safety submissions. |

Acknowledging that the dutyholder will require time to develop an Action Plan, good practice is to set an initial action to ‘Provide Action Plan to ONR by ….’

**Closure Statement**:

Acceptable:

ABC has implemented appropriate improvements to address the shortfalls covered by this issue. The ONR carried out an inspection on 27 Mar 24 and concluded that each of the ten agreed actions had been adequately addressed.

The DDD DMG agreed to close this issue on 25 Apr 24 [refer to WIReD document tab for minutes of meeting].

ABC have performed an extent of condition review and identified four MBAs use spreadsheets for making calculations on data used for physical inventory takes (PIT) reporting activities. As the facilities are moving into post operational clean out, I agreed that it was proportionate for them to be reviewed at the time of the PIT [refer to WIReD documents tab of this issue].

Unacceptable:

The dutyholder has now confirmed work is complete and this can now be closed.

**Progress:**

Acceptable:

|  |  |  |  |
| --- | --- | --- | --- |
| Name: | Receipt of Action Plan | Inspector Review: | No |
| From: | Dutyholder |  |  |
| Date: | 25/6/2024 |  |  |
| Source: | ABC’s Letter ONR/24/1224N [CM9 Ref: 2024/45987] | | |
| Progress Update: | Action plan received under covering letter ONR/24/1224N dated 25 Jun 24 in response to Action 1. This will be reviewed and formally agreed at the L3 RIM scheduled for 2 Jul 24. | | |
| RAG Status: | Green | Significant: | No |

|  |  |  |  |
| --- | --- | --- | --- |
| Name: | [Automatically populated on saving] | Inspector Review: | Yes |
| From: | ONR |  |  |
| Date: | 28/08/2024 |  |  |
| Source: | Call with Duty Holder | | |
| Progress Update: | ABC preparing a set of standards for the production of LIIs for sharing with all facilities as part of their toolbox talks (not just the facilities that have formulas in the LII spreadsheet). This was not identified as an action in the initial discussions, I consider it to be an improvement. An additional action has been included to cover this activity (Action 3).  An action will remain on ABC to provide evidence that the formulas within the spreadsheets used to calculate declared values in the MBAs have been protected (or an additional peer check has been introduced) to ensure the data is not overtyped.  Evidence to close the action will be demonstration of the protection/checks that have been put in place for the spreadsheets as used to produce the 2024 PIL and MBR.  ABC will review the spreadsheets just prior to the PITs so a due date of 20 December has been identified for this action, however this will be monitored and updated as required. | | |
| RAG Status: | Green | Significant: | No |

|  |  |  |  |
| --- | --- | --- | --- |
| Name: | [Automatically populated on saving] | Inspector Review: | Yes |
| From: | ONR |  |  |
| Date: | 12/4/2024 |  |  |
| Source: | ONR-DDD-CR-24-032 [CM9:2024/24365] | | |
| Progress Update: | L3 meeting with the Operations Director and Materials Disposition Project Manager to discuss permissioning of the commencement of ‘Material’ processing within the Z21 Facility as part of the Material Consolidation Programme. To date ABC has yet to adequately address the technical queries raised following ONR’s assessment of ABC’s safety justification document Z21-SJ-20-003 Issue 5, as agreed at Actions 3 and 4 of this issue. Specifically, ONR considers that Technical Note 11-18-C dated 27 Mar 21 submitted in response to Actions 3 and 4 stills fails to adequately address the criticality hazard associated with HEU Liquor transfer and the radiological dose uptake to operators [as detailed in Email: ONR to ABC of 7 Apr 24 (Uploaded to MS SharePoint). It was agreed that a further meeting between the Project Team and ONR’s RP Specialist Inspector be arranged for the w/c 24 Apr 24 to clarify ONR’s expectations.  Consequently, it was agreed that Actions 3 and 4 remain overdue and that progress in addressing this issue be rated as Amber. | | |
| RAG Status: | Amber | Significant: | Yes |

|  |  |  |  |
| --- | --- | --- | --- |
| Name: | Endorsement for Closure | Governance Review: | Yes |
| From: | ONR |  |  |
| Date: | 2/3/2024 |  |  |
| Source: | DDD Management Group Meeting of 2 Mar 24 | | |
| Progress Update: | Basis for closure submitted for endorsement under Agenda Item 9.  I consider that the detailed justification provided within ‘Note for the Record’ CM9 Reference: 2024/82716 provides an adequate basis for closure.  Decision: The proposal to close RI-10321 is endorsed. | | |
| RAG Status: | Green | Significant: | Yes |

Unacceptable:

|  |  |  |  |
| --- | --- | --- | --- |
| Name: | [BLANK] | Inspector Review: | No |
| From: | ONR |  |  |
| Date: | 13/11/2024 |  |  |
| Source: | IR-53056 | | |
| Progress Update: | Refer to Intervention Record. | | |
| RAG Status: | Green | Significant: | No |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name: | [Automatically populated on saving] | Governance Review: | | Yes |
| From: | ONR | |  |  |
| Date: | 2/5/24 | |  |  |
| Source: | [BLANK] | | | |
| Progress Update: | Endorsed. | | | |
| RAG Status: | Green | | Significant: | No |

# Appendix 2: WIReD Data Entries – Examples of Accepted Practice for Transport Competent Authority issues

Below is an example of what represents acceptable practice for recording data within the Transport issues ‘fields’ in WIReD:

**Title:** ABC - Transport compliance inspection

**Issue:** Following a transport inspection, several non-compliances were recorded, further information can be found in IR-51835

**Actions:**

|  |  |
| --- | --- |
| Title:  Owner:  Due Date:  Detail: | Radiation Risk Assessment - IRR17 Regulation 8  Dutyholder  30/12/2022  ABC should further revise their transport RRA to address the following issues:  Section 70(b) – ABC should confirm doses of drivers with all their carriers as well as the total dose to ABC shipping operators. Section 70(f) – Not all engineered control measures which are used by ABC were mentioned (e.g. trolleys). Section 70(k) – Information relating to breakage of vials during the transport process should be included within this section due to recent incidents that have occurred. Section 71(j) – ABC should provide information of the designated areas within the ABC facility within the RRA which relate to transport operations. ABC transport RRA should be the higher tier document that informs the content of lower tier documents and only refers out to specifically referenced procedures where applicable. There are instances where some information, for instance dose investigation level (section 71(f))) and engineering arrangements (Section 70(f)) are included in lower tier documents but not the RRA. |
| Title:  Owner:  Due Date:  Detail: | Transport Package Certificate of Compliance – ADR 5.1.5.2.3  Dutyholder  31/03/2023  ABC to confirm the current type A packages are still compliant with IAEA standards, and if not find a suitable type A package replacement. |

|  |  |
| --- | --- |
| Title:  Owner:  Due Date:  Detail: | DGSA Report – ADR 1.8.3  Dutyholder  30/12/2022  From reviewing the report, I informed ABC that the DGSA Report was incorrect for certain aspects (incidents reported to ONR in accordance with ADR 1.8.5 and CDG Regulation 24 &amp; Schedule 2 as well as any non-compliance with the applicable radiation and contamination limits occurred during the reporting period to comply to ADR 1.7.6.)  I advised that the DGSA report be amended to take in the above aspects or be covered within the next DGSA report. |

# Appendix 3: Regulatory Issues Level Guidance Chart

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Issue Level | ONR Oversight[[1]](#footnote-2) (Governance) | EMM Expectation (refer to [2]) | Operational Impact | Inspection/ Assessment Rating (refer to [4] and [5] respectively) | Potential to undermine ONR’s Strategic Objectives |
|
| 1 | Chief Nuclear Inspector and/or Senior Director of Regulation and (Regulatory Leadership Team) | Improvement Notice, Direction, Specification or Enforcement Notice | Potential cessation of operations  Direction to cease Construction | Red  (Demand Improvement) | Major threat  Failure of the UK to meet international safeguard’s obligations that provide a basis for possible escalation or formal sanction by IAEA and/or NCA partners |
| 2 | Director of Regulation  (Directorate Board) | Improvement Notice, Direction, Specification or Enforcement Notice  Enforcement Letter | Withholding of a Permission | Red  (Demand Improvement) | Moderate threat |
| 3 | Head of Regulation  (Sub-Directorate Board/ Management group) | Enforcement Letter  Regulatory Advice | Minor restrictions on operations | Amber  (Seek Improvement) | Minor threat |
| 4 | Inspector | Regulatory Advice | N/A | Green  (Minor shortfall(s) identified) | Negligible threat |

# References

[1] ONR-WIR-GD-003: WIReD User Guide - Issues.

[2] ONR-CNSS-POL-001: The Nuclear Industries Security Regulations 2003: Classification Policy for the Civil Nuclear Industry.

[3] ONR-ENF-GD-006: Enforcement.

[4] ONR-INSP-GD-064: General Inspection Guide.

[5] ONR-TAST-GD-096: Guidance on Mechanics of Assessment.

1. Heads of Profession may be consulted at any level to provide specialist advice and guidance on issues relating to their area of specialism. [↑](#footnote-ref-2)