

INSPECTION MANUAL

REGULATORY SERVICES

ARPANSA-REG-INS-MAN-280W

**May 2019**

[1.1 Objectives 4](#_Toc5290051)

[1.2 Appointment of inspectors 4](#_Toc5290052)

[1.3 Responsibilities & personal conduct of inspectors 5](#_Toc5290053)

[1.4 Assignment of inspectors 5](#_Toc5290054)

[1.5 Graded approach to inspection 5](#_Toc5290055)

[1.6 Regulatory priority of a facility 6](#_Toc5290056)

[Determining the RP of a facility 6](#_Toc5290057)

[Evaluating the hazard of a facility 6](#_Toc5290058)

[Evaluating the control of a facility 7](#_Toc5290059)

[Review of regulatory priority 8](#_Toc5290060)

[1.7 Inspection schedule 8](#_Toc5290061)

[Facility inspection frequency 8](#_Toc5290062)

[Source inspection frequency 8](#_Toc5290063)

[Complex Sites 10](#_Toc5290064)

[1.8 Types of Inspection 10](#_Toc5290065)

[Scheduled, augmented and unannounced inspections 10](#_Toc5290066)

[e-inspections 10](#_Toc5290067)

[1.9 Functional inspection areas 10](#_Toc5290068)

[1.10 Preparing for an inspection 11](#_Toc5290069)

[1.11 Conducting an inspection 11](#_Toc5290070)

[1.12 Inspection reports and findings 11](#_Toc5290071)

[1.13 Follow-up 12](#_Toc5290072)

[1.14 Site Visits 12](#_Toc5290073)

[2.1 Purpose & scope 13](#_Toc5290074)

[2.2 Inspection file (optional) 13](#_Toc5290075)

[2.3 Inspection team 13](#_Toc5290076)

[2.4 Document review 13](#_Toc5290077)

[2.5 Timetable 14](#_Toc5290078)

[2.6 Notification 14](#_Toc5290079)

[2.7 Logistics 15](#_Toc5290080)

[2.8 Entrance meeting 15](#_Toc5290081)

[2.9 Information gathering 15](#_Toc5290082)

[2.10 Exit meeting 16](#_Toc5290083)

[2.11 Inspection report 16](#_Toc5290084)

[2.12 Review draft report 17](#_Toc5290085)

[2.13 Approval and issue 17](#_Toc5290086)

[2.14 Record keeping 18](#_Toc5290087)

[2.15 Publish report & request post-inspection survey 18](#_Toc5290088)

[2.16 Review of facility regulatory priority 18](#_Toc5290089)

[2.17 Follow-up areas for improvement and potential non-compliance 18](#_Toc5290090)

[2.18 Feedback & lessons learned 18](#_Toc5290091)

[3.1 Skills 19](#_Toc5290092)

[3.2 Knowledge 19](#_Toc5290093)

[3.3 Training & skills development 19](#_Toc5290094)

[Recognition of prior learning 19](#_Toc5290095)

[Refresher training 19](#_Toc5290096)

[4.1 Radiation protection 21](#_Toc5290097)

[4.2 Travel safety and security 21](#_Toc5290098)

# Inspection program overview

### Objectives

The fundamental objective of ARPANSA’s inspection program is to inform ARPANSA of the safety performance of controlled persons operating under a licence issued by, or on behalf of the CEO of ARPANSA. The program will assist in providing assurance to the Australian community that activities involving radiation facilities and sources do not pose undue radiation risks to people and the environment.

The inspection manual elaborates on the policy statement and supporting principles outlined in the [Policy for ARPANSA’s Regulatory Activities](https://www.arpansa.gov.au/regulation-and-licensing/regulation/regulatory-integrity/policy-arpansas-regulatory-activities) (ARPANSA-POL-002) as relevant to inspections. The Policy is aligned with the [IAEA General Safety Requirements (GSR Part 1 Rev 1) *Governmental, Legal and Regulatory Framework for Safety*](http://www-pub.iaea.org/MTCD/publications/PDF/Pub1713web-70795870.pdf)*.*

Requirement 27 of GSR Part 1 states: The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization.

The inspection program is designed to:

1. Identify activities prohibited under the *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act) that are being undertaken without appropriate authorisation or exemption[[1]](#footnote-1).
2. Assess and verify licence holder compliance with the Act, the Australian Radiation Protection and Nuclear Safety Regulations 2018 (the Regulations) and licence conditions.
3. Appropriately respond to non-compliance, areas for improvement, abnormal occurrences, incidents and accidents.

At no time does an inspection diminish the licence holder’s primary responsibility for safety.

### Appointment of inspectors

To exercise powers and perform functions as an inspector, a person must:

1. be appointed by the CEO under subsection 62(1) of the Act
2. hold an identity card meeting the requirements of section 83 and schedule 2 of the Regulations

To be appointed as an inspector, a person must:

1. have appropriate qualifications in science or engineering and/or experience in radiation protection and nuclear safety and security, or related industry subject to stringent safety requirements
2. have completed or be actively seeking to complete the required components of the inspectors’ training and skills development program (see Section 3)
3. possess or be actively acquiring a recognised certification in audit, investigation and/or enforcement eg. Certificate IV in Government (Statutory Compliance) or equivalent from a Registered Training Organisation
4. possess an appropriate security clearance (minimum Baseline level)

NOTE: ARPANSA does not contract inspectors however a contractor, an external regulator from another jurisdiction or another suitably experienced staff member may be involved in an inspection as a technical adviser or subject matter expert.

### Responsibilities & personal conduct of inspectors

Inspectors must behave in accordance with the [APS Values and APS Code of Conduct](http://www.apsc.gov.au/publications-and-media/current-publications/aps-values-and-code-of-conduct-in-practice) to uphold the reputation of ARPANSA. Inspectors are expected to be impartial, committed to service, accountable, respectful, and ethical. They have a responsibility to gather, use and protect information in accordance with the Australian Government Protective Security Policy Framework.

Inspectors are required to perform inspections in a professional manner and comply with the licence holder’s arrangements (where safe to do so) regarding:

1. site, building or room entry
2. adherence to security protocols
3. fire and emergency arrangements
4. workplace health and safety, including but not limited to, hazardous substances, dangerous goods or biohazards
5. ASNO safeguards, noting section 82 of the Act.

Inspectors are required to make an annual declaration of conflict of interest in accordance with the ARPANSA *Accountable Authority Instruction* (AIMS-AAI-COI-1). Guidance on conflict of interest is available in the ARPANSA intranet site.

### Assignment of inspectors

A lead inspector is usually assigned for each licence (by the Director of Source Safety and Security or the Director of Facility Safety) based on experience and competence and taking into account any declared conflict of interest.

Lead inspectors should be rotated periodically to:

1. improve organisational resilience
2. contribute to succession planning
3. improve teamwork and cooperation
4. avoid regulatory capture
5. enhance inspector experience and engagement

### Graded approach to inspection

Fundamental differences exist between facilities and sources including the complexity of operations, the life-cycle of controlled material and apparatus and their inherent hazards. A graded approach informed by risk is applied to the scope and frequency of inspections.

Inspection frequency is normally based on regulatory priority (RP). Facilities are assigned a RP using the methodology described in section 1.6. Sources are assigned a RP based on inherent hazard as described in Table 4.

### Regulatory priority of a facility

The following methodology is used to establish the regulatory priority of a facility. It is based on hazard and control – these two parameters are considered suitable as they are straightforward to assess based on existing information available to the lead inspector.

***Hazard***is a measure based on the consequence of potential harm to people and/or the environment. The hazard of a facility is determined in the application (Safety Analysis Report) and is assigned a number between 2[[2]](#footnote-2) (lowest hazard) and 4 (highest hazard).

***Control***is defined as the demonstrated ability to maintain safety of the facility. The control is assigned a number between 1 and 5. It is based initially on an evaluation of the licence application, and later by the licence holder’s compliance history.

#### Determining the RP of a facility

Table 1 should be used to calculate the regulatory priority of a facility. Guidance on how to evaluate the hazard and control of a facility is provided below.

TABLE 1: Regulatory Priority of Facilities

Control

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Hazard | Very high  1 | High  2 | Medium  3 | Limited  4 | Very limited  5 |
| 2 | 2 | 4 | 6 | 8 | 10 |
| 3 | 3 | 6 | 9 | 12 | 15 |
| 4 | 4 | 8 | 12 | 16 | 20 |

|  |  |  |
| --- | --- | --- |
|  | 1-4 | Low priority |
|  | 5-9 | Medium priority |
|  | 10-12 | High priority |
|  | 15-20 | Very high priority |

#### Evaluating the hazard of a facility

Table 2 should be used to categorise the hazard of a facility. The hazard is established according to the potential for significant consequences outside the facility or site.

TABLE 2: Hazard Level of a Facility

|  |  |
| --- | --- |
| Hazard category of facility | Hazard level  (to feed into matrix in Appendix B) |
| F3 potential for significant consequences outside the site | 4 |
| F2 potential for significant consequences on the site outside the facility, but not outside the site | 3 |
| F1 no potential for significant consequences outside the facility | 2 |

#### Evaluating the control of a facility

*Control* is defined as the demonstrated ability to maintain safety of facilities. There are five levels of control:

1. Very high

2. High

3. Medium

4. Limited

5. Very limited

Control is based initially on an evaluation of the licence application and later by the licence holder’s compliance history. This includes evaluation of a number of parameters and assessment of information available to ARPANSA. The assessment should take into account various sources of information which include the following:

* Inspection findings and licence holder’s response
* Information from quarterly reports
* Other reports provided to ARPANSA (for example incident or accident reports)
* Information presented to ARPANSA in various types of submissions
* Information obtained in meetings with licence holders

The table in Appendix B can be used as a guide to assist in determining the control for a licence holder. The list is not exclusive and the parameters should not be considered as absolute criteria. Other factors considered to impact on the control should be considered if relevant. The highest number obtained when assessing the licence holder against the criteria should be used as the control. This number will feed into Table 1 to determine the regulatory priority. If the control of the facility is not known a default control of 4 (limited) is used.

The level of engineered safety provisions will vary in type and scope of operation depending on the complexity of the facility and the stage of licensing. A graded approach should be applied, for example, a less sophisticated facility will not require as comprehensive plans and arrangements as a nuclear reactor.

ARPANSA guidelines such as [REGULATORY GUIDE: Plans and Arrangements for Managing Safety](https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/regulatory-guides#plans-and-arrangements-for-managing-safety) and [REGULATORY GUIDE: Holistic Safety Guidelines](https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/regulatory-guides#holistic-safety) may provide further guidance.

#### Review of regulatory priority

The RP of facilities is reviewed at least annually; RP will usually be reviewed after an inspection, following changes to a facility, or after an accident or incident. The flow chart in Appendix A shows the review process.

### Inspection schedule

ARPANSA maintains a three-yearly baseline inspection schedule for facilities and a six-yearly baseline inspection schedule for sources. Inspection schedules are reviewed annually. Licence holders have access to their relevant inspection schedule.

#### Facility inspection frequency

Table 3 provides the baseline inspection frequency for facilities. Adjustments to the schedule may be made in response to specific circumstances.

TABLE 3: Inspection Frequency for Facilities

|  |  |
| --- | --- |
| Regulatory Priority | Inspection Frequency |
| Very low | 4 – 5 years |
| Low | 3 - 4 years |
| Medium | 1 – 2 years |
| High | Annual |
| Very High | Quarterly |

#### Source inspection frequency

Table 4 provides the RP and inspection frequency for source licences. Inspection effort is based on regulatory priority, complexity of licence holder activities, and on site/geographical considerations and constraints. Where appropriate, an inspector may conduct a source inspection alone taking into account the location and complexity of the licence holder (see Table 5). To ensure efficient use of resources, source inspections may be conducted within a time window and be considered to having met the inspection schedule. Inspection of licence holders with sources of RP1 or RP2 may vary around the scheduled date by ± one quarter year. Inspections of licence holders with sources of RP3 to RP6 may vary around the scheduled date by ± two quarters.

Where a licence holder has a significantly large number of low hazard sources a subset or sample of sources may be inspected. In using this method, the inspector should consider the licence holder’s level of safety management over the sources.

Where an inspection of RP5 or RP6 sources is scheduled, a simplified approach such as an e-inspection or a limited scope inspection may be used. As a substitute for scheduled inspections of RP5 or RP6 sources, the frequency of licence holder compliance reporting may be increased from annual to six monthly.

Sources at remote locations may be inspected by e-inspection. Situations may arise where an e-inspection is also appropriate for sources other than RP5 or RP6. If so, approval should be sought from the Director, Source Control.

ARPANSA conducts information-sharing and educational activities to supplement this graded approach to regulatory oversight. Should compliance reports reveal any concerns, the regulatory officer reviewing the report is responsible for taking appropriate action which may include conducting an e-inspection or a physical inspection to verify compliance.

Where an inspection of RP5 or RP6 sources is scheduled, an e-inspection or a simplified approach such as a limited scope inspection may be used. Sources at remote locations may also be inspected by e-inspection. Situations may arise where an e-inspection is also appropriate for sources other than RP5/RP6. If so, approval should be sought from the Director, Source Control.

The performance of the licence holder will determine whether inspection frequency should be increased for low performance or whether a simplified inspection approach such a limited scope inspection has been earned for high performance.

Table 4: Regulatory Priority & Inspection Frequency for Sources

|  |  |  |  |
| --- | --- | --- | --- |
| Hazard Levela | Items from  Section 4 of Regulations | Regulatory Priority (RP) | Minimum Inspection Frequency (years) |
| 3 | G2-9, G3-1, G3-2, G3-7 | 1 | 1 |
| G3-3, G3-4, G3-5, G3-6, G3-8 | 2 | 2 |
| 2 | G1-4, G2-3, G2-4, G2-5, G2-6, G2-7 | 3 | 3 |
| G1-9, G1-15, G1-23(Class 4 ≥50W),G2-1, G2-2, G2-9(IED),G2-10, G2-11, G2-12, G2-13, G2-14 | 4 | 4 |
| 1 | G1-3, G1-6, G1-7, G1-8, G1-10, G1-12, G1-23(Class 4 <50W & Class 3B), G1-24(OFCS), G1-25, G2-8, G2-15 | 5b | 5 |
| G1-1, G1-2, G1-5, G1-11, G1-13, G1-14, G1-16, G1-17, G-1-18, G1-19, G1-20, G1-21, G1-22(all UV), G1-26 | 6b | 6 |

1. Based on hazard grouping Schedule 3C, Part 1 ARPANS Regulations
2. A simplified approach is suitable (e.g. e-inspection, limited scope inspection, review of licence holder quarterly or biannual reports)

Table 5: Regulatory Priority & Inspector Numbers

|  |  |  |
| --- | --- | --- |
| Regulatory Priority Based on Inherent Hazard of Source/Apparatus | Number of Inspectors | Frequency of Inspection (years) |
| 1 | 2 or more | 1 |
| 2 | 1 or 2 | 2 |
| 3 | 1 | 3 |
| 4 | 1 | 4 |
| 5 | 1 | 5a |
| 6 | 1 | 6a |
| Complex Sites | 2 or more | 3 |
| Augmented Inspections | As required | 0b |

1. A simplified inspection approach may be used (e.g. e-inspection, limited scope inspection)
2. May be triggered by, but not limited to, poor inspection results, notifications, incidents, accidents or significant compliance issues

#### Complex Sites

With the approval of the Director Source Safety and Security, a CSIRO site or geographical location with multiple CSIRO Business Units may be regarded as a ‘complex site’ and inspected by a team of two or more inspectors. A similar approach may be taken to inspections of Defence and Australian Federal Police sites or regions.

### Types of Inspection

#### Scheduled, augmented and unannounced inspections

Inspections are usually scheduled according to the baseline frequency described in section 1.7. Unscheduled inspections beyond the baseline may also be conducted. These ‘augmented’ inspections are likely to occur in response to specific circumstances such as an incident, accident, non-compliance or area for improvement. In such cases, targeted inspections of a defined scope will be planned, scheduled, and communicated to the licence holder.

In certain circumstances, it may be necessary to conduct an unannounced inspection. Such inspections are in response to a specific situation or event. The licence holder will be notified of the inspection prior to entry.

#### e-inspections

Licence holders with low hazard sources or with sources located in remote locations may be asked to provide evidence of effective control in the form of documentation and photographs for desktop review as an alternative to an inspector visiting the site. This inspection method is especially useful for sources located in remote areas or overseas, for example an X-ray baggage scanner located at an overseas embassy.

Inspectors may also consider relevant aspects of the [Performance Objectives and Criteria (PO&C)](http://www.arpansa.gov.au/regulation/inspections/POandC.cfm) including cross cutting aspects when undertaking an e-inspection.

### Functional inspection areas

Each inspection will focus on one or more of the eight functional areas in Table 6.

TABLE 6: Functional Inspection Areas

|  |  |  |
| --- | --- | --- |
| 1 | Performance Reporting Verification | A. Human Performance  B. Safety Culture  C. Performance improvement |
| 2 | Configuration Control |
| 3 | Inspection, Testing and Maintenance |
| 4 | Training |
| 5 | Event Protection |
| 6 | Security |
| 7 | Radiation Protection |
| 8 | Emergency Preparedness |

The cross-cutting aspects of human performance, safety culture, performance improvement usually apply to most inspected entities. PO&C are defined for each area and there is a single set of PO&C for sources.

### Preparing for an inspection

Inspectors should be thoroughly prepared. Preparation will depend on the type of inspection, and its scope and complexity. Preparation may include a review of the following:

* regulatory requirements relating to the source or facility and conditions of licence
* experience feedback relating to the inspection area
* findings and any unresolved issues from previous inspections (including areas for improvement)
* any enforcement actions in connection with the licence holder
* past correspondence between the regulatory body and the licence holder relating to the inspection area
* safety documentation and operational limits and conditions
* documentation on operation and design of the source or facility
* the licence holder’s management system
* performance history
* any other information made available to the lead inspector, including self-reported and independently reported information

### Conducting an inspection

All inspections (other than e-inspections) are conducted in accordance with the procedure described in section 2 of this manual using one or more of the following methods:

* monitoring and direct observation such as of work practices, performance of personnel, managerial attitudes, sources and equipment
* discussions with personnel
* examinations of procedures, records and documentation such as procedures and schedules for maintenance and testing; survey results and data; operational and maintenance records; records of deficiencies and incidents; modification records; training records; dose records
* confirmatory tests or measurements such as dose rate measurements

Inspectors do not normally conduct confirmatory tests or measurements that make it necessary to assume operational control of a source or facility or any of its systems. Where necessary, inspectors should seek the cooperation of the licence holder; for example, if an inspector wants to take measurements while a facility or source is in use, the licence holder should be asked to assist.

### Inspection reports and findings

The lead inspector prepares an inspection report to document the assessment of licence holder performance and record inspection findings. The report should be reviewed and approved according to the procedure described in section 2.

Inspection reports are distributed electronically, as per the procedure in section 2. Inspectors should discuss inspection findings at regular meetings to share lessons learned.

Inspection reports are published on the ARPANSA website. Security or commercially sensitive information is withheld.

### Follow-up

Inspectors are required to follow-up on inspection findings within three months and record actions in the appropriate RMS file and in LAD.

### Site Visits

Site visits supplement the inspection program but are not inspections. Generally, site visits are used by inspectors to familiarise themselves with processes, procedures or personnel. The information gathered is usually used to inform a decision-making process such as licence assessment, section 63 or section 65 request, or some other approval required under a licence condition. Site visits may also be used to share information with a licence holder or educate them on regulatory matters relevant to the activities they undertake.

Observations and information are recorded in a Site Visit Report. This report is not provided to the licence holder or published, however observations are expected to be discussed with management/personnel during the visit where relevant.

If non-compliance is identified during a site visit an unannounced inspection may be initiated. In this situation, the inspector should announce that they are now collecting evidence on behalf of the CEO of ARPANSA to assess compliance with the Act and Regulations. The inspection should proceed in accordance with the procedure in section 2 of this manual as appropriate.

The inspector must record site visits in LAD as they would for an inspection.

|  |
| --- |
| International guidance relevant to inspection:   1. TECDOC-1526 Inspection of Radiation Sources and Regulatory Enforcement (IAEA, 2007)   [Contains sample checklists for a variety of sources and facilities]   1. GSG-12 Organization, Management and Staffing of the Regulatory Body for Safety (2018) 2. GSG-13 Functions and Processes of the Regulatory Body for Safety (IAEA, 2018) |

# Inspection procedure

NOTE:

1. The lead inspector is responsible for implementing this procedure unless otherwise indicated
2. Not all parts of this procedure apply to e-inspections

# Preparation & planning

#### Purpose & scope

The purpose and scope of every inspection must be defined. For scheduled inspections this is usually focussed on one or more of the eight baseline inspection areas plus the three cross cutting areas. The associated PO&C are used to aid inspection planning and conduct.

Augmented inspections will generally focus on a particular area where there is evidence of possible non‑compliance or need for improvement.

#### Inspection file (optional)

The lead inspector may ask the Licence Admin Officer (LAO) to create an inspection file in the licence holder’s file container in the records management system (RMS) where all records relating to the inspection should be maintained (see Record Keeping in section 2.3.4). Alternatively, records may be saved in the licence file.

#### Inspection team

Members of the inspection team are selected based on the purpose and scope of the inspection and on the relevant experience and expertise required. Expert advice or technical assistance from other branches, jurisdictions or consultants may be sought where appropriate. The lead inspector should determine whether officers from another agency (e.g. Comcare or ASNO) should be involved. Security clearances should be considered as necessary depending on the licence holder’s access requirements. The lead inspector should ensure that team members have completed conflict of interest and confidentiality agreement declarations where appropriate.

Where the inspection involves facilities, sources or controlled apparatus used for medical purposes, the lead inspector should liaise with Medical Radiation Services Branch to involve officers from that branch in the inspection or to seek advice in planning. Further, if additional emergency preparedness and response expertise is required, advice should be sought from staff within the Radiation Health Services Branch – Monitoring and Emergency Response section.

Where ARPANSA is the licence holder, an officer from a state or territory regulatory authority must accompany ARPANSA inspectors to provide independent oversight. This is to fulfil the CEO’s obligation, and the obligation of all staff carrying out inspections on behalf of the CEO under subsection 15(2) of the Act, to take all reasonable steps to avoid any conflict of interest between regulatory functions and other functions. The lead inspector should discuss this with the relevant section director who will arrange for an appropriate regulator to participate in the inspection.

#### Document review

Documents are reviewed to identify issues relevant to the inspection. Such documents should include:

* PO&C
* Current licensing basis
* Recent applications for changes
* Recent regulatory assessment reports
* Licence holder’s policies/plans/procedures/source inventory workbook or other documentation
* Relevant correspondence between ARPANSA and the licence holder
* Previous inspection reports and outcomes
* Recent site visit reports and observations made
* Regulatory guides
* International Best Practice/ relevant international publications
* Previous inspection file notes
* Licence holder’s quarterly/annual compliance reports
* Any reports of accidents or incidents, including abnormal occurrences or near misses
* Endorsed security plan or other specific security considerations relevant to RPS11

#### Timetable

An inspection plan should be drafted which entails sufficient flexibility to allow for unforeseen events or the pursuit of further enquiries that emerge during the inspection.

Inspections should be performed during the licence holder’s normal working hours, unless special circumstances dictate otherwise. If performing an inspection outside working hours, the consent of the licence holder or occupier of the premises should be obtained. Where possible, the timing should consider the licence holder’s operations.

#### Notification

For scheduled inspections prior notification must be provided to avoid disruption of the licence holder’s operations, and to ensure that appropriate personnel are available.

The lead inspector should send an email notification to the licence holder/nominee and licence holder contact person at least two weeks prior to the inspection. The notification email should be copied to the relevant director.

In the case of an unannounced inspection, the notification email must be authorised by the Chief Regulatory Officer or delegate and provided to the licence holder prior to entry, where applicable.

The notification process may also include phone calls or emails to request documents before the inspection and/or to identify any documents to be produced at the inspection (such as internal audit reports, logbooks). Inspectors should identify persons or groups required for interview, any plant and equipment to be available, and any demonstration that may be required.

A *Workplace Hazard Identification Checklist* should be emailed to the licence holder for completion prior to the inspection where possible. Alternatively, the appraisal of hazards that may be encountered during an inspection may be discussed over the phone or during the entrance meeting and the information recorded. Workplace Identification Checklists should be saved in the RMS for work health safety purposes.

For e-inspections the notification will include a request for specific information and declaration. The date for submission will typically be 14 days from the date of notification.

The lead inspector must update LAD with details of the inspection when the notification is sent.

#### Logistics

Relevant checklists should be prepared and any equipment identified. For example: radiation detection equipment, specialised safety equipment or other electronics such as recording devices.

The lead inspector should determine the inspection timetable and travel arrangements and co-ordinate with any team members outside of Regulatory Services. Approvals are sought as necessary (See [Appendix C - Inspection flowchart](#_Appendix_1:_Report)).

# Conducting the inspection

#### Entrance meeting

An initial meeting with licence holder representatives is typically held for introductions and to:

* Confirm inspection purposes, scope, and timetable. In case of an unannounced inspection, where applicable, the inspection notification letter (signed by the branch head) is shown to the licence holder
* Reiterate inspection criteria
* Determine the approximate timing for the exit meeting
* Review relevant site safety and emergency procedures for the inspection team (review hazard notification form if necessary)
* Explain the role of inspectors
* In some cases, an introduction to ARPANSA and its regulatory functions may be appropriate.

The inspector must record all attendees. This may be done using the *Record of Meeting template*.

#### Information gathering

As outlined in section 67 of the Act, inspectors can gather information by searching, inspecting, examining, questioning, taking measurements of, conducting tests, taking photographs, video recordings, audio recordings or making sketches, and taking extracts and copies.

Problem development statements should be prepared during the course of the inspection and used as discussion points. These will form the basis of the inspection findings in addition to any identified potential non-compliance. Good practices should also be noted.

The inspection team should review the facts relating to the scope of the inspection to ensure information is adequately recorded. Draw preliminary conclusions and recommendations. All statements should be clear and substantiated. Agreement amongst team members is important.

If during the inspection or analysis of an inspection an issue is identified which has an immediate and significant impact on radiation or nuclear safety, it must be dealt with urgently and in advance of the formal inspection reporting process. The Chief Regulatory Officer must be notified as soon as reasonably practicable. Issuing an improvement notice may be appropriate under certain circumstances.

For multi-day inspections it may be useful for inspectors to conduct a review at the end of each day and a planning meeting each morning.

The transparency about findings is important so the licence holder has an opportunity to supply further information. Inspectors should not prescribe a solution for any identified issue as this responsibility rests with the licence holder.

#### Exit meeting

An exit meeting is held with licence holder representatives to outline observations and preliminary findings and reach agreement on the facts. The exit meeting does not have to be immediately after the inspection especially if there are documents to review or complex issues to resolve. The meeting may be held by phone or video conference as necessary.

Licence holder representatives should be informed that the inspection report will be made available for verification of technical accuracy and the final report will be published on the ARPANSA website. Where the report identifies areas for improvement they are expected to be addressed in a timely manner and within three months where possible.

Potential non-compliance, such as suspected failure to comply with the requirements of a licence condition, is more significant. Although the inspection team may describe a finding as a potential non-compliance, only the CEO (or delegate) can decide whether it is a breach. Should a potential non-compliance be identified in the report the licence holder will have an opportunity to make a written response. The licence holder should be reminded of their obligation under section 57 of the Regulations to investigate and rectify any potential breach as soon as reasonably practicable.

Ensure a record of attendees is made. Record of Meeting templatemay be used for this purpose.

# Reporting Inspection Outcomes

#### Inspection report

The appropriate report templateis used to document the inspection.

The report should be factual and concise, and should focus on the inspection scope*.* It should not identify any security or commercially sensitive information, such as security arrangements, or reveal any intellectual property. There must be evidence to support all potential non-compliance[[3]](#footnote-3) or areas for improvement. The body of the report should not contain the names of individuals; refer only to position title e.g. CEO, RSO, Nominee, WHS Manager. A table of names, positions and email addresses is included in the addendum that is removed before the report is published.

If measurements were taken during the inspection, the instrument used should be identified by make, model and serial number, and calibration details noted. If samples were taken, there should be a description of the sampling method and information on where, when, and how the samples were taken, and the process for measurement or assessment described.

Any additional matters identified during the inspection should be noted and addressed separately.

Where there has been independent oversight of the inspection, this must be indicated and where possible the report signed by the officer involved.

#### Review draft report

Draft inspection reports generally undergo the following reviews prior to sign-off:

1. **Peer review** by alternate inspector, other inspection team member (or optional review by another inspector)
2. **Licence holder review:** Where no non-compliance is found the inspector should send the draft report to the licence holder within 10 working days. The accuracy of the report should be agreed and any sensitive issues regarding publication of the report should be discussed.
3. **Section Director review:** The directors of Source Safety and Security and Facility Safety are responsible for the quality of inspection reports. The director should check the following:
   1. Use of correct template
   2. Observations address the scope of the inspection and provide sufficient detail and evidence to support findings
   3. Areas for improvement, potential non-compliance, and good practices are appropriate
   4. Consideration is given to common cause and extent of condition when defining areas for improvement or potential non-compliance
   5. Findings are described clearly and accurately and are within scope
   6. Directors will also determine whether a factual check by other expertise in ARPANSA is required and seek as necessary
4. **Quality review**: After the draft is cleared by the section director the lead inspector seeks a review from Safety Systems. The reviewing officer will provide advice on the report to the lead inspector and section director. Acceptance of advice is at the discretion of the section director.
5. **Legal review:** only required where there is potential non-compliance

* The lead inspector must also seek the legal opinion from the Legal Officer/General Counsel on potential non-compliances(Refer to the *Compliance & Enforcement Manual*)*.*

1. **Independent review** *–* only required where an inspection of ARPANSA is conducted. The lead inspector will seek the views of the independent regulatory officer (currently from Queensland Health) for independent verification purposes

#### Approval and issue

The final report is signed (electronically) by the lead inspector and the Chief Regulatory Officer (or delegate). Where there is potential non-compliance the Chief Regulatory Officer must sign the report.

Where there is no non-compliance the final report should be issued within 20 working days. This period includes steps 1–4 and 6 in paragraph 2.12.

Where there is potential non-compliance the inspector should issue the final report within 40 working days. This period allows for all review steps 1-6 in paragraph 2.12.

The lead inspector should consider any information sharing that may be relevant under a MOU with another agency such as Comcare or ASNO.

The lead inspector should also consider whether the report contains any sensitive findings likely to require media management or that need to be brought to the Minister’s attention. In such cases the Office of the CEO (OCEO) should be advised to allow sufficient lead-time to prepare talking points, briefs etc.

The final report is sent to the LAO[[4]](#footnote-4) who converts it to a pdf and emails it to the nominee and licence holder representatives.

NOTE: Because the inspection report is agreed with the licence holder prior to its issue the need to reissue a report is unlikely to occur. However, should this be required, the reason for reissue should be clearly documented and the same approval process followed. The report should be marked accordingly.

#### Record keeping

The report must be saved in the RMS using the ‘Inspection Report’ record type.

All documents associated with preparation, performance, reporting and follow-up of the inspection must be saved in the appropriate the RMS records file; this may include scanned checklists or handwritten notes, photos and/or electronic recordings.

Relevant information must be entered into LAD. Areas for improvement must be separately entered. Where an inspection report covers more than one licence any areas for improvement should be assigned against the relevant licence.

Where an inspection file has been raised actions against any potential non-compliances or areas for improvement should be recorded before it is closed. Potential Non Compliances must also be entered into LAD.

#### Publish report & request post-inspection survey

The LAO removes the addendum and sends a request to the Office of the CEO (OCEO) for this public version of the final report to be published after taking into account any security or sensitive issues. The LAO also requests the OCEO to organised a post-inspection survey.

# Review & Follow-up

#### Review of facility regulatory priority

The regulatory priority for facilities should be reviewed and revised as per Appendix A and LAD updated accordingly.

#### Follow-up areas for improvement and potential non-compliance

Actions to address areas for improvement are expected to be taken within three months. Inspectors should follow up with the licence holder and record the actions in LAD.

In the case of potential non-compliance, the inspector should ensure that the licence holder responds within the defined period. The licence holder’s response should be taken into account to determine the appropriate action in accordance with the Compliance and Enforcement Manual.

#### Feedback & lessons learned

Feedback from the online survey is regularly collated and analysed by Safety Systems section. Outcomes from inspections and licence holder feedback should be discussed at section meetings and are evaluated during review of the inspection program described in section 1. An analysis of inspection outcomes is periodically published on the ARPANSA website.

# Inspector competencies

### Skills

Inspectors shouldpossess or be actively acquiring the following skills, and periodically undertake refresher training in the use of these skills:

* Methods of audit and investigation
* Report writing
* Radiation monitoring and measurement
* Principles of evidence gathering

### Knowledge

Inspectors should possess or be actively acquiring knowledge of the following:

* Regulatory framework: High-level knowledge of the level of responsibility of ARPANSA inspectors and the extent of their authority as set out in the Act and Regulations.
* Safety and security: High-level knowledge of applicable radiation protection and nuclear safety requirements, standards and codes of practice.
* The licence: High-level knowledge of the controlled facility, controlled apparatus or controlled material and specific knowledge of the licence holder’s conduct or dealing. This includes expert knowledge of the content of the Act and Regulations, the licence, licence conditions and current licensing basis.
* The licence holders’ systems: Good knowledge of the licence holder’s policies, procedures and practices for ensuring effective control, safety management, radiation protection, radioactive waste management, security, emergency response, and environment protection.
* Appropriate methods of information/evidence collection, labelling and storage.
* Inspection criteria

### Training & skills development

The inspector training and skills development program is a set of training courses and workshops approved by the Chief Regulatory Officer, to provide an inspector or prospective inspector with the skills and competencies necessary to effectively exercise inspection powers and perform inspection functions under the Act (see Table 7).

#### Recognition of prior learning

Previous training and experience of an individual will be taken into account to determine training requirements.

#### Refresher training

Inspectors should actively maintain the currency of their knowledge and skills pertinent to inspections and site visits and participate in a sufficient number of inspections per year to maintain proficiency.

**TABLE 7: Inspector Training Requirements**

|  |  |  |
| --- | --- | --- |
| Training Requirement | Approximate Duration | Provider |
| Certificate IV in Government (Statutory compliance) or equivalent | 3 days (face to face) + post-course assignments | External |
| Legal Awareness | ½ day | In-house |
| Report writing | ½ day | In-house |
| Radiation monitoring instrumentation | ½ day | In-house |
| WHS for Inspectors and familiarisation with the PACE technique (Preparation, Accountability, Communication, Evacuation route) | 1 day | External and  In-house |
| Methods of collecting information and evidence | 1-2 days | External |
| Security Awareness | ½ day | In-house |
| Holistic Safety Awareness | ½ day | In-house |

NOTE: Attendance at the nominated courses is mandatory unless an inspector can demonstrate alternative completion or equivalent experience.

# Inspector health, safety & security

Each inspector must take steps to protect his/her own health and safety. The *ARPANSA Radiation Safety Policy*, *Radiation Safety Manual* and *Ionising Radiation Safety Procedures* provide radiation safety advice for general radiation protection situations.

### Radiation protection

Inspectors and other team members should be fully aware of the radiation protection and nuclear safety issues likely to be encountered during a particular inspection. In preparation for an inspection, the Workplace Hazard Identification Checklist should be reviewed to identify potential hazards that may be encountered onsite. If required, inspectors should obtain further advice from the licence holder’s Radiation Safety Officer (RSO) or representative.

The following safety measures should be implemented:

* Inspectors must ensure that a personal dosimeter is worn at all times, positioned externally on the clothing somewhere appropriate between the waist and chest.
* The inspection team should ensure they either carry an electron personal dosimeter (EPD) if ambient external dose rates are expected to be significantly above background or confirm with the licence holder representative if they will be issued for use during the inspection. The EPD should be checked at frequent intervals during the inspection to monitor the dose recorded.
* If using an EPD, the inspector should establish normal ambient radiation levels and set appropriate alarm levels on the EPD before entering any radiation area. Any radiation dose recorded on an EPD should be noted. If an EPD should alarm, the inspector should move to an area of lower radiation dose rate and assess the situation.
* If the inspector has to enter a clean area, then they should follow the local procedures described by the licence holder representative. Clean area procedures may include the inspector wearing a laboratory coat or apron, gloves, hair cap, shoe covers and using a hand and foot monitor.
* If there is a radiological incident, the inspector should follow the advice from the licence holder’s RSO and comply with local procedures. On return to the office an ARPANSA incident form should also be completed.

### Travel safety and security

Inter-city travel and travel to larger regional centres will generally not require any special considerations beyond normal travel precautions.

However, for inspections or site visits to remote locations a risk assessment should be carried out by the lead inspector prior to travel. It should determine whether it is safe for an inspector to travel and work alone. The need for suitable communication equipment such as satellite phone or a personal satellite tracking device must be considered.

[Comcare guidance on working in remote and isolated locations](https://www.comcare.gov.au/Forms_and_Publications/publications/services/safety_and_prevention/safety_and_prevention/guide_to_remote_or_isolated_work) or [Safework Australia remote or isolated work](https://www.safeworkaustralia.gov.au/remote-work) may be useful in the risk assessment.

# Review of inspection program

The inspection program is regularly reviewed to ensure that it is risk informed and flexible to meet the needs of licence holders while assuring compliance with the Act and maintaining high levels of nuclear and radiation safety and security. To achieve this, a number of review processes are implemented which include:

* A review of the inspection schedule following any significant inspection findings to determine whether an augmented inspection is required. This is undertaken by the lead inspector.
* A survey sent to the licence holder after each inspection. The survey results are analysed on a six monthly basis to identify any improvements to the inspection program or process.
* A quarterly review of inspection findings and survey responses and results circulated to all inspectors.
* An annual review of inspection findings, emerging trends, significant issues, compliments, complaints and quality audit finding.
* The mandatory annual self-assessment of ARPANSA’s regulatory performance in accordance with the Government Regulator Performance Framework.
* Periodic review of lead inspector assignment (see paragraph 1.3)
* Review of this manual on a two-yearly cycle as required by the Regulatory Management System or sooner as necessary.

These reviews are used to facilitate continuous improvement in the regulatory framework and practices and to inform the Regulatory Services training program.

Any non-conformance with this procedure or identified improvements will be managed through the corrective action program established under the agency’s integrated management system. Information on the outcomes of such reviews is published on the ARPANSA website.

# Terms and definitions

|  |  |
| --- | --- |
| Term | Definition |
| Area For Improvement (AFI) | an identified opportunity to improve performance to achieve best practice rather than minimal compliance. It is distinct from a non-compliance with the Act, the Regulations or a licence condition. An area for improvement may be found where, despite reasonably practicable steps taken by the licence holder, an isolated instance of non-conformance with low safety significance has occurred. |
| Augmented Inspection | an inspection beyond the baseline. |
| Controlled person | is defined in the Act as  a Commonwealth entity  a Commonwealth contractor  a person, in the capacity of a Commonwealth contractor  a person an a prescribed Commonwealth place |
| DiD | Defence in Depth |
| e-inspection | an inspection that is conducted remotely via a desk top review without the need for an inspector to attend the site. This type of inspection may be used for licence holders with low hazard sources or sources in remote locations or overseas. |
| EPD | Electronic Personal Dosimeter |
| Good practice | a program, practice, activity or arrangement that the inspector regards as superior to that generally observed elsewhere. A good practice goes beyond the fulfilment of current requirements or expectations; and is worthy of the attention of other licence holders as a model in the pursuit of excellence. |
| Inspection | the act of assessing licence holder performance to determine whether controlled material, controlled apparatus or a controlled facility is being used safely and in compliance with the Act, the Regulations and licence conditions. Inspections are generally proactive, that is, scheduled and planned but may be reactive in response to regulatory events such as relevant changes, incidents, accidents or non-compliances. |
| Inspection Schedule | ARPANSA’s program of inspections of licence holders and other controlled persons including Commonwealth contractors. The schedule is informed by the licence holder’s compliance record and radiation and nuclear safety performance commensurate with the hazards and risks associated with the particular conducts and/or dealings authorised under the particular source or facility licence which is reflected in their risk ranking or regulatory priority. The baseline inspection schedule defines the minimum number of inspections to evaluate licence holder performance over the baseline period. |
| Inspection Team | a group of persons involved in a particular inspection. In addition to the inspector(s), the group may comprise other regulatory officers or technical/scientific experts from ARPANSA or other agencies. Distinctions between inspectors and team members who are not appointed as inspectors will be carefully managed to ensure appropriate exercise of inspection powers. |
| Inspector | a person appointed or employed by the Commonwealth or by a State or Territory who is appointed by instrument in writing under section 62 of the Act. |
| LAD | the Licence Administration Database |
| LAO | Licence Administration Officer |
| Lead Inspector | the leader of an inspection team. In most cases, this will be the inspector responsible for the assessment of a controlled person’s licence application(s) or monitoring of the licence holder’s compliance. |
| MOU | Memorandum of Understanding |
| Potential non-compliance | the situation that exists when facts indicate that requirements in the Act, the Regulations, or one or more licence conditions may not have been met. |
| Radiation risk | is defined in the Policy for ARPANSA’s Regulatory Activities (ARPANSA-POL-002) as: Detrimental health effects of exposure to ionising radiation including the likelihood of such effects occurring, and other risks including environmental risks, that might arise from exposure to ionising radiation; the presence of radioactive material (including radioactive waste) or its release to the environment; or a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation; alone or in combination.  Health effects and health risks associated with acute or prolonged exposure to non-ionising radiation such as ultraviolet radiation, radiofrequency radiation, optical radiation and other types of non-ionising radiation; either in occupational settings or as members of the public. |
| RP | Regulatory Priority |
| Safety | For the purpose of this manual, safety refers to all factors that contribute protection of people and the environment from harmful effects of radiation, which includes radiation protection and safety, nuclear safety, waste safety, transport safety, physical protection and security, and emergency preparedness and response. |
| Site Visit | a visit by an inspector to the premises of an applicant or licence holder for the purpose of gathering information about a facility or source, associated processes or procedures, and/or personnel. It may also be for information sharing or educational purposes relevant to the licence. |
| SS | Safety Systems |
| SSC | Structured Systems and Components |
| Technical/Scientific Advisor | a technical/scientific expert requested to provide advice or scientific services or to participate in an inspection. |
| WHS | Work Health and Safety |

## 

# References

|  |  |
| --- | --- |
| Acronym/abbreviation/ Document ID | Title |
| The Act | [Australian Radiation Protection and Nuclear Safety Act 1998](https://www.legislation.gov.au/Details/C2016C00977) |
| The Regulations | Australian Radiation Protection and Nuclear Safety Regulations 2018 |
| AS/NZS 2243.4:2018 | Australian Standard - Safety in Laboratories. Part 4, Ionizing Radiations |
| NDRP | National Directory for Radiation Protection |
| REG-COM-SUP-274A | REGULATORY GUIDE: Reporting an Accident |
| REG-LA-SUP-280B | REGULATORY GUIDE: Plans and arrangements for managing safety |
| ARPANSA-POL-002 | Policy for ARPANSA’s Regulatory Activities |
| AIMS-AAI-COI-1 | ARPANSA Accountable Authority Instruction |
| PO&C | Performance Objectives and Criteria |
| REG-LA-FORM-242B | [Site Visit Report](trim://R10%2f05424?db=VP&edit) template |
| ARPANSA-REG-COM-MAN-270 | [Compliance & Enforcement Manual](trim://R15%2f08485/?db=VP&edit) |
|  | [Comcare guidance on working in remote and isolated locations](https://www.comcare.gov.au/Forms_and_Publications/publications/services/safety_and_prevention/safety_and_prevention/guide_to_remote_or_isolated_work) |
|  | [Safework Australia remote or isolated work](https://www.safeworkaustralia.gov.au/remote-work) |

# Appendix A: Review of regulatory priority



# Appendix B: Levels of control for facilities

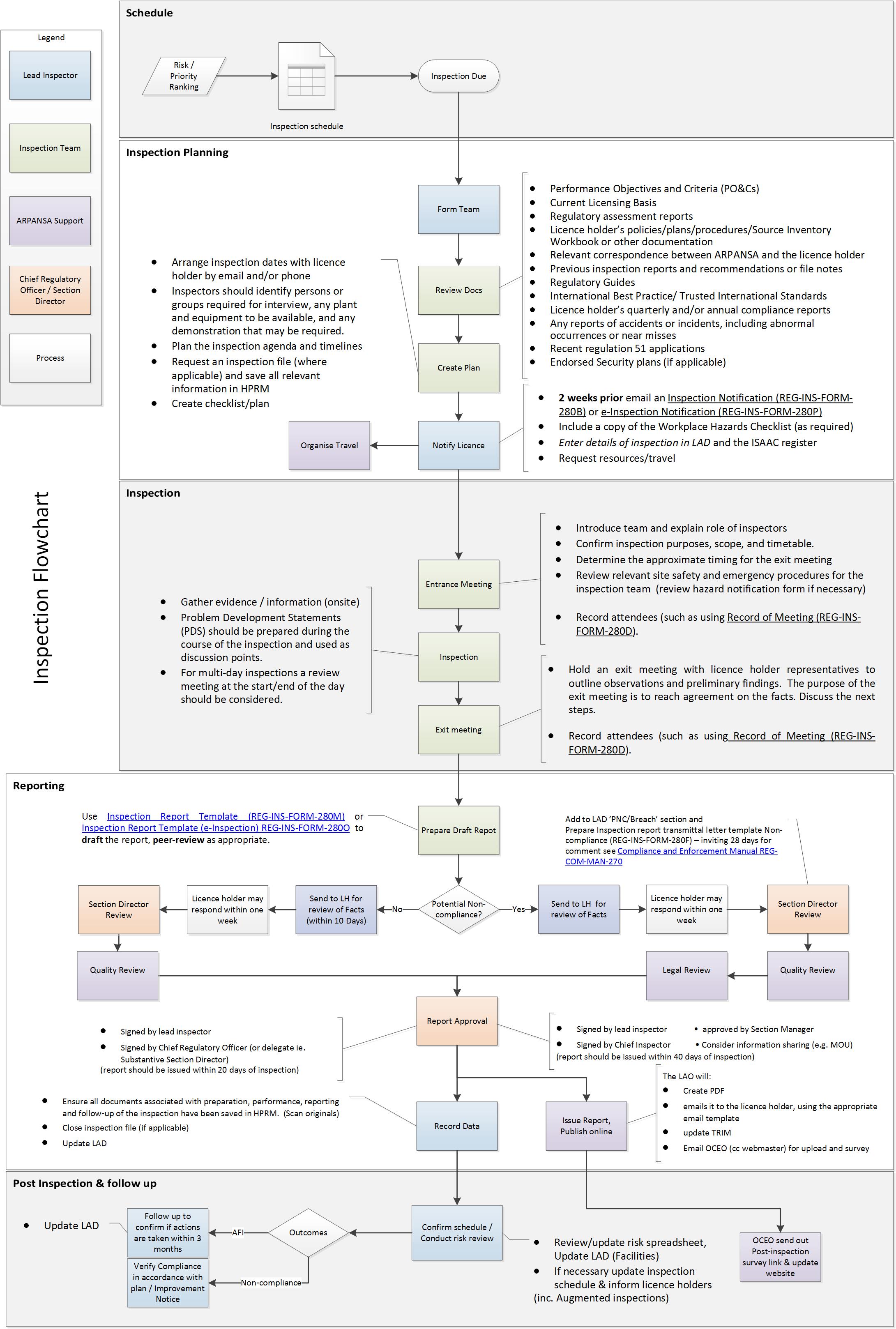
| Control | Areas for improvement (AFI) | Site visits | Compliance with licence conditions having significant implications for safety | Compliance with licence conditions having no or minor implications for safety | Incidents/ Accidents1 | Defence in Depth (DiD) (if relevant) | Plans and Arrangements3 | Safety performance and change control monitoring | Other holistic safety2 aspects |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1  Very high | No AFI within last 12 months or scheduled inspection cycle, whichever period is greater | Site visit has been conducted within last year | No non-compliances within last year | No non-compliances within last year | No incidents or accidents within last year | DiD well designed and well implemented, maintenance of all SSC of all levels is effective. | Detailed knowledge of plans and arrangements exists. P&As are well developed and reviewed annually | Safety performance is systematically monitored  Change is systematically monitored for effectiveness | Detailed knowledge of holistic safety exists & assessed as good |
| 2  High | One or more AFI within last 12 months or scheduled inspection cycle, whichever period is greater | Site visit has been conducted within last 2 years |  |  |  | DiD well designed and well implemented, maintenance of some systems of some levels of DiD has shortfalls with no consequences on prevention, control and mitigation of potential accidents | General knowledge of plans and arrangements exists. P&As are well developed and are reviewed annually | Safety performance is not systematically monitored  Change is not systematically monitored for effectiveness | General knowledge of holistic safety exists & is assessed as good |
| 3  Medium | Five or more AFI within last 12 months or scheduled inspection cycle, whichever period is greater | Site visit has not been conducted within the last 2 years |  | A non-compliance within the last year |  | DiD is designed and implemented acceptably. Some SSC of DiD level 1, 2, 4 and 5 have minor insufficiencies which could impact on prevention of accidents and mitigation of their consequences | Plans and arrangements fulfil minimum requirements. The most important documents are reviewed annually by the licence holder | Safety performance is not monitored  Change is never monitored for effectiveness | No indications that holistic safety is inadequate |
| 4  Limited | Ten or more AFI within last 12 months or scheduled inspection cycle, whichever period is greater |  | A non-compliance within the last year | Several non-compliances within the last year | One incident or near-miss within the last year | DiD is designed and implemented acceptably. Some SSC of DiD level 3 – safety systems have minor insufficiencies which could impact on control of accidents  Some SSC of DiD level 1, 2, 4 and 5 have major insufficiencies which could impact on prevention of accidents and mitigation of their consequences | Plans and arrangements do not fulfil minimum requirements |  | Holistic safety assessed as inadequate |
| 5  Very limited | 20 or more AFI within past 12 months or scheduled inspection cycle, whichever period is greater |  | Several non-compliances within last year |  | One accident within the last year | DiD designed and implemented acceptably; systems of multiple levels of DiD are poorly maintained or operated with potential major impact on DiD prevention, control and mitigation of accident situations. | Plans and arrangements are well below minimum requirements |  | Holistic safety assessed as poor |

1 Incidents are as defined in Schedule 13 of the National Directory for Radiation Protection ([NDRP](https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/national-directory-for-radiation-protection)) and accidents defined in [REGULATORY GUIDE: Reporting an Accident](https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/regulatory-guides#reporting-an-accident)

2 Refer to the [Holistic Safety Guidelines](https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/regulatory-guides#holistic-safety) for more detail.

3Refer to [REGULATORY GUIDE: Plans and Arrangements for Managing Safety](https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/regulatory-guides#plans-and-arrangements-for-managing-safety)for more detail.

# Appendix C: Inspection flowchart



1. Inspection program will only identify prohibited activities undertaken by controlled persons who are licensed for another activity. Targeted awareness campaigns will be conducted periodically to promote licensing and identify prohibited activity. [↑](#footnote-ref-1)
2. Scale starts at 2 to provide greater resolution [↑](#footnote-ref-2)
3. Use only the term ‘potential non-compliance’. Whether a potential non-compliance constitutes a breach will be determined after further consideration and after the licence holder has been given the opportunity to respond – see Compliance & Enforcement Manual. [↑](#footnote-ref-3)
4. If the LAO is not available, the inspector may send the pdf report to the licence holder but must send a copy to Licence Administration. [↑](#footnote-ref-4)