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| ONR Procedure  Management of Regulatory Issues |



ONR Procedure

Management of Regulatory Issues

**Process Owner**: Technical Division Director

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**Approved by**: Professional Lead – Operational Inspection

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Table - Revision commentary

|  |  |
| --- | --- |
| 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. |

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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, part ONR’s WIReD application 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 process, to be adhered to consistently by all ONR inspectors, irrespective of function or specialism.

## Definitions

Table – 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) * Divisional Board * Sub-Division Board * Delivery Management Group * Intervention Management Group * Issues Review Group |
| Regulatory Issue | Any safety or security matter 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 ‘security’ refers to all matters related to Civil Nuclear Security and all matters related to Safeguards. |

# Management of Regulatory Issues within ONR

1. A regulatory issue can arise at any point during a regulatory activity be it site inspection, permissioning or conducting a formal technical assessment. It is important to note that the identified safety, security or Safeguard’s shortfall is the licensee/duty holder’s responsibility to address: It is important that, in discussions concerning the raising of a regulatory issue, the duty-holder understands the nature of the shortfall in the context of the regulatory expectation and, 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 the RID, a component of ONR’s WIReD application. This includes routine issues identified and managed by ONR inspectors, through to high level strategic issues that may have long resolution timescales.
3. Information entered into the RID, by ONR staff should provide a full auditable trail of the issue; this includes the actions placed on licensees/duty holders, reference to any associated enforcement, reference to all relevant correspondence, monitoring of progress including a history of all interactions between ONR and the duty-holder relating to the resolution of this issue (including key decisions and agreements) and the basis for closure. It is important to appreciate that WIReD is ONR’s principal knowledge management mechanism and each Issue should be cross referenced (sign-posted) to source documentation held within either within WIReD or CM9.
4. The RID provides assurance to the ONR Board, the Senior Leadership Team (SLT) and Regulatory Leadership Team (RLT) that ONR is effectively managing and tracking its regulatory issues and any associated enforcement actions to satisfactory closure. ONR’s

## Issue Level

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

* To indicate its safety or security significance.
* To assign an appropriate level of management scrutiny.

1. The level assigned also reflects the level of oversight ONR expects the issue to receive within the licensee’s/duty holder’s organisation.
2. The following guidance is provided to promote consistency of approach across ONR irrespective of specialism or function. 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 the RID.

### 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 the Executive Director of Operations (EDO) and Regulatory Leadership Team (RLT). Examples include:

* The potential cessation of licensee/duty holder operations.
* 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 the EDO but nonetheless merit oversight by the relevant Divisional Director. 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 Delivery Lead. This would apply to ‘routine’ compliance shortfalls resulting in an inspection/assessment rating of ‘Amber’ (Seek Improvement). Level 3 Issues would ordinarily require an enforcement communication to be sent to the duty-holder.

**Level 4**: This level applies to those matters identified by inspectors that do not merit proactive management by the Delivery Lead. Typically, these are matters arising from ONR interventions that have attracted an ONR inspection/ assessment rating of Green (No Formal Action) but where minor shortfalls/ improvements have been identified. Level 4 issues do not require an 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. This level assigned to a regulatory issue may be increased (escalated) or reduced (de-escalated) at the discretion of the appropriate management group to reflect licensee/ duty holder performance in addressing the issue. This is discussed in more detail under ‘Issues Management (Governance)’ at Section 3.

## Recording Information on the RID

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 RID ‘data fields’ (tabs) should be met (examples of accepted practice and unacceptable practice are provided at Appendix 1).

### 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 the RID.
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 duty holders progress in responding to the issue **must** be selected. This system will default to the person raising the entry in the RID. ’s name from the drop-down list.

### Duty-holder and Site

1. A duty-holder **must** be assigned for each issue from the drop-down menu provided. A site should be selected were relevant.

### Issue

1. The ‘Issue’ entry should be kept as short as practicable but provide sufficient information to enable the licensee/duty holder 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 either CM9 or MS SharePoint.

### 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. It is important to discuss any corrective actions and their timetable with the licensee/ duty holder to ensure that they are appropriate and achievable. It is also important to gain assurance of the licensee’s/duty holder’s commitment to address the actions agreed and to ensure they understand the regulatory implications should they fail to be progressed adequately.
3. Actions arising from a Level 1, 2 or 3 regulatory issues should be confirmed in writing via the appropriate ‘Enforcement communication’ (letter or email).
4. It is permissible to modify or refine the specified actions and/or their associated dates in the RID in light of changing circumstances. In these instances, the issue owner **must** ensure that a record is made within the ‘Progress History’ tab providing the justification for any changes.
5. To meet the SMART requirement, actions **must** meet the following criteria:

* **Specific**: The actions must specify the activity that the licensee/duty holder 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 licensee/duty holder must be proportionate to the significance of the issue with regards scope and timescales and, within the capability of the licensee/duty holder to reasonably deliver.
* **Relevant**: The actions must contribute directly to closing the issue and result in the licensee/duty holder achieving the required standards of safety and security [address 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 recommended to assign a numeric label to the Action within the ‘Name’ field to support subsequent referencing within the Progress pane   
   (refer to Appendix 1).
2. The Actions pane within WIReD also provides for actions to be raised against ONR. Any such actions should only be raised where a duty-holder’s ability to deliver the required improvement activities to the timescales agreed is predicated on ONR meeting an agreed commitment, in response to a duty-holder’s deliverable, within a specified timeframe. In addition, the placing of an action against ONR to support the duty-holder’s action plan requires Delivery Lead or Professional Lead approval. This should be recorded as an entry in the Governance Review panel to indicate that the allocation of the required resource has been considered and approved.
3. The Issues database, specifically the Action pane, can also be used to capture findings from assessments as part of a longer term/strategic programme of regulatory oversight and permissioning. This may include actions on ONR to ensure that duty-holders address, in future deliverables, the areas of regulatory interest as part of their comprehensive submission. This approach must be approved by the Delivery Lead who will set an appropriate review periodicity commensurate with the nature of the ‘issue’. Appendix 2 provides specific guidance in this area.

### Review Frequency

1. The Issues database provides the capability to set the frequency of reviews conducted by the inspector in their oversight of duty-holder progress in resolving the issue, and the frequency of ‘governance’ reviews conducted by the Delivery Lead. 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 the RID this is the maximum time period (in months) between formal reviews, conducted by the issue owner, of the licensee’s/duty holder’s progress in addressing the actions agreed to close out the issue.   
   These reviews are termed ‘inspector reviews’ within the WIReD progress history tab.
2. The inspector review frequency should not normally be longer than six 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 due date for review at a periodicity greater than the six months limit.

#### Governance Review Frequency

1. The Delivery Lead is accountable for setting a periodicity, in months, between their formal review of the licensee’s/duty-holder’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.

### Division and Sub-division

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

### Progress History

1. The ‘Progress History’ 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 licensee/duty holder, following receipt of written updates, or to record decisions made by the management group. These updates must make reference to the relevant records (e.g., Intervention Records, Contact Records, Assessment Reports, minutes of meetings) or other correspondence held on WIReD or CM9.
2. The ‘Progress History’ 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 at paragraphs 59 to 62).
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 Delivery Lead as soon as practicable.
5. The information provided within the ‘Progress History’ Tab provides the audit trail of ONR’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 systems ‘audit history.
6. The database provides for three types of progress history inputs:

* Discrete activities 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 the relevant reference and details of the document or information received from the duty holder and their future intent (refer to Appendix 1).
* Inspector Reviews: These generally cover any formal inspection activity undertaken by the inspector, including an inspection, assessment or review meeting with site. In these instances, the Inspector Review ‘toggle’ would be set to ‘Yes’. Once the details of the review have been entered, the review pane provides the capability for the inspector to either confirm or change the RAG status [Progress], review periodicity, and the Level assigned. They also have the option to highlight if this review was significant [discussed below].
* Governance Reviews: These are the reviews conducted by the Delivery Lead (or delegated DMG Lead) and can be either ad hoc reviews conducted in direct response to an issue or the formal schedule of sub-division 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 Delivery Lead to either confirm or change the RAG status [Progress], review periodicity, and the Level assigned. 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].

1. The Inspector and Governance Review panes provided 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 Status from Green to Amber or Amber to Red.
* The review provides the justification and endorsement for closing an issue at Level 3 or above.

### Document References

1. The entries made on the RID should provide a complete auditable record of the issue. Issue owners should attach copies of significant correspondence and other relevant information, such as IRs and CRs that report interactions between ONR and the licensee/duty holder, in the Documents tab. Alternatively, CM9 references should be included in the “Source of the issue” panel or Progress History

### Basis of Issue Closure

1. To demonstrate a complete auditable record of the management of the regulatory issue from being raised through to closure, the basis against which the issue has been closed must be recorded in the Closure Statement panel.
2. 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.

# 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 11. For issues at Level 3 and above, the 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.
* Confirm at appropriate intervals (and at least six monthly) that the issue is being appropriately managed, and that relevant interactions and evidence are being recorded within the RID.
* Confirm the ‘ONR Progress RAG’ Status.
* Agree to the closure of issues where the action plan has been completed.

1. In addition, Sub-Divisional 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 six-monthly basis.
2. In addition to the regular review of progress by issue owners with licensee/duty holder staff, Delivery Leads should make arrangements for regular engagement with the licensee/duty holder, at an appropriate level, to review overall performance in progressing and closing regulatory issues.
3. It will be for each management group to decide which protective security 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 security 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.
4. Naval Nuclear Propulsion Plant Information (NPPI) caveated material   
   **must** **not** to be held on the RID.

## Changing the Level Assigned to a Regulatory Issue

1. There may be circumstances where slippage in progress towards closure of an issue reaches a point where greater regulatory attention is warranted (refer to paragraph 13). In such circumstances the relevant management group may increase the ‘Issue Level’ in order to leverage improvement by raising the visibility of the issue within ONR and the licensee/duty holder organisation. When the level assigned to an issue is raised, the licensee/duty holder must be informed by the relevant enforcement communication commensurate with new level.
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 or where emergent information indicates that the issue is not as important as first thought. This is particularly relevant to long term significant safety issues where the improvement activities undertaken by the licensee/duty holder demonstrate:

* An improved understanding of the technical issues associated with the regulatory issue.
* The licensee/duty holder is demonstrably progressing to a position of improved compliance with the regulatory expectation.
* There is a demonstrable reduction in the risk gap.

1. A commentary to explain changes to the ‘Issue Level’ is to be provided in the RID ‘Progress History.’

## RAG Indicators

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

* Time (automatically assigned)
* Progress - ONR view (manually assigned)
* Progress – Licensee/Duty holder view (manually assigned)

### RAG Indicator – Time

1. The RID will automatically apply a ‘Time RAG’ status, 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 indicator include:

* Action due date
* Inspector [progress] review due date
* Governance review due

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 and security 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 history, explaining the significance of the overdue work and regulatory response.
2. ‘Time RAG’ status definitions are provided in the WIReD Issues Process Manual [1].

### RAG Indicators - Progress (ONR and Licensee/Duty holder)

1. The ‘ONR Progress RAG’ indicates how ONR perceive the licensee’s/duty holder’s performance in addressing the close out of each issue. The issue owner is responsible for allocating an initial RAG status when first entering data onto the RID and for updating the RAG status following each progress review.
2. The ‘Licensee/Duty holder RAG’ provides the means by which the licensee/duty holder can record their own perception of their progress in addressing the satisfactory close out of the issue. This information is recorded in the RID by ONR using information supplied by the licensee/duty holder. Where there is a discrepancy between the ‘ONR and the Licensee/Duty holder RAG’ status, the issue should be reviewed and investigated by the Delivery Lead.
3. ‘The Progress RAG’ indicators 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 indicators are to be reviewed and updated at each management group meeting by the issue owner. A commentary to explain changes to RAG indicators is to be provided in the RID ‘Progress History’ tab.
4. ‘Progress RAG’ status definitions are provided at Table 2.

Table - RAG Status Definitions – Progress [ONR and Licensee/Duty Holder]

|  |  |
| --- | --- |
| Definition for RAG Status | RAG Status |
| **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 may be owned by the relevant project inspector due to their regular interactions on site. The issue owner is responsible for:

* Identifying potential issues during the course of inspections, assessments or other interventions and agreeing the need for some form of remedial or corrective action(s) with the licensee/duty holder.
* 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 details of issues raised onto the RID.
* Drawing proposed new Level 1, 2 and 3 issues to the attention of the Delivery Lead, for endorsement at the appropriate management group forum (refer to paragraph 65).
* Agreeing an action plan with the licensee/duty holder 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 licensee/ duty holder.
* Lead discussions with licensees/duty holders at an appropriate level and frequency to:
  + share information held on the RID.
  + monitor progress.
  + determine an appropriate ONR RAG status progress indicator.
* obtain licensee/duty holder comments where views on progress differ.
* Ensuring that progress is recorded on the RID by updating the ‘progress history’ tab issue progress statement and ensuring that the due date is managed.
* Recording any change made to the action plan and the justification for that change.
* Reporting progress to Delivery Leads/DMGs, making recommendations for escalation/de-escalation as appropriate and updating RID entries if changes are agreed.
* Closing the issue when suitable evidence has been obtained that the issue 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].

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

## Delivery Lead

1. The Delivery Lead 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 the RID.
* Regularly reviewing due dates and assessing whether sufficient justification has been recorded where action plans have changed.
* Reporting to the Divisional Director on progress with Level 1 and 2 issues.
* Engaging with licensee/duty holders on their performance in closing regulatory issues.
* Ensuring the management of regulatory issues fully aligns with relevant regulatory strategies.

## Divisional Director

1. The Divisional Director is responsible for:

* Ensuring the right level of oversight is maintained by Delivery Leads/DMGs.
* Overseeing the management of Level 1 and 2 issues and reviewing the regulatory response proposed by Delivery Leads/DMGs.
* Contributing to RLT’s oversight of Level 1 issues (including those owned by other Divisions) and advising the CNI.

## Executive Director of Operations (EDO)

1. The EDO is responsible for overseeing the management of Level 1 issues at RLT meetings.

## Divisional Delivery Support (DDS)

1. Where there is such a role within a Division: DDS teams are responsible for the day-to-day administration of the database including:

* Transfer issues between inspectors (provided both the inspectors consent).
* Entry of duty holder process updated into the RID.
* Provide statistical information and graphical output for senior management and Governance meetings.
* Maintenance of sub-division specific maser data.
* Engagement with WIReD System Administrators to request creation and deletion of user accounts; access rights; reopening of erroneously closed issues; deactivation of erroneously created issues.
* Maintenance of Divisional issues data quality.

## Process Owner

1. The process owner is responsible for periodic audit and review of the health of implementation of this procedure across Regulatory Directorate.   
   The process owner is also responsible for ensuring the RID software configuration continues to reflect business needs, approaching ITDD to initiate amendments to the system as required.

## Licensee/Duty Holder

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

# Database Access

1. The Regulatory Issues Database (RID) can be accessed from the WIReD Landing Page.
2. ONR staff should contact their Divisional Delivery Support (DDS) to have an account created. The account will be activated following completion of self-directed training. The process for enrolling on this training will be advised by DDS.

# 

# Appendix 1: RID 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 the RID:

**Name**:

Acceptable:

Shortfalls in corporate arrangements for the engineering substantiation of EC&I based safety systems.

Legionella risk posed by the Y15 Cooling Tower.

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

No documented process for the conduct of Security Vulnerability Assessments.

Unacceptable:

Fire Dampers.

LLETP.

**Issue**:

Acceptable:

During an SBI conducted on 6 Aug 20, it was identified that the site has significant stocks of reject fuel and components with no route for their disposal [ONR-DDD-IR-20-321 refers].

A routine inspection of operational records conducted on 7 Apr 20 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 [ONR-DDD-20-123 refers].

Unacceptable:

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

**Action**:

Acceptable:

|  |  |
| --- | --- |
| Name: | Revise nuclear baseline |
| Due Date: | 13/5/2020 |
| 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: | Update asbestos management arrangements |
| Due Date: | 30/3/2020 |
| Action Detail: | ABC to review and update their asbestos management arrangements to meet legislative/ACOP requirements by 30 Mar 20. |

Unacceptable:

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

No Actions identified.

Acknowledging that the duty holder 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 20 and concluded that each of the ten agreed actions had been adequately addressed [ONR-DDD-IR-20-101 refers].

The DDD DMG agreed to close this issue on 25 Apr 20 [refer to WIReD document tab for minutes of meeting].

Unacceptable:

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

Following completion of Action 5.

**Progress Statement**

Example of an acceptable series of ‘progress’ entries:

|  |  |  |  |
| --- | --- | --- | --- |
| Name: | Receipt of Action Plan | Inspector Review: | No |
| From: | Dutyholder |  |  |
| Date: | 25/6/2020 |  |  |
| Source: | ABC’s Letter ONR/21/1224N [CM9 Ref: 2020/345987] | | |
| Progress Update: | Action plan received under covering letter ONR/21/1224N dated 25 Jun 20 in response to Action 1. This will be reviewed and formally agreed at the L3 RIM scheduled for 2 Jul 21. | | |
| RAG Status: | Green | Significant: | No |

|  |  |  |  |
| --- | --- | --- | --- |
| Name: | Formal Quarterly Review of Progress | Inspector Review: | Yes |
| From: | ONR |  |  |
| Date: | 11/7/2019 |  |  |
| Source: | ONR-DDD-IR-19-111 [CM9 Ref: 2019/635721] | | |
| Progress Update: | Formal review of progress carried out on 11 Jul 19 with the Head of Maintenance and Engineering Support [ONR-DDD-IR-19-111 refers]. I reviewed the outcomes of an independent internal audit conducted in May 19. This identified that there has been an improvement in the number of satisfactory work orders from 80.9% in Jan 19 to 85.4% in May 19 however the overall evaluation from the internal audit remains at 'Seek Improvement'. Overall, I am satisfied that ABC remains on track to close out this regulatory issue during the LC28 inspection scheduled for Dec 19. | | |
| RAG Status: | Green | Significant: | No |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name: | Endorsement at Level 3 | Governance Review: | | Yes |
| From: | ONR |  | |  |
| Date: | 15/9/2020 |  | |  |
| Source: | ONR-DDD-IR-20-471 [CM9 Ref: 2020/529472 | | | |
| Progress Update: | Issue reviewed and endorsed on approval of ONR-DDD-20-471. | | | |
| RAG Status: | Green | Significant: | | No |
| Name: | L3 RIM | | Inspector Review: | Yes |
| From: | ONR | |  |  |
| Date: | 12/4/2021 | |  |  |
| Source: | ONR-DDD-CR-21-032 [CM9:2021/24365] | | | |
| 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 21 (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 21 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: | 2/3/2021 |  |  |
| Source: | DDD Management Group Meeting of 2 Mar 21 | | |
| 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: 2021/382716 provides an adequate basis for closure.  Decision: The proposal to close Issue 3287 is endorsed. | | |
| RAG Status: | Green | Significant: | Yes |

Examples of unacceptable ‘progress’ entries:

|  |  |  |  |
| --- | --- | --- | --- |
| Name: | [BLANK] | Inspector Review: | Yes |
| From: | ONR |  |  |
| Date: | 13/11/2020 |  |  |
| Source: | ONR-DDD-IR-20-386 | | |
| Progress Update: | Refer to Intervention Record. | | |
| RAG Status: | Green | Significant: | No |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name: | [BLANK] | Governance Review: | | Yes |
| From: | ONR | |  |  |
| Date: | 2/5/21 | |  |  |
| Source: | [BLANK] | | | |
| Progress Update: | Endorsed. | | | |
| RAG Status: | Green | | Significant: | No |

# Appendix 2: Guidelines for the Use of the RID to Capture and Manage Regulatory Findings

In certain circumstances, the RID can be used to capture and manage regulatory findings arising from assessments undertaken in support of long term or strategic level programmes of work. In these instances, inspectors are to gain approval from their Delivery Lead who will ensure that this approach is in accordance with their regulatory oversight and permissioning strategy for that programme.

Where the use of the RID to record and manage regulatory findings has been approved, the following guidelines apply:

**General Principle**:

As a general principle, an issue raised to address long term/strategic findings from an assessment activity follows the same principles as any issue raised against a shortfall in regulatory expectation. As such, the guidance in Sections 2.1, 2.2, 3 and Appendix 1 of this document apply with the following additional considerations:

**Issue Name**:

This should capture the nature of the findings in a manner that makes it unique and readily identifiable from other issues raised to cover regulatory findings. Suggestions include:

Chemical Engineering Assessment of ABC-Z12-21-003.

Explosives withstand of the ABC Y21 Facility.

**Issue:**

This should capture succinctly the source and nature (and where appropriate, the timescales) of the findings covered by this entry within the database. An example would be:

The Chemical Engineering assessment of ABC-Z12-21-003, covering the safety justification supporting the design and proposed operation for the recovery and re-processing of the ‘Out of Tolerance’ HEU Fuel elements within the new Z12 Processing Facility, has identified a number of regulatory findings [refer to Actions] that will need to be addressed by ABC prior to commencement of the construction of this facility. Construction is currently not scheduled to commence until May 2025.

**Actions:**

The findings from the assessment should be captured as a series of individual ‘actions’ following the guidance provided in Section 2.2. Acknowledging the nature of the programme of work to which these findings [actions] relate, the target dates must be set with due consideration of the duty-holder’s programme and the regulatory oversight and permissioning strategy approved by the Delivery Lead. It is also acknowledged that the nature of these findings [actions] may require actions to be placed on ONR to ensure that the duty-holder’s accountability to address findings in a timely manner is not unduly impacted by delays in ONR’s supporting activities.   
As discussed in Section 2.2, any action placed on ONR must be approved by the Delivery Lead.

An example is provided below as guidance.

|  |  |
| --- | --- |
| Name: | Criticality Safety Double Contingency |
| Due Date: | 30/2/2024 |
| Action Detail: | The PCSR supporting Phase 3 [Process Equipment] to demonstrate the RGP and expectations of ONR SAP ECR2 within the automated process line for the processing of the out of tolerance Odin Reactor HEU fuel elements. |

**Review Frequency/Governance:**

The principles within Sections 2.2 and 3 of this document apply acknowledging that the periodicity of both Inspector and Governance Reviews may fall out with the recommended three-month period. Where review periodicities extend beyond six months, Delivery Lead approval is required, and a periodicity set commensurate with the timescales associated with the duty-holder’s programme and the agreed regulatory oversight and permissioning strategy.

**Findings Becoming Issues:**

Individual findings should be ‘marked as superseded’ and a new specific regulatory raised when, in the opinion of the inspector and the Delivery Lead, that finding now represents a clear shortfall in regulatory expectation with the potential to impact the lifting of a permissioning hold-point or meeting a clearly defined regulatory requirement.

# Appendix 3: Regulatory Issues Level Guidance Chart

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Issue Level | ONR Oversight [Governance] | EMM Expectation (refer to [2]) | Operational Impact | Inspection/ Assessment Rating (refer to [3] and [4] respectively) | Potential impact on ONR’s Reputation |
|
| 1 | Chief Nuclear Inspector  [Regulatory Management 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 | Divisional Director  [Divisional Board] | Improvement Notice, Direction, Specification or Enforcement Notice  Enforcement Letter | Withholding of a Permission | Red  [Demand Improvement] | Moderate threat |
| 3 | Delivery Lead  [Sub-Division Board/ DMG] | Enforcement Letter  Regulatory Advice | Minor restrictions on operations | Amber  [Seek Improvement] | Minor threat |
| 4 | Inspector | Regulatory Advice | N/A | Green  [Minor shortcomings identified] | Negligible threat |

# References

|  |  |
| --- | --- |
| [1] | ONR, “ONR-WIR-GD-003: WIReD Process Manual”. |
| [2] | ONR, “ONR-ENF-GD-006: Enforcement”. |
| [3] | ONR, “ONR-INSP-GD-064: General Inspection Guide”. |
| [4] | ONR, “ONR-TAST-GD-096: Guidance on Mechanics of Assessment”. |