



Office for
Nuclear Regulation

ONR Guidance Document

ONR-INSP-GD-059: Guidance for Inspection Strategy Planning and Recording

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Authored by – Operational Safety Inspector

Approved by – Operational Inspection Professional Lead

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Revision Commentary

Issue No.	Description of Update(s)
8.2	<p>Minor amendments to support deployment of WIReD Release 3a2 (Inspection database) and replacement of IIS database. Minor terminology changes, including replacement of:</p> <ul style="list-style-type: none">- “IIS Database” with “Inspection Database”- “Annual IIS plan” with “Annual Inspection Plan (AIP)”.- Expectation Intervention records stored in CM9 replaced with requirement to file in WIReD.- Amendments to compliance and SBI inspection appendices to clarify that targets and frequency should be set by Division/sub-Division.- Format and references updated.

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1. Introduction

1. ONR’s expectations for the development and recording of planned regulatory Inspections on nuclear licensed sites and other duty holders are defined in this document and reflected in the applicable ONR Management System processes (refer to HOW2 for further information).

2. Purpose and Scope

2. This document provides guidance to ONR staff with responsibilities in the regulatory Inspection process, i.e., from creation of regulatory inspection plans (known as Annual Inspection Plan or AIP), through reporting and recording, to assist in achieving compliance with ONR’s expectations for the development and delivery of planned regulatory inspections. Planning, conduct and reporting of individual inspections is covered in ONR Technical Inspection Guidance (TIG) – ‘General Inspection Guidance’ (ONR-INSP-GD-064) (reference document [1]).

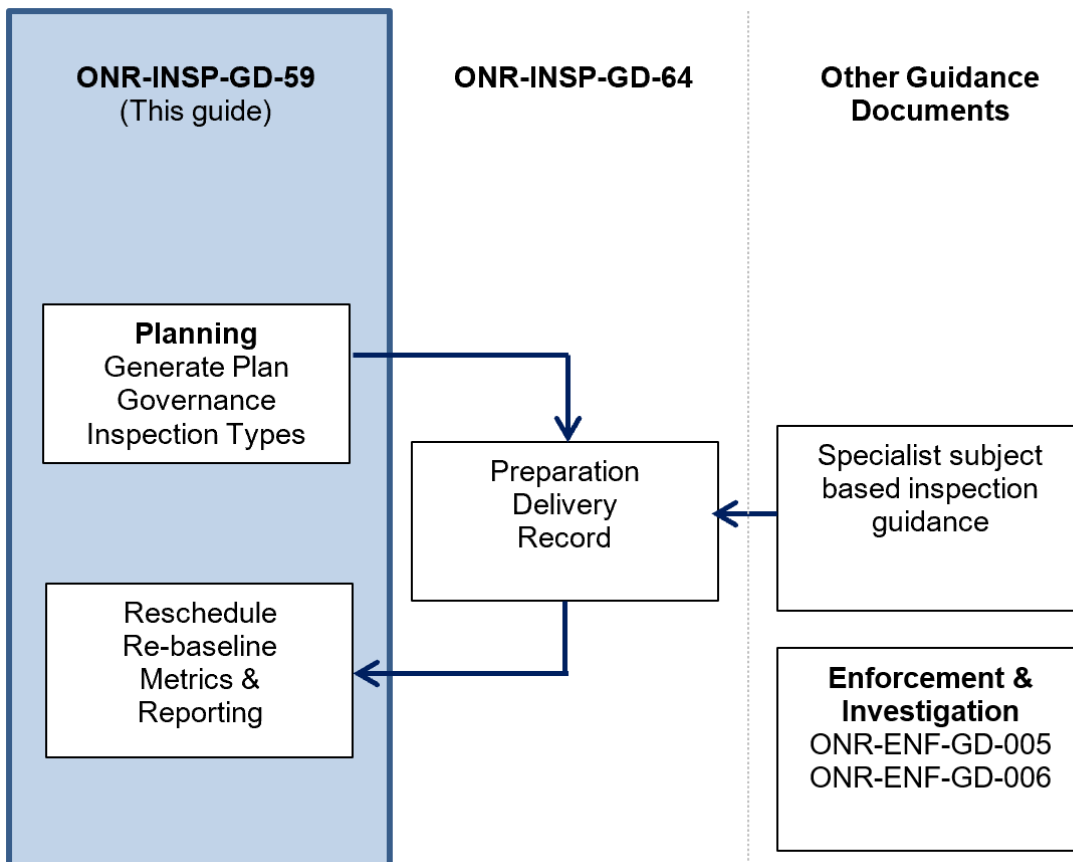


Figure 1 - Alignment with other guidance documents

3. Creation of Regulatory Inspection Plans (Annual Inspection Plans)

3. Regulatory activities place a burden on the dutyholder and as such the type and frequency of activities should be determined by the relevant strategies and plans of ONR considering the ONR Enforcement Policy Statement (EPS) (ref. [2]) and Regulators Code (ref. [3]).
4. All Inspection plans should derive from the ONR Corporate Plan, associated Division and Sub-Division strategies (and where appropriate, the relevant sub-specialism strategy) and be subject to Division Board(s) oversight. Inspection plans should be consistent with the principles of enforcement described within the EPS and where practicable integrated across all ONR purposes. Division Directors delegate responsibility for development and oversight of inspections to Sub-Division Boards (SDBs) led by Delivery Leads (DLs) who are tasked to ensure that the regulatory activity of all inspectors is integrated and co-ordinated in a proportionate and targeted way.

4. Regulatory Attention Levels

5. Strategically, the level of regulatory attention applied to duty holders is based on an overall judgement across all ONR purposes. It reflects the level of hazard and risk posed by the facility or activity and also the duty holder's safety, security or safeguard performance. ONR's judgement is underpinned by qualitative and quantitative measures, gathered through its regulatory activities, such as:
 - The number and significance of regulatory issues recorded against the site and their timely resolution;
 - The number and significance of incidents on the site notified to ONR;
 - Enforcement action being taken or considered in relation to the site;
 - Delivery of agreed safety, safeguards and security enhancements;
 - Any organisational changes that may have a significant adverse impact on the site;
 - Current safety and security performance levels and trends for the site;
 - Previous licensee / duty holder performance;
 - Safety Culture (refer to ONR Technical Inspection Guide (TIG) – 'Safety Culture Guide for Inspectors' (NS-INSP-GD-070) (ref. [4]).
6. ONR recognises and applies three levels of regulatory attention to licensees and duty holders, across its purposes as follows:
 - Routine regulatory attention applies to those sites where ONR considers that no additional attention, over and above that which was deemed necessary, is required, based on the above factors.
 - Enhanced regulatory attention describes a higher level of regulatory activity applied to the licensee and duty holder, driven by the factors detailed above.
 - Significantly enhanced regulatory attention is based upon the factors above with additional factors, such as emergent or long-standing safety and/or security issues and/or the risk associated with the facilities in question.
7. Further information on regulatory attention levels can be found in ONR Guidance Document 'Guidance on the assignment on Dutyholder attention levels' (ONR-GEN-GD-013) (ref. [5]).
8. Each respective Divisional regulatory strategy/plan should accurately reflect the regulatory attention status of the site and should provide details of the mechanism(s) by which the site can progress to a lower level of regulatory attention.

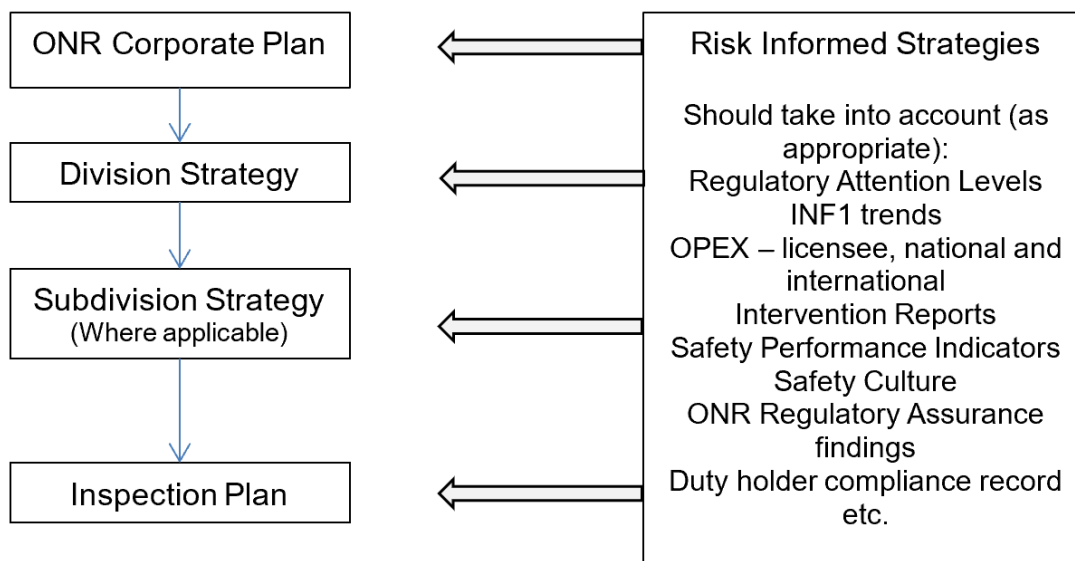


Figure 2 - Alignment of the Inspection Plan with divisional and corporate plans

9. The regulatory activity of all inspectors across all ONR purposes must align with the relevant Division, Sub-Division and Sub-Specialism strategy, as appropriate. In turn, the Divisional strategies must align with ONR’s regulatory priorities stated in the annual Corporate Plan and ONR EPS. Divisional strategies and inspection plan should include all inspection activity across all ONR purposes. They should provide a summary of the regulatory issues or divisional/sub-divisional strategic objectives that ONR intends to address (including compliance) in the year(s) to which they relate, what ONR is seeking to achieve and how it intends to achieve its objectives for the year. Every inspector should be able to establish where and how their regulatory inspection activity fits into the relevant inspection plan. If this is not the case then it is possible that either the proposed inspection is out with Division intentions, or that inspection planning and Division oversight are insufficiently developed. Active participation of inspectors in Division management and communication within delivery teams is fundamental to the development of effective inspection strategies and plans. These will, in turn, feed into the relevant Divisional strategies which will be used to support the ONR prioritisation process.

10. Division Strategies and inspection plans should consider available intelligence to inform inspection priorities and ensure that the inspection plan is risk informed. To provide the necessary inputs, the revised Regulatory Intelligence Process requires Professional Leads (PLs) or Specialisms to hold an annual intelligence review that identifies specific Sub-Division or generic actionable intelligence, for consideration in inspection planning. These reviews consider a range of conditioned intelligence and regulatory experience and effectiveness inputs e.g.:
 - INF1 trends and causation analysis,
 - ONR internal regulatory experience,
 - licensee learning and intelligence,
 - National and International OPEX (operational experience),

- ONR Regulatory Issues database,
 - intervention reports,
 - Leadership and Management for Safety (LMfS) Reviews and Safety Performance Indicators (SPIs),
 - Safety Culture (refer to ONR Technical Inspection Guide (TIG) – ‘Safety Culture Guide for Inspectors’ (NS-INSP-GD-070) (ref. [4])).
11. It should be noted that this is not an exhaustive list of intelligence sources. Ideally these sources should be available a minimum of four weeks before the Division inspection planning round. Note, that in the case of LMfS reviews, the decision as to which licensees will be reviewed in any one year should be made by the relevant DL in consultation with the LMfS Inspector and the LMfS PL.

4.1. Resource Allocation

12. The ONR Executive and the ONR Division Directors determine the overall resource allocation priorities. Programme managers and DLs are expected to allocate resources to optimum effect; the authorities of key staff are defined in the ONR Management System. Decisions on resource allocation will be made under the ONR Division management arrangements. Each Division will estimate the resource required to deliver its proposed strategy and submit a bid to the Division management process. Once resources have been assigned by the respective Professional Leads, it will be the Division Director and DLs’ responsibility to deliver against the supported strategy and priority objectives.

5. Inspection Types to be Considered for the Integrated Intervention Strategy

ONR utilises a range of inspection types as identified in Appendix 1. Divisional strategies identify the range of inspection techniques that are to be utilised to deliver the divisional objectives. For convenience they are also listed in

13. Table 1.

Table 1 - Types of compliance inspections

Inspection Types	Appendix 1
Licence Condition Compliance Inspections	A
Themed Compliance Inspections	B
System Based Inspections (SBIs)	C
Chief Nuclear Inspector (CNI) Inspections	D
Nuclear Security and Safeguard Inspections	E
Not Used	F
Not Used	G
Transport Inspections	H
Conventional Health and Safety Sub-Specialism	I
Fire Safety Inspections	J
Not Used	K
Supply Chain and Quality Inspections	L
Readiness Inspections	M
Demonstration Exercises – Undertaken to Demonstrate Adequacy of Emergency Arrangements and Plans	N
Planned vs. Reactive Unplanned (RUP) Inspections	O
Announced vs. Unannounced Inspections	P

6. The Annual Inspection Plan

14. For inspection plans associated with nuclear licensed sites it is the Nominated Site Inspector (NSI) who is responsible for delivery of all nuclear safety inspection and coordinating the delivery of the AIP. The security, conventional health & safety, Environmental Impact Assessment for Decommissioning Regulations (EIADR), safeguards and transport inspections will be the responsibility of the nominated individual for each associated inspection.
15. Candidate LCs for themed inspections, are proposed prior to the start of the inspection year and are those LCs that are judged to be relevant to the inspection theme to be examined. Should insufficient evidence be acquired during such inspections against an individual LC (which is legitimate if previous intelligence required a variation in scope or focus), the rating may be denoted as 'N/A'. However, this should be an exception rather than the norm, intended to provide flexibility during planning.
16. To engender a degree of flexibility in planning and to avoid the potential for repeated re-baselining of inspection plans, the overall governance key performance indicator (KPI) for completion of themed inspections reflects the execution of the inspection as a whole and not individual LC ratings. This is equivalent to the governance adopted for SBIs.
17. Safety, safeguard and security inspectors are to consult on preparation of the annual inspection plans. This is to ensure that any synergies can be exploited. For example, an inspection of the site perimeter can cover protective security and site Licence Condition 2 and LC4 – Restrictions on Nuclear Matter on the Site covers aspects of NSR19. Some duty holders, particularly where they are smaller and staff have responsibilities covering multiple disciplines, may have limited resource to facilitate a concurrent inspection covering different aspects of safety and security. It is therefore also important that the inspection plan is managed to avoid possible resource burdens on duty holders. Furthermore, inspectors should liaise to ensure that the plan is de-conflicted to minimise the impact of other concurrent activities such as exercises or plant outages.
18. **Note:** ONR CNS security and safeguard vires do not extend to Defence sites.

7. Additional Requirements

19. As a general inspection protocol, we expect all ONR inspectors planning to visit a site to inform the NSI.
20. All inspectors planning a rateable compliance inspection should enter the information on the plan at least three months in advance and in consultation with the NSI (to avoid resource clashes).
21. The NSI should review the issues database entries for the licensed site on a monthly basis with the licensee to allow this to be reviewed in good time for the Sub-Division Board Meeting update.
22. The NSI will meet the safety representatives annually, as a minimum.
23. For all inspections, the General Inspection Guide (ref. [1]) should be used. Guidance in the ONR Inspection Rating Guide is to be used when judging the rating and for determining the appropriate follow up action.

7.1. Dutyholder Engagements – Levels of Communication

24. For written communications and working meetings, there are generally four levels denoting hierarchy between ONR and the licensee. The output of engagements at each level should be a set of agreed records or minutes of the meeting. There may be slight differences in attendance across ONR Divisions (e.g., Defence Division where the most senior level of engagement is denoted by “Level 0”), but the levels can generally be described as follows:
 - **Level 1:** Policy (ONR CNI accompanied as necessary by ONR DCI).
 - **Level 2:** Strategic Direction (ONR DCI accompanied as necessary).
 - **Level 3:** Operational and Technical Issues (ONR SI, ONR Nominated Site Inspectors accompanied by other inspectors as necessary).
 - **Level 4:** Information Exchange (ONR Operational and Specialist Inspectors).

7.2. Definitions

25. **Policy:** Level 1 interactions determine policy typically over a five-year time frame. They identify key policy matters, major organisational issues and resolve matters from Level 2 interactions.
26. **Strategic Direction:** Level 2 interactions determine strategic direction typically over a two-year time frame. They provide information on the future direction of the licensee, identify matters of strategic importance, agree programmes to resolve strategic issues, monitor progress on agreed programmes and resolve matters from Level 3 interactions.

27. Operational and Technical Issues: Level 3 interactions provide information on operational and technical issues. They provide an opportunity for monitoring progress, decision making, resolving technical issues and also considering matters arising from Level 4 interactions as appropriate.
28. Information Exchange: Level 4 interactions enable information exchange and gathering. Monitoring and clarification of technical issues is undertaken, and appropriate routes agreed to seek resolution on technical issues.

8. Other Site Engagements

29. There are several regulatory activities that are not rated (non-compliance) which should be considered as part of the planned overall interactions within a regulatory year.
30. Non-rated regulatory activities can be broadly separated into two distinct groups, strategic engagements and operational or technical engagements.
31. Operational and technical engagements include regular planned engagements which are necessary to achieve efficient and effective regulation. They provide an alternative means of regulatory oversight (e.g., regulatory issues) also enable ONR to collect intelligence to:
 - Inform divisional intervention strategies.
 - Search for, and identify, common themes.
 - Improve/better target our regulatory approaches as per the EPS.
32. Strategic engagements may include external stakeholders such as other governmental departments.
33. The type and frequency of activities should be determined by the relevant Division or sub-Division according to the particular circumstances of their dutyholders, strategic significance and the associated regulatory attention level.
34. The following engagements are typically considered by ONR:
 - Strategic engagement including (but not limited to);
 - Level 1 Regulatory Review
 - Level 2 Regulatory Interface Forum
 - Local Liaison Committee/ Site Stakeholder Group
 - Other governmental departments (e.g. Ministry of Defence, Environment Agency, Scottish Environmental Protection Agency, etc)
 - VIP visits and tours
 - Operational and technical engagements including (but not limited to);
 - Level 3 Regulatory Interface Forum
 - Level 4 Regulatory Review Meetings
 - Meetings with Safety Representative
 - Annual Review of Safety Meetings

- Meetings with Licensee Internal Regulators
 - ONR Issues Meetings
 - Engagement on Safety Culture
 - Engagement on Lifetime Plan
 - Engagements relating to consent or permission (for example, projects or permissioning)
35. Un-rated activities should be recorded in contact records and subject to appropriate governance as determined by each Division and sub-Division.

9. Governance and Approval of Inspection Plans

36. Approval and monitoring of the inspection plan will be via the SDBs and oversight by the Division Regulatory Review Board (RRM). All annual inspection plans, which provide the baseline for the year, should be formally approved by the relevant Delivery Lead the 1st of April each year.
37. Delivery Leads should ensure that approved annual inspection plans aligns with the Sub-Division strategy and that there is clear link to the higher level ONR strategies and plans.
38. The Division Regulatory Review Board will check progress with the Division/Sub-Division strategies. Progress with the associated inspection plans may be reported to allow adjustments to plans and resources as necessary; however, inspection plans are primarily monitored by the relevant SDB.
39. Regulatory review is an important element of the delivery process. Its purpose is to determine whether sufficient progress is being made against appropriate targets and to make any adjustments to plans that appear to be necessary, together with associated resourcing changes. The review process is a fundamental element of Division performance management.
40. Reviews are carried out at different management levels, but the process is generally the same at each level. At the SDB level, they should as appropriate:
 - Use regulatory intelligence and experience derived from:
 - Regulatory issues
 - Outcomes from inspections
 - Operational experience feedback
 - Corporate inspections (LMfS)
 - Stakeholder intelligence
 - Regulatory intelligence (Advice Notes)
 - Division objectives
 - Identify the current status of the duty holder - where are they now, strengths and weaknesses.
 - Assess progress with extant delivery plans, and confirmation or otherwise of the relevance of current aims and objectives.

- Use information on effectiveness of inspections and identification of alternative approaches where the need for this is indicated. This can include seeking explanations for better or worse than expected performance. Successful and unsuccessful inspections can both usefully inform future strategy.
 - Agree overall priorities and objectives for the forthcoming planning period and the inspections intended to realise objectives, including those with duty holders and stakeholders other than site licensees.
 - Identify any need for resourcing adjustments.
41. Furthermore, SDBs should ensure that the inspection plan links to any strategies or guidance developed by SDBs and include longer term strategies set out for the site in question. The inspection plan gives a snapshot of intentions for the planned year, it does not give the longer-term explanation of what those plans are intended to achieve. This will be detailed in the appropriate sub-Division or Division strategy.

10. Multi-Facility Sites

42. Sites fall into two broad categories, those which are considered and inspected as a site in their own right such as power station sites (e.g., Heysham 1, Sizewell B etc.) and multi-facility sites (e.g., Sellafield Ltd).
43. Multi-facility sites are those sites which due to operational inspection requirements are broken down into smaller facility or functional areas, generally with separate AIP plans. For example, Sellafield is divided into Waste Vitrification Plants, THORP, Solid Waste, etc. Some de-commissioning sites may also fall within the category of multi-facility sites as they may have waste processing and storage facilities.
44. When planning inspections at multiple facility sites, it is important to ensure consistency in the naming of facility or functional areas, which the site has been split into. A list of facility or functional areas should be retained within the Division/Sub-Division and provided to the Regulatory Performance Team (RPT).
45. Licence condition inspections at multi-facility sites at each separate facility or area should be similar in size and scope to a normal licence compliance inspection at that site or facility (typically around ½ day for higher hazards sites). For other ONR purposes the intent is that a consistent approach is adopted across each facility.

11. Recording LC7 “Incidents on Site” Inspections on the AIPP

46. If during a planned LC7 inspection any issue is highlighted that indicates shortfalls in the licensee’s compliance against another LC, then the lead inspector has the options of:
 - a) Expanding the scope of the LC7 inspection to include the additional LC. Note that the additionally scoped inspection should be of similar size and scope to a normal licence compliance inspection at that site or facility (typically around ½ day for higher hazards sites). Any additional LC inspection considered during a planned LC7 inspection must be recorded as “Reactive Unplanned” on the subsequent Intervention Record (IR).
 - b) Add an additional LC inspection to the AIP to cover the area of concern via the normal re-baselining process. This would be considered a normal “planned” inspection and is generally ONR’s preferred approach.

12. Change Control

47. The Divisional baseline inspection plan is developed and agreed at the beginning of the financial year (nominally 1 April).
48. Inspections can be cancelled or rescheduled in year subject to an appropriate justification (for example because of an emergent issue on site, a significant change to the operational status of a nuclear reactor plant or facility, adverse weather conditions or staff unavailability (ONR or duty holder)).
49. Any changes baseline inspection plan must be justified by the lead inspector and approved by the DL. Once approved the lead inspector should notify the NSI and the division DDS by email giving details of:
 - The identity of inspection to be rescheduled.
 - Justification for the change.
 - Whether the inspection is cancelled or rescheduled.
 - If rescheduled, the revised date should be given and be within the current financial year. Inspections should be rescheduled 4 weeks in advance unless special circumstances arise.
50. Baseline changes and justification reasons will be recorded by DDS.

13. RD Metric Governance

51. The following RD metrics (KPIs) have been defined for compliance inspection:
 - 90% of all compliance inspections achieved in year compared to plan.
 - 95% of all planned SBIs achieved in year compared to plan.
 - 90% of all planned Themed Inspections achieved in year compared to plan.
52. On receipt the completed and approved intervention report from the lead inspector, DDS will file the report within the WIReD Inspection database and record the results in the database.
53. Within the WIReD inspection database, the expected timescales for completion of the relevant database entries (record of inspection and related actions) will be set to be consistent with guidance within the ONR Management System. These expected timescales include time given to the lead inspector to complete all records after the inspection, the time allowed for the Delivery Lead (or nominated delegate) to review and approve the element of the database update that will be published, and the time required for the DDS team to complete all post-inspection administration.
54. If DDS are not informed of a change to an inspection plan before the end of the month of the scheduled inspection, the inspection will be recorded as missed, even if subsequent approved justification is provided.
55. Planned compliance inspections not delivered in year, deleted or rescheduled without approved justification will be reported as 'missed'.

14. Responsibilities

14.1. Nominated Site Inspector

56. Every nuclear licensed site has a full warrant Nominated Site Inspector (NSI) assigned to it. Many sites also have Lead or Facility Site and Project Inspectors in addition to the NSI.
57. The NSI role is to act as ONR's principal point of contact for that site for interactions with the Licensee and the public at stakeholder meetings. The NSI is generally assigned to a site based on ONR's primary regulatory focus or attention for that site (e.g., nuclear safety or security). However, it is important for the NSI to have sufficient knowledge of regulatory activity relating to the site across all of ONR's purposes.
58. It is incumbent on the NSI and his/ her colleagues across all of ONR's purposes to engage and communicate to ensure that ONR is seen to be acting as one regulator. As a minimum, the NSI is expected to maintain a suitable level of oversight across the areas of intervention strategies, plans and significant matters of enforcement activity.
59. The NSI is not accountable for the delivery or control of all intervention and enforcement activity. However, they should be kept suitably well informed. This will require the cooperation of the NSI's colleagues, professional judgement and good relationships to ensure appropriate information is shared and collaboration maintained.
60. To avoid confusion the term Nominated Site Inspector should be reserved for the role described above. Where there are multiple Inspectors dealing with a site and across different facilities and purposes other terms should be used. For example, this could be Lead or Nominated 'Facility' Inspector or Lead or Nominated 'Safety or Project'
61. The Nominated Site inspector shall coordinate and lead development of the annual site inspection plan. All such plans should be drafted in WIReD inspection data base for approval by the relevant Delivery lead (or nominee).
62. The Nominated Site Inspector shall engage with lead inspectors and monitor delivery of their site's approved inspection plan. If in-year change to approved inspection plans is required, amendments will be made by nominated inspectors using the WIReD system. The addition of new inspections, cancellation of approved inspections, or rescheduling of inspections > one month will require approval of the Delivery Lead (or their nominee). Rescheduling inspections into the next Financial Year (FY) will also require Delivery Lead approval.

14.2. Division Delivery Support (DDS)

63. DDS staff support inspectors, delivery leads and Directors by monitoring on delivery against approved inspection plans. It is considered good practice for DDS team to monitor WIReD to:
- Identify amendments to approved inspection plans awaiting approval and flag to Delivery Leads as appropriate.
 - Identify inspections within two weeks of delivery and have not progressed to “ready for inspection” and notify Lead Inspectors and the relevant Nominated Site Inspector
 - Monitor the recording of inspection findings, highlighting those inspectors approaching the KPI due date to the Lead inspector, nominated site inspector and delivery lead in accordance with Divisional governance arrangements.
 - Routinely review the quality of the division’s inspection data. Working with the process owner, DDS Take steps to promote continuous improvement with inspection plans and inspection records in accordance with Divisional governance arrangements and local job guides (as appropriate).
64. The DDS will provide monthly updates of the inspection plan to help the relevant inspectors ensure that the information remains current – any missed inspections should be identified, and a reason captured on the Inspection database. DDS will be responsible for co-ordinating this into the inspection database so that the BIT Performance Manager has the information they need for monthly performance reporting.

References

- [1] ONR, "ONR-INSP-GD-064 - General Inspection Guide".
- [2] ONR, "Enforcement Policy Statement," 2021.
- [3] Department for Business Innovation and Skills, "Regulators Code 2014".
- [4] ONR, "NS-INSP-GD-070 - Safety Culture Guide for Inspectors".
- [5] ONR, "ONR-GEN-GD-013 - Guidance on the assignment on Dutyholder attention levels".
- [6] ONR, "ONR-RIO-PROC-001 - Management of Regulatory Issues".
- [7] IAEA, "IAEA Safety Standards - SSR-6 - Regulations for the Safe Transport of Radioactive Material," 2018. [Online]. Available: https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1798_web.pdf.
- [8] ONR, "NS-INSP-GD-066 - The Carriage of Dangerous Goods and use of Transportable Pressure Equipment".
- [9] ONR, "NS-TAST-GD-077 - Supply Chain Management Arrangements for the Procurement of Nuclear Safety Related Items or Services".
- [10] ONR, "NS-PER-GD-001 - The Purpose and use of Permissioning".

Appendix 1 – Compliance Inspection Types

Appendix 1 identifies the range of commonly utilised compliance inspections that should be considered during development of the inspection plan.

Table 2 - Types of compliance inspections

Inspection Types	Appendix 1
Licence Condition Compliance Inspections	A
Themed Compliance Inspections	B
System Based Inspections (SBIs)	C
Chief Nuclear Inspector (CNI) Inspections	D
Nuclear Security and Safeguard Inspections	E
Not Used	F
Not Used	G
Transport Inspections	H
Conventional Health and Safety Sub-Specialism	I
Fire Safety Inspections	J
Not Used	K
Supply Chain and Quality Inspections	L
Readiness Inspections	M
Demonstration Exercises – Undertaken to Demonstrate Adequacy of Emergency Arrangements and Plans	N
Planned vs. Reactive Unplanned (RUP) Inspections	O
Announced vs. Unannounced Inspections	P

Appendix 1A – Licence Condition Inspections

One of the strategic objectives of ONR is to undertake a coordinated programme of safety related inspections on Nuclear Site Licence Holders in relation to their arrangements for compliance with relevant statutory provisions of:

- The Energy Act 2013
- The Health and Safety at Work etc. Act 1974 (HSW Act).

Sections 1, 3-6, 22 and 24A of the Nuclear Installations Act 1965 (NIA65) are key Relevant Statutory Provisions of the Energy Act. It provides for a nuclear site licence to be granted to a named corporate body to install or operate specified nuclear installations in a defined location. NIA65 requires ONR to attach to each nuclear site licence such conditions as it considers necessary or desirable in the interests of safety or with respect to the handling, treatment and disposal of nuclear matter. Inspection of LC compliance at nuclear licensed sites forms a significant part of ONR's activities.

Each Division/Subdivision should set out in their strategy the way in which they intend using LC compliance inspection, with the targets and frequency of all planned compliance inspection being proportionate to the risks and hazards from the relevant site(s).

LC compliance inspection is one element of a number of regulatory activities that can be deployed to achieve regulatory outcomes, and compliance inspection should be deployed only where its impact is considered the most effective and efficient method of achieving our regulatory aims.

Specific planned LC compliance inspections are either identified as part of ongoing reviews of site/dutyholder performance, or from the output of the annual operational planning activity described earlier in this document. These planned inspections are managed within the WIReD regulatory database and are formally endorsed by the relevant sub-Division as part of their lifecycle management. No expectation is made of a minimum frequency of inspection for each LC; the need for any inspection should be set by the relevant sub-Division. If Divisions/sub-Divisions consider that a multi-year framework (defining periodic and/or repeated inspections) of LC compliance inspections is merited, they should identify this within their relevant strategy, and provide appropriate rationale for its use.

Normally the amount of effort for a typical licence compliance inspection at a higher hazard site would be in the order of ½ day site inspection plus with additional time for planning and preparation. However, inspection times may vary to allow for an adequate LC inspection depending on the LC under inspection and will be proportional to the level of hazard and risk posed by the site and duty holder safety or security performance. Hence at some sites the inspection time may be reduced. As part of licence compliance inspection, there will be a requirement for an inspection to focus on the adequacy of the licensee's arrangements as well as their implementation. However, on sites where the arrangements are well developed more benefit is derived by focussing the inspection on the implementation of the arrangements. The ONR rating against the LC is a combined judgement relating to the adequacy of the arrangements and their implementation.

The opportunity for combining LC inspections with inspection of the relevant statutory provisions (RSPs) under HSWA should also be considered; there is considerable cross-over in many areas, and joint inspections will reduce the risk of duplication, thereby reducing the burden on industry and increasing the effectiveness and efficiency of ONR.

15. Appendix 1B – Themed Inspections

LC compliance may be evaluated under the framework of an over-arching themed or cross-cutting inspection, particularly where a subject of regulatory interest reads across more than a single LC. Such inspections may be cross functional in nature, drawing upon site inspector and specialist resource where relevant. For example:

- **Conduct of Operations.** Such inspections typically embody aspects such as plant status control (LC 23 and LC 27), planning and sequence of maintenance to manage nuclear risk (LC 28) and safe execution of work through appropriate operating instructions (LC 24) and control and supervision (LC 26) of operations by suitably qualified and experienced persons (LC 12).
- **Organisational Learning.** Such inspections examine compliance with the requirements of LC 7 in relation to incidents on the site; however organisational learning is a more pervasive topic that embodies application of operating experience from incidents at the site level, nationally and internationally into training packages (LC 10) and corrective action to operational practice.
- **Engineering Governance.** Such inspections examine the responsibilities and accountabilities for engineering governance within the licensee organisation. This may include examination of the responsibilities for ensuring adequate engineering by suitably qualified and experienced persons (SQEP) (LC 12); the nuclear baseline to verify appropriate engineering capability for nuclear safety (LC 36); responsibilities for defining reporting criteria to ensuring that risk gaps identified at a system or component level get the appropriate level of attention with the licensee organisation (LC 17 and 26).

Individual divisional strategies should link any themes examined against a relevant strategic outcome. Such a strategic outcome could relate to ONR's regulation of a single multi-facility site (such as Sellafield, Aldermaston, Dounreay or Devonport), the EDF Energy operating fleet of reactors, or decommissioning (legacy) sites.

The following set of principles help Divisions and inspectors in planning and executing cross-cutting or themed inspections:

Planning Themed Inspections

ONR's operational experience has shown it useful to nominate a lead inspector to manage the planning and execution of themed inspections where they are undertaken on a multi-facility site or across multiple sites or licensees. This ensures continuity and consistency of approach so that the original inspection outcomes being sought are addressed. Deployment of the same inspection team on a multi-facility site or across multiple sites or licensees also provides similar benefits.

Where such inspections are utilised, divisions should judge the breadth and depth to which such inspections are carried out. This will be influenced by the outcomes being sought and, the nature and magnitude of the hazard and risk. Take into account the outcomes from

individual inspections (for example a reactor site or single facility on a multi facility site) when planning for subsequent inspections. This allows emergent regulatory intelligence to influence the scope and direction of subsequent inspections if common themes or issues emerge.

The use of common question sets, evolving as the inspection year progresses, helps guide consistency but should not necessarily be used verbatim to allow for flexibility and inspector judgement (as informed for example, by ONR guidance, OPEX and Divisional strategy).

There should be proactive input from site inspectors, project inspectors and specialist inspectors in shaping the themes and developing the question sets and agreeing the agenda.

The nature of themed inspections undertaken across a number of facilities or individual sites may require different LCs to be rated following the inspection compared to original planning intent. This could occur if intelligence acquired during or prior to an inspection requires a slightly different emphasis. To this end, Divisions may adopt an alternative template which differentiates LC inspections examined under a themed inspection from those undertaken individually.

Execution of Themed Inspections

Themed or cross-cutting inspections are cross-functional, integrating site inspector, project inspector and relevant specialist inspectors. They may also be adapted to undertake an inspection across more than one of ONR's core purposes such as joint LC – NISR (Nuclear Industry Security Regulations) or LC – CDG (Carriage of Dangerous Goods) Regulations.

Themed inspections benefit from (for example) 2-4 inspectors allowing the topics to be divided into sub inspection teams to optimise inspection coverage.

Themed inspections may also involve joint inspections involving the licensee's internal regulator or other regulatory agencies.

Themed inspections enable substantial intelligence to be acquired in a consistent manner on an individual site or group of sites such as the EDF Energy operating reactor fleet. This provides an opportunity for ONR to regulate the restoration of compliance or continuous improvement with a greater evidence base than individual LC inspections. Periodic reporting to senior licensee management of findings from themed inspections strengthens ONR's ability to influence improvements.

Appendix 1C – System Based Inspections

Identifying Safety Systems and Structures

SBI consist of a series of inspections to establish how the basic elements of a site or facility safety case are implemented in Safety Systems and Structures (SSS) and fulfil their safety functional requirements. Similar SBI approach will be used for safeguards purposes, to judge that an operator's safeguards systems and structures are fit for purpose and will fulfil their safeguards functional requirements.

The number and type of SSS to be targeted will vary with the hazard and risks presented by the site. Additionally, the approach taken to identify the key SSS associated with an SBI on a multi-facility site is different to that required for a reactor site. Whilst approximately 15-25 key SSS may be identified for a higher hazard site; for a lower hazard facility (such as a radioactive waste store) 2 or 3 systems might be appropriate as determined or informed by the relevant safety case.

The creation or alteration of new site, facility codes or SSS identifiers needs to be controlled to ensure consistency across ONR. Therefore, the creation of new site or facility codes or SSS identifiers will require approval of the Sub-Division board and the master list retained in the Sub-Division strategy. RPT should be kept informed of any changes to the codes.

Operational sub-Divisions should be aware of the regulatory impact that SBI can have, and where and how their benefit can be used. Since an SBI examines the implementation of key safety case claims for a given system, sub-Divisions are expected to define, within their regulatory strategy, how SBI will be deployed as part of a coherent planned regulatory footprint across the relevant site(s). As part of that strategy, sub-Divisions should take into account the frequency with which the dutyholder reviews system safety performance, the risks and hazards being controlled by the dutyholder at site (and the relative contribution of each SSS to that control), and the regulatory outcomes that they are seeking. Whilst this guidance does not mandate a specific frequency for each SBI inspection, if Divisions/sub-Divisions consider that a multi-year framework of SBI is merited (defining both scope and frequency of each potential inspection area), they should identify this within their relevant strategy, and provide appropriate rationale for its use.

Typically, for a SBI on an operational reactor or complex nuclear chemical plant it will need about two to three days site-time to carry out a meaningful inspection with an expectation that this will be undertaken by inspectors of appropriate disciplines. The NSI will normally (but doesn't have to be) part of the team. So, for example, for the gas circulator system on an AGR power station the team may be the NSI, plus mechanical and electrical specialists. The specialist support may also come from a Technical Support Contractor (TSC). For simpler SBIs it may be sufficient to plan for a day on site undertaking inspections and may only require a single inspector.

If the sub-Division has identified a multi-year framework of SBI, those identified for completion in the relevant year should form part of the annual inspection plan for that site/facility along with the other compliance inspections and interventions.

SBI inspections should be coordinated, where possible, across several facilities within a sub-Division/Division to allow inter-facility comparisons to be made (if that would be beneficial) and in order to be as efficient and effective as possible. In addition, the site visits should be coordinated with other planned visits to achieve efficiency and deliver value for money.

Undertaking the Inspections

To carry out an SBI, check the SSS against the arrangements LCs 10, 23, 24, 27, 28 & 34. This is not a review of the arrangements that the licensee has put in place for each of the LCs. It is to assess the adequacy of their implementation in relation to a particular SSS. The inspection team should identify beforehand the relevant matters from the safety case that will allow them to determine whether the SSS will adequately meet its safety functional requirements. The inspectors are required to form an overall judgement as to whether the SSS adequately fulfils the requirements of the safety case.

Record the findings of the SBI in an IR in the WIReD inspection database so that when this SSS is re-inspected (nominally five years later) the work does not have to be completely re-done but can be reviewed to check that it is still valid. It is appropriate for individual Sub-Divisions to maintain this information centrally with the five-year plan. LCs that will be inspected are presented in Table 3.

Table 3 - LCs inspected under SBIs

Licence Condition	Purpose	Notes
LC 10 Training	To ensure that the operators and maintainers are adequately trained in the operation and maintenance of the SSS	
LC23 Operating Rules	To ensure that the limits and conditions identified in the safety case are properly implemented.	
LC24 Operating Instructions	To ensure that the operators and maintainers of the SSS comply with the safety case and have adequate written instructions relating to ensuring compliance with the limits and conditions above	
LC27 Safety Mechanisms, Devices and Circuits	To ensure that if there are safety mechanisms as part of the SSS they are properly connected and in good working order	

Licence Condition	Purpose	Notes
LC28 Examination, Inspection, Maintenance and Testing	To ensure that the SSS is being adequately examined, inspected, maintained and tested.	
LC34 Leakage and Escape	To ensure that the SSS is not leaking radioactive materials, liquids, sludges, gases etc. To ensure that the containment provided by the SSS is and will continue to be adequate.	Whilst this LC refers to radioactive materials, where there is flammable material (such as hydrogen or hydraulic oils etc.) involved in the SSS being inspected or located adjacent to it, the inspector should check that this does not present an unacceptable internal hazard (e.g., fire) to the SSS or other safety related plant.

The experience and judgement of the ONR inspection team is fundamental in coming to a decision whether the SSS will fulfil the requirements of the safety case.

During the course of the inspections, it is likely that minor deficiencies will be noted, for example a document being beyond its review date, or an operator’s training being out of date. Such minor shortcomings should be recorded by raising a Level 4 Regulatory Issue(s) and followed up later during routine inspections to the degree that their significance warrants. However, the overriding purpose of the inspections is to determine whether the SSS is capable of fulfilling its safety functional requirements. It is quite possible therefore to find several deficiencies but still judge that the SSS meets the requirements. So, in the case of an operator’s training being formally out of date, if in the inspector’s judgement, the operator is still suitably skilled, knowledgeable and experienced then the requirements of the LC10 element of the system should be considered to have been met and the training issue taken up later as necessary.

Note that in some cases it is not appropriate to inspect a SSS against all six licence conditions. For example, if a system does not contain radioactive materials, then it may not be necessary to check against LC34 and; therefore, the IR must record that it was not applicable on this occasion and provide an appropriate justification.

However, it is essential that the inspector makes a judgement whether the SSS fulfils its safety function and adequately implements the safety case. This must be formally recorded in the inspection database since this judgement forms the basis of the ONR KPI. It is not acceptable for an inspector to record this judgment as being ‘not applicable’ since only a confirmation that it meets the requirements (‘yes’) or does not meet the requirements (‘no’) are permitted.

Early planning and clear deliverables are essential to achieve a high-quality inspection for SBIs where a team approach is adopted. The planning and delivery phases developed and tested during TSC supported SBI inspections are set out in ONR-INSP-GD-064 (ref. [1]). This approach should be applied for all SBIs where more than one inspector, or an inspector plus TSC are needed to deliver the appropriate breadth and depth of inspection.

SBIs for Decommissioning Sites

A modified approach to SBIs should be adopted for decommissioning sites. Once decommissioning has commenced, the facility is permanently shut down and the safety case is progressively modified as each successive decommissioning project is implemented to defuel, decommission and remove systems and equipment. The safety case is periodically re-baselined at key points in the process, for example, completion of the removal of the reactor fuel. This means that the safety case is in a constant state of change with a general trend of reducing risk; noting however that there may be finite periods of significant increases in risk during de-commissioning work where novel processes and techniques are deployed

In order for ONR to establish that implementation of the safety case is fit for purpose, it is necessary to align the SBI programme with the de-commissioning activities on the site. For inspection planning purposes, the key site de-commissioning projects and milestones should be obtained from the site's de-commissioning programme and used to build a suitable five-year plan.

In the immediate period following the final shut down of the facility the programme will retain a significant proportion of SBIs on operational safety systems. This will then reduce and transition to SBIs on decommissioning projects as the de-commissioning progresses.

LC 22 (modification or experiment on existing plant) is of prime importance when undertaking compliance inspections on decommissioning sites as de-commissioning activities result in the continual modification of existing plant until all intermediate level (radioactive) waste is in a passively safe form and stored in a purpose-built store. LC 22(4) requires adequate documentation to justify the safety of the proposed modification, which defines the de-commissioning operating rules LC 23 and instructions LC 24.

Although the standard list of SBI LCs should be used as the basis of most inspections, this should be tailored to reflect the current status of the de-commissioning site in question. Furthermore, LC 19 (construction or installation of new plant) and LC 21 (commissioning), may be appropriate for consideration if a project requires a specific plant to be built and commissioned to remediate nuclear material on the site. Inspections of active decommissioning projects could therefore be adequately covered via LCs 19 to 24 and 26 to 28. Additional LCs should be considered if appropriate such as LC 32 (accumulation of radioactive waste), LC 34 (leakage and escape of radioactive material and radioactive waste) and LC 35 (decommissioning) which naturally lend themselves to joint inspection by ONR and the environment agency for the area of the country where the decommissioning site is located.

Appendix 1D – Chief Nuclear Inspections

Chief Nuclear Inspector (CNI) Inspections differ from compliance inspections and SBIs in that they are specifically identified and commissioned by the CNI. The purpose of these inspections is to inform the CNI's position on regulatory matters that are of a strategic nature, for example, having high current or potential safety or security significance, or having the potential to adversely impact public confidence.

CNI Inspections are focused and targeted on a specific regulatory matter. They provide ONR with an alternative approach to more routine regulatory options, for example where we need to look detail at a high-profile matter, or lever strategic improvements or where there is a need to provide additional assurance to meet the expectations of Government and other external stakeholders.

CNI Inspections will usually involve engagement at a senior level and may involve multiple sites and duty holders, as well as other stakeholders with an interest in the safety or security matter being inspected. They may, where necessary, include visits and engagement internationally.

Consequently, CNI Inspections will be led by a senior warranted ONR inspector who has been nominated by the CNI for this purpose and will be accountable for effective delivery of the inspection. The lead inspector will be supported by appropriate specialist inspectors and DDS as appropriate. Where there is benefit in providing an independent view, the CNI Inspection may involve inspectors from outside the immediate safety or security topic area. Further support may also be sought from other UK national and international regulators and agencies where the matter transcends regulatory vires or has an international dimension.

CNI Inspections are targeted and bespoke inspections that are expected to be commissioned typically once or twice per year. Technical Division will provide independent oversight of all CNI Inspections. Examples of where the CNI may choose to commission a CNI Inspection include:

- UK nuclear industry response to national and international events;
- Informing potential changes to levels of Regulatory Attention published in our Annual Report and Accounts;
- Inspection of international supply chain partners supplying significant nuclear safety or security equipment;
- As a means of informing closure of a Level 1 Regulatory Issue.

Undertaking and Reporting CNI Inspections

To ensure that the scope of the CNI Inspection is targeted and proportionate, the CNI will define Terms of Reference for the inspection. A Task Sheet will then be prepared by the inspection team that:

- Describes the scope and purpose of the inspection;
- Defines the detailed inspection activities and the corresponding role and resource requirements;
- Clarifies the participation and respective roles of any other regulators and agencies involved;
- Is agreed by the lead inspector.

The lead inspector, in cases where the CNI is not the lead inspector, will submit the Task Sheet to the Technical Director (TD who will act on behalf of the CNI) for agreement, along with an appropriate Change Control Request if this is required. In preparing the task sheet:

- Duty holders and stakeholders subject to the CNI Inspection, along with other regulators and agencies proposed to be involved, will be consulted (and any matters of disagreement or difficulty recorded on the sheet);
- The TD Oversight Team will review the Task Sheet and provide comments to the lead inspector.

The findings and outcomes of the CNI Inspection are recorded in an IR. The IR should be written to a standard suitable for publication since it is possible that the decision will be taken to publish the entire IR to demonstrate transparency or in response to a Freedom of Information (Fol) request. The CNI may also request additional documents be written to describe the inspection (e.g., a separate published report). Shortfalls found during the inspection should be progressed through Divisional governance processes in accordance with ONR Procedure – ‘Management of Regulatory Issues (ref. [6]).

In view of the unusual nature of the IR and associated Contact Records (CRs), the usual timescales and processes for finalising the record will not apply. Instead:

- A first draft of the IR should be prepared within one month of the inspection;
- All licensees, duty holders, other regulators and agencies will be given one month to comment on the draft IR;
- The IR (or its Executive Summary, see next paragraph) should be published on the ONR website within a further month, i.e. within three months of the original inspection;
- The IR should be agreed (through an acceptance review) by the lead inspector, reviewed by the Communications Team and then approved for publishing by the CNI. (Where the CNI is the lead inspector, the acceptance review role will be delegated to a senior member of the inspection team).

The CNI may sanction the production and subsequent publication of additional reports, separate from the IR, to describe the CNI Inspection. In such cases, only the IR Executive Summary will be published on the ONR website. Bespoke arrangements and timescales for governing the publishing of additional reports will be agreed by the CNI.

Appendix 1E – Nuclear Security and Safeguard Inspections

Safety, safeguard and security inspectors are to consult on preparation of the annual inspection plans. This is to ensure that any synergies can be exploited. For example, an inspection of the site perimeter can cover protective security and site LC 2 and LC 4 – Restrictions on Nuclear Matter on the Site covers aspects of NSR19. Some duty holders, particularly where they are smaller and staff have responsibilities covering multiple disciplines, may have limited resource to facilitate a concurrent inspection covering different aspects of safety and security. It is therefore also important that the inspection plan is managed to avoid possible resource burdens on duty holders. Furthermore, inspectors should liaise to ensure that the plan is de-conflicted to minimise the impact of other concurrent activities such as exercises or plant outages.

Note: ONR CNS security and safeguard vires do not extend to Defence sites.

Security Inspections

Nuclear security inspections are an essential element of ONR's overall inspection strategy in relation to a nuclear site, licensed carrier or holder of Sensitive Nuclear Information (SNI). ONR must approve Nuclear Site Security Plans (NSSPs) under the Nuclear Industries Security Regulations (NISR 2003), and it will use its findings from the assessment of duty holders' security plans and regulatory intelligence to inform its inspection priorities. Inspectors should be guided by The Security Assessment Principles (SyAPs) 2017 and associated TAGs and TIGs when making regulatory judgments as to the adequacy of compliance with approved security plans.

Safeguards Inspections (from January 2021)

Nuclear safeguards inspections are an element of ONR's overall intervention strategy in relation to a nuclear site or a Small Holder of Nuclear Material (SHNM). ONR must judge operators' compliance with The Nuclear Safeguards (EU Exit) Regulations 2019 (NSR19) and will use its findings from assessment of operators' Accountancy and Control Plans (ACP's) and regulatory intelligence to inform its inspection priorities. Inspectors should be guided by the ONR guidance for Nuclear Material Accountancy, Control and Safeguards (ONMACS) and the associated TIG and TAG when making regulatory judgements on the adequacy of compliance. Intervention plans will be aligned with ONR priorities. ONR is also responsible for facilitating safeguards inspections by the International Atomic Energy Agency (IAEA) at selected facilities in the UK

Appendix 1F – Not Used

Appendix 1G – Not Used

Appendix 1H – Transport Inspections

For the purposes of the IAEA Regulations for the Safe Transport of Radioactive Material (SSR-6) (ref. [7]) upon which GB regulatory requirements are based, 'transport' comprises all operations and conditions associated with and involved in the movement of radioactive material; these include the design, manufacture, maintenance and repair of packaging, and the preparation, consigning, loading, carriage including in-transit storage, unloading and receipt at the final destination of loads of radioactive material and packages.

Transport Inspections are based on the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (refer to ONR TIG – 'The Carriage of Dangerous Goods and use of Transportable Pressure Equipment' (NS-INSP-GD-066) (ref. [8])). They may be grouped into the following topic areas:

- Compliance with transport regulatory requirements (including classification; packaging; consignment; emergency arrangements; radiological protection; and carriage)
- Compliance with duty holder management system requirements
- Incorporation and deployment of safety controls into duty holders' arrangements

In relation to the incorporation and deployment of safety controls into duty holders' arrangements, Inspectors and Regulatory Officers look for objective evidence that safety controls required by the transport safety case are deployed in practice. Since the transport regulations adopt a graded approach to safety (where the package performance standards are graded and commensurate with the radiological hazard potential of the contents), not all safety cases require competent authority approval. Transport inspections are informed by risk and are used to verify incorporation and deployment of safety controls in duty holders' arrangements for both those packages which require competent authority approval; and those which do not. However not all duty holders' arrangements are inspected on an annual basis. Many smaller duty-holders, that only rarely transport small amounts of radioactive material, may be inspected at a proportionately low frequency if general compliance is considered adequate. These inspections can also examine compliance with safeguard requirements.

Undertaking the Transport Inspection

The inspections are designed to determine whether the transport requirements are being met by the duty holder. In order to do this, Inspectors and Regulatory Officers check the duty holders' management systems against the relevant legislation. It is therefore important that inspectors identify beforehand the relevant type of company being inspected and inspect proportionately. A management system inspection of a Package Designer for a 'nuclear flask' will be very different to that of a small courier transporting 'excepted packages'.

Note: ONR transport vires do not extend to Defence sites.

Appendix 1I – Conventional Health and Safety (CHS) Inspection

ONR Specialist CHS Inspectors (within the Nuclear Internal Hazards and Site Safety (NIHSS) Specialism) are now embedded within operational divisions. They oversee the regulation of the relevant statutory provisions (RSPs), including COMAH, which relate to CHS hazards and risks across all licensed and authorised nuclear sites. They also provide expert advice to site and project inspectors on the application of these RSPs where they impact nuclear safety and overlap with SAPs and licence conditions. The regulation of new nuclear reactor construction is currently delivered by ONR-warranted HSE inspectors under a Memorandum of Understanding, with CHS Specialist oversight. The majority of work delivered by CHS Specialists is now generated by multi-disciplinary resourcing bids to NIHSS arising from the Divisional Workplans. There remains some stand-alone CHS specific work which is delivered to operational divisions via a CHS annual work plan, and this takes into account intelligence from previous/ongoing interventions and ONR's priority CHS topics.

CHS Specialist Inspectors play a central role in supporting ONR's investigation sub-specialism. As part of the Investigation Core Team, they carry out (or support nuclear safety colleagues who are carrying out); reactive investigations of reportable incidents; fatal and other accidents; reportable diseases and dangerous occurrences, and; follow up health and safety concerns raised externally.

Appendix 1J – Fire Safety Inspections

Conventional Fire Safety Inspection has been integrated into the Nuclear Internal Hazards and Site Safety (NIHSS) Specialism has, enabling Conventional and Nuclear Fire safety inspectors to work in a more collaborative manner. ONR Fire Safety Inspectors enforce the provisions of the Regulatory Reform (Fire Safety) Order 2005 and Fire (Scotland) Act 2005, which applies to all buildings and plant on nuclear licensed sites and requires the duty holder to make adequate provisions for life safety from fire.

A risk-based inspection programme prioritising high life risk and high fire risk buildings is undertaken to confirm compliance with legislation and to ensure that the licensees have appropriate management and procedural arrangements in place. Audits focus on selected themes which are informed by regulatory and operational intelligence which include site specific issues and generic areas of interest that apply across the nuclear industry.

Inspections can also include process fire safety issues made at the request of other ONR Inspectors; these may include examination of fire protective systems and equipment or assessment of emergency response capability. As with CHS, specialist fire safety resource is also provided to the New Reactors Division, including GDA and licensing, and to the development of the planned GDF. It is more effective and efficient to address fire safety requirements during the design of a facility than to backfit or modify after construction is complete.

Appendix 1K – Not Used

Appendix 1L – Supply Chain and Quality Inspections

The ONR Supply Chain and Quality (SC&Q) group conduct cross programme inspections of licensees and their extended supply chain arrangements. The regulatory expectations are defined in ONR Technical Assessment Guidance (TAG) Document - 'Supply Chain Management Arrangements for the Procurement of Nuclear Safety Related Items or Services' (NS-TAST-GD-077) (ref. [9]).

NS-TAST-GD-077 applies to arrangements for the control of the licensees and their supply chain for the procurement of safety significant items or services on existing and new nuclear facilities. The TAG also addresses the specific issues associated with the procurement and oversight of items or services in advance of nuclear site licence granting, for example; manufacture of long lead items.

Supply Chain inspections cover two general categories:

- Inspection of licensee's supply chain arrangements to assess their compliance for the delivery of nuclear safety significant items or services along with the application of adequate independent oversight and management focus commensurate with the item or service safety significance. These inspections are carried out as compliance inspections in line with LC17 Management Systems.
- Direct inspection of key licensee suppliers to assess that adequate arrangements are in place and are being implemented, delivering safety significant items or services to contract requirements with sufficient oversight and management focus commensurate with the safety significance of the item or service being provided. These inspections are identified as; supplier or vendor inspections which will sample that licensee's (customer) supply chain and quality arrangements are being cascaded to main suppliers and in turn to the suppliers extended supply chain. These inspections are included in the ONR vendor inspection programme. The reporting regime for supplier interactions will be by CR for general contact and by IR for inspections undertaken. These inspections are rated in accordance with the ONR rating guidance. Outcomes from supplier inspections will inform the broader assessments of licensee's arrangements.

Appendix 1M – Readiness Inspections

The purpose of ONR's readiness inspection is to build regulatory confidence in a licensee's ability to conduct activities or implement modifications made under LC19, 20, 21, 22 and 35 and inform whether to grant permission to a licensee's requested activity. It is carried out within the framework of the ONR permissioning regime.

The intent, broad scope and resource required should be documented as part of the permissioning strategy (i.e., Decision Record part 1) and agreed with the DL. The lead inspector for readiness inspection should ensure that the NSI is full informed such that synergies with the wider inspection plan can be established. Results of the inspection should also be clearly documented with a regulatory judgment made against appropriate LCs.

Readiness Inspections are not routine activities but may be carried out for permissions which are of high safety significance, complex or novel. They can also be used to close out assessment findings.

ONR takes confidence from the quality of a safety case submission, adequacy of licensee arrangements, and how a licensee implements the safety case. This is supported by other inspection intelligence, for example, ONR may have carried out related site inspections. As a result, the decision to carry out readiness inspection(s) may happen later in the assessment process if issues start to emerge that require further assurance.

Readiness inspections should be carried out when the licensee declares that the evidence being sought is ready for inspection and as close to the required permissioning release date as reasonably practical.

Examples of when ONR may carry out a readiness inspection are:

- A modification associated with significant safety risks;
- A modification that is considered novel or complex;
- A modification that has seen ONR assessment difficulties or results in outstanding recommendations or issues requiring resolution before permission can be granted;
- A modification that has been the subject of other intelligence requiring ONR to seek additional confidence prior to releasing the hold point or granting permission;
- When ONR has imposed regulatory control through derived powers or flexible permissioning (NS-PER-GD-001 (ref. [10])) and assessment is judged not to be necessary; and
- New build facilities associated with significant safety risks.

Through routine engagements with the licensee, the inspector should judge the need for and most appropriate time to conduct a readiness review and communicate this in good

time to the licensee. The readiness review will normally take place independently from and after the completion of the licensee conducting their readiness review or activity.

Readiness inspections should look at a proportionate and targeted sample of the implementation of the safety case associated with process, people and plant. The broad scope of what the readiness inspection will cover (see relevant LC TIG for further guidance) should be communicated to the licensee in good time. This will provide them with the broad areas that ONR wish to sample. It may be appropriate to sample areas that have already been looked at by the licensees' own internal review.

It is ONR policy to positively and demonstrably strengthen licensees' self-regulatory processes. Therefore, we should avoid undermining a licensee's own internal challenge function. Consider using the licensee internal challenge function to seek assurance in specific targeted areas where it is appropriate and proportionate to do so.

Examples of safety case implementation areas to sample are given below;

Process

- Is the safety case implementation complete or sufficiently close to completion?
- Have instructions been prepared by SQEP personnel and completed due process (operating rules / safety case assumptions / emergency arrangements)
- Have emergency arrangements been tested? What was the outcome and have shortfalls been addressed?
- Are new limits and conditions recorded in a clear and unambiguous manner in relevant plant documentation and ready for implementation?
- Is there an adequate configuration management process from safety case through to operating instruction, operator training and competence assurance?
- Has the Internal readiness review completed and have any resulting actions been resolved?

People

- Are Roles and Responsibilities adequately defined?
- Have sufficient people completed their training?
- Do interviews with key operations personnel demonstrate a comprehensive understanding of safety case requirements and that training objectives have been met?
- Are there strong lines of accountability for safety issues which are clearly described?
- Leadership and governance – check the robustness. Are there shortfalls in setting of standards or holding to account when standards or timescales have slipped?

Plant

- Is the pre-commissioning test report adequate? Has the appropriate level of management and oversight been applied to the project?
- If applicable, are the commissioning schedule and criteria adequate?
- Has the licensee adequately implemented its arrangements for managing technical queries (TQs) and concessions?
- If applicable, are the commissioning results signed off as acceptable?
- Is plant labelling adequate?
- Is there relevant OPEX available?
- Are plant systems configured correctly in accordance with safety case claims, including correct setting of set-points and calibration?
- Is the examination, maintenance inspection and testing (LC28) schedule up to date and consistent with the safety case?
- Have you completed a plant walk down to assess plant condition and housekeeping?

Readiness inspections require:

- Enough pre-supplied material to ensure that the inspection is effective and will aim to use a minimum of licensee's resource.
- Typically half to one day.
- Hot feedback provided to the duty holder prior to the conclusion of the inspection.
- The output recorded in an IR in accordance with normal ONR processes.
- An ONR Project Inspector to lead them, potentially assisted by a minimum number of specialist inspectors (typically one to two) as required and members of the licensee internal challenge function as appropriate.

It should be noted that readiness inspections are:

- Not routine: they are used as necessary where regulatory confidence is needed ahead of safety significant hold point release.
- Not an opportunity for further ONR assessment. They are to sample the implementation of the safety case associated with a permissioning request.
- Not to unnecessarily impede or delay implementation – but are used to ensure ONR has sufficient evidence on which it can confidently decide whether to proceed with granting permission/releasing a hold point.

- Not carried-out months in advance of the expected permissioning date.

The output from the readiness inspection will be documented as an IR with any regulatory issues raised as necessary and RAG rated in accordance with normal ONR processes.

Appendix 1N – Demonstration Exercises: Undertaken to Demonstrate Adequacy of Emergency Arrangements and Plans

All Level 1 Exercises, Transport Exercises (CDG 2009 Regulation 24 and Schedule 2) and Security Exercises should be evaluated and a formal ONR Inspection Rating (against LC11 for Level 1 exercises) recorded in an associated IR. This IR may reference out to formal letters detailing observations and improvement points but should include justification on the basis for the rating. All Level 1 Exercises, Transport Exercises and Security Exercises should be included as planned compliance inspections on the baseline inspection plan.

Exercise review meetings present a valuable opportunity to review and assess the development of a site's emergency arrangements, including Security and Counter Terrorism (CT) arrangements. It must be remembered however, that in order to effectively rate an exercise review meeting against LC11, Transport, Nuclear Site Security Plan or CT contingency plan compliance, the inspection must be similar in size and scope to a normal licence compliance inspection at that site/facility (typically around ½ day for higher hazards sites).

Appendix 1O – Planned vs. Reactive Unplanned (RUP) Inspections

ONR's inspection strategies should be based on planned inspection. However, there will be a need for ONR inspectors to react to emergent issues or events. The time allocated for reactive inspections should be considered when developing inspection plans as the reactive workload between similar sites can be expected to vary significantly based on the site's event history etc. and a contingency allowance for such should be made in the annual planning cycle.

Planned Inspections

Planned inspections are those inspections which have been included on the approved inspection plan, including those inspections which have been subsequently added via the normal re-baselining process.

Reactive Unplanned (RUP) Inspections

RUP inspections (e.g., follow up inquiries) are those inspections which by definition were not on the approved inspection plan. RUP inspections generally result from emergent issues and are recorded via IR or CR as appropriate. Investigations are generally reactive in response to an event. These are dealt with under a separate ONR process. Inspectors should use discretion when deciding how to react to emergent issues. Consideration should be given to prioritisation between emergent issues and planned inspection if any planned work is to be deferred or cancelled. Consideration should also be given to the timing of any ONR intervention that could pre-empt the licensee's due process of investigation and reporting of events. In this case, information gathering may be appropriate, and a more detailed follow-up "planned" inspection may be scheduled for a later date.

RUP inspections should be recorded in the IR and marked as "RUP". RUP inspections should be rated only if the effort expended is similar in size and scope to a normal compliance inspection at that site or facility (typically around ½ day for higher hazards sites).

Appendix 1P – Announced vs. Unannounced Inspections

Both planned and reactive inspections may be announced or unannounced. The majority of all ONR inspections are planned and announced. This approach ensures the correct duty holder or licensee staff are available and documents and records are accessible, enabling the inspection to be completed in an efficient manner. Most reactive inspections will also be announced, again because it ensures the correct people and records are available when the inspection is made.

All sites may be subject to unannounced inspection, either planned or reactive, but reactive unannounced inspection is unusual and should be agreed between the inspector (or inspection team leader) and the DL or Division Director, and a clear record made of why a reactive unannounced inspection is appropriate.

To ensure a graded approach is applied, for higher hazard sites, one planned unannounced nuclear safety and nuclear security inspection should be undertaken each year. The exact number and type of sites subject to planned unannounced inspection will be determined by the Divisions, noting that due to security and access controls, some sites may be excluded as justified by the Division. For a site with multiple high hazard facilities, more than one planned unannounced inspection is expected. Most low hazard sites will still be subject to planned unannounced inspection, but at a lower frequency, some may not be appropriate at all. Exact criteria for which sites and what topics are most suitable for planned unannounced inspection cannot be specified.

Unannounced inspections do not have to be undertaken out of normal business hours, but they can be effective if they are out of hours. In such cases, inspectors should ensure they have considered all relevant risks to their personal safety and discussed their mitigation and management with their DL.

Adding and recording planned unannounced inspections on the inspection plan - which in most Divisions is shared with the licensee - clearly risks disclosing the inspection. To ensure such inspections remain unannounced, specific system codes will be applied to ensure they are not evident on any plan shared with the licensee.

Table 4 provides examples of when a planned unannounced inspection is valid.

Table 4 - Examples of when a planned unannounced inspection is valid

Topic	Appropriate	Not appropriate
Timing	On a separate day to the agenda issued to site for the planned inspection e.g. For a planned 3-day inspection Tuesday to Thursday, an unannounced inspection would be on Monday or Friday (in normal hours)	A short “add-on” to a day already planned to be on site. E.g., For a planned 3-day inspection, Tuesday to Thursday, it would not be a recorded as planned unannounced to stay after 5pm for a few hours beyond the timed inspection on the agenda sent to site.
Timing	An out-of-hours inspection not on the agenda of a planned inspection. E.g., Returning to site after 7pm, or arriving at site at 05:00	
Timing	A separate day or out of hours alongside a planned inspection	A one-off visit to site solely to complete unannounced inspection (inefficient)
Duration	Typically, 3-4 hours of inspection	Less than 2 hours
Planning	A plan for the inspection will be drawn up, but not shared	No plan prepared; inspection determined on the day based on experience/topics of interest to inspector
Planning	Inspection planned for ONR inspectors only	No joint inspections with other external or internal regulators or TSCs – to ensure inspections are demonstrably unannounced.
Notice	Site informed unannounced inspection will occur during the year	Site given notice of “unannounced” inspection at the next visit/month, or of content
Content	Implementation of arrangements	Inspection of arrangements (because correct staff not normally available or prepared, therefore inefficient).
Content	Following a job (select a job/task from the work pack, job card issue, briefing, conduct, review, closure)	
Content	Inspect shift handover	

Topic	Appropriate	Not appropriate
Content	Observe and interview out of hours staff (e.g., cleaners, other workers) for control and supervision, setting to work, work control	Unplanned general “chats” with available staff
Report	Normal Intervention Record, setting out purpose, objectives, activity, findings, and IF APPROPRIATE, rating	No account in intervention record.
Record	Entered on inspection plan in advance (but not shared with duty holder), tick or rating to confirm complete	Entered in arrears – otherwise it is reactive/unplanned