



## **REGULATORY SERVICES**

# **INSPECTION MANUAL**

Guide for regulatory officers on the management & implementation of ARPANSA's inspection program

## Introduction

ARPANSA's Regulatory Activities Policy (ARPANSA-POL-0002) provides the over-arching framework for efficient and effective regulatory activities to achieve the object of the Australian Radiation Protection and Nuclear Safety Act 1998 (the Act) which is to protect the health and safety of people, and to protect the environment, from the harmful effects of radiation. This manual should be read in conjunction with that policy.

This manual provides guidance to regulatory officers on ARPANSA's inspection program, in particular the planning, conduct and reporting of inspections. It provides information on how a graded approach is applied to determine inspection scope and frequency.

By making the manual available on ARPANSA's website, licence holders and interested parties are informed of how ARPANSA manages and implements its regulatory inspection program. Process descriptions, flow-charts, templates, and other detailed elements of the integrated management systems are not included in the online version of this Manual.

ARPANSA's processes for review and assessment of licence applications, requests for exemption, significant changes, and other submissions seeking to undertake activities that require prior approval from the CEO of ARPANSA are described in the Review & Assessment Manual, while the Compliance Manual describes how ARPANSA promotes compliance and manages non-compliance.

Inspection does not diminish the prime responsibility for safety of the licence holder and cannot substitute for the control, supervision and verification activities that the licence holder is expected to implement.

### In this document:

- 1. <u>Inspection principles</u>
- 2. <u>Inspection process</u>
- 3. Inspector health, safety and security
- 4. Glossary

### Detailed management system elements that are not part of the online version of this manual:

Appendix 1: Levels of controls for facilities

Appendix 2: Inspection flowchart

Appendix 3: Radiation monitoring equipment

Appendix 4: Report writing guide

Appendix 5: Convention for citing legislation

Appendix 6: Record of meeting template

Attachment A: Email templates

### Summary of changes to this version of the manual:

- Note added to paragraph 1.2 that only appointed inspectors are to sign the inspection report.
- References to LAD updated to RAD, along with information to explain the use of RAD for certain processes.
- Updates of and additions to: Appendix 4 Report Writing Guide and Appendix 5 Convention for citing legislation.
- Updates of Attachment A: Email and letter templates.
- Updates of some links.
- Update of measurement equipment storage and calibration process.
- Updates following the decision to stop publishing inspection reports from March 2025.

# 1. General inspection principles

This manual elaborates on the policy statement and supporting principles outlined in ARPANSA's Regulatory Activities Policy (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. Much of the practical guidance in this manual is taken from IAEA publications including Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards GSR Part 3, 2014 and General Safety Guide GSG-13 Functions and Processes of the Regulatory Body for Safety, 2018.

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.

### 1.1 Objectives

The fundamental objective of ARPANSA's inspection program is to review and assess safety of licence holders' activities. The program will assist in providing assurance to the Australian community that activities involving radiation facilities and sources do not pose an undue radiation risk to people and the environment.

The inspection program is designed to:

- identify activities prohibited under the *Australian Radiation Protection and Nuclear Safety Act*1998 (the Act) that are being undertaken without appropriate authorisation or exemption<sup>1</sup>
- assess and verify licence holder compliance with the Act, the Australian Radiation Protection and Nuclear Safety Regulations 2018 (the Regulations) and licence conditions
- 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.

### 1.2 Competence of regulatory staff & appointment of inspectors

The qualifications, competence and training required to be appointed as an inspector under section 62 of the Act are described in <u>ARPANSA-GDE-1765 Inspector training & competence manual.</u>

The Lead Inspector exercising inspection powers must be a properly appointed Inspector. This appointment takes the form of having been issued with a valid 'Inspector Badge' by the CEO of ARPANSA. The Lead Inspector signs the inspection report, in addition to other appointed inspectors present.

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

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<sup>&</sup>lt;sup>1</sup> ARPANSA's 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.

### Responsibilities & personal conduct of inspectors

Inspectors must behave in accordance with the APS Values and APS Code of Conduct 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:

- site, building or room entry
- adherence to security protocols
- fire and emergency arrangements
- workplace health and safety including, but not limited to, hazardous substances, dangerous goods or biohazards
- 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 (ARPANSA-FORM-2193). Guidance on conflict of interest is available at: https://arpansaonline.sharepoint.com/sites/AMS/SitePages/Conflicts-of-interest-(AAI).aspx

### 1.4 Assignment of inspectors

A Lead Inspector is assigned for each licence based on experience and competence and taking into account any declared conflict of interest.

Lead Inspectors are rotated periodically to:

- improve organisational resilience
- contribute to succession planning
- improve teamwork and cooperation
- avoid regulatory capture
- enhance inspector experience and engagement.

### 1.5 Graded approach to inspection

Fundamental differences exist between facilities and sources including the complexity of operations, the life-cycle of facilities, 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 paragraph 1.6. Sources are assigned a RP based on inherent hazard and aligned with Groups 1 - 3 in section 4 of the Regulations.

### 1.6 Regulatory priority of facilities

### Establishing Prescribed Radiation Facility (PRF) risk (includes legacy sites)

Two groups of PRFs are distinguished based on their complexity and potential hazard:

Group 1: includes low hazard facilities with a relatively low level of complexity such as waste stores, LINACs, general irradiators and accelerators.

Group 2: includes facilities with a higher hazard level and complexity such as waste repositories, synchrotrons, pharmaceutical production / research facilities and waste research facilities, waste processing facilities and pool-type irradiators.

The resultant numbers presented in the matrix in Table 1 are indicators of the risk level (the higher the risk, the higher the number). Note non-linearity of the risk level as it best matches the range of PRFs.

TABLE 1: PRESCRIBED RADIATION FACILITY (PRF) RISK GROUPING

PRF	Level of Control					
(type, complexity, potential hazard)	Very High	High 2	Medium 3	Lower 4	Limited 5	
LINAC, general irradiator,     accelerator	1	2	3	5	6	
Medium risk PRF - waste     repository, synchrotron,     pharmaceutical and waste     research, waste processing, pool- type irradiator	2	4	6	8	10	

TABLE 2: INSPECTION SCHEDULING BASED ON REGULATORY PRIORITY

		200	Inspectio		
Reg priority	Risk level indicator	POC module cycle length (years)	# of inspections in POC module cycle	Depth (# of POC modules)	# of quarters between inspections
PRF Very Low (VL)	1-2	2-3	1	8	8-12
PRF Low (L)	3-4	2	1	8	8
PRF Med (M)	5-8	1-2	1	8	4-8
PRF High (H)	9-11	1-2	2	4	2-4

### Determining the level of control of a PRF

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. Lower
- 5. 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:

- 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

Appendix 1 should be used as a guide to assist in determining the level of control for a facility. The list is not exclusive and the parameters should not be considered as absolute criteria. The highest number obtained when assessing the licence holder against the criteria should determine the level of control. This number is entered into Table 1 to determine the regulatory priority. If the control of the facility is not known a default control of 4 (lower) should be 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 and REGULATORY GUIDE: Holistic Safety Guidelines may provide further guidance.

## Determining the inspection schedule for PRFs

From the facility risk group and assessed level of control the Lead Inspector will determine the format of the inspection schedule. The colour coded regulatory priority established in Table 1 allocates the level of risk; this together with the POC module cycle length, number of inspections per POC module cycle, and number of POC modules per inspection, determines the inspection frequency. Where a value range instead of a single value is presented in Table 2 the Lead Inspector establishes an appropriate POC module cycle at her/his discretion.

ARPANSA maintains a three-yearly inspection schedule for PRFs and provides this to licence holders.

### Establishing Nuclear Installation risk

The risk grouping is based on the emergency planning categorisation (EPC) as defined in ARPANSA's RPS G-3. ARPANSA currently regulates only two facilities that are categorised as EPC II. These are the OPAL Reactor and ANSTO ANM. The OPAL reactor is more complex than ANM and as such OPAL is allocated to a higher risk group.

There are four hazard groups for nuclear installations:

Group 1: includes facilities of lowest hazard and complexity such as waste stores and facilities normally of higher risk but which are currently under a 'possession or control', siting or construction licence. This group includes the HIFAR defuelled facility and the Intermediate Waste Store.

Group 2: includes waste processing facilities and radiopharmaceutical facilities that have no off-site consequences. This group includes ANSTO Waste Management and Health Products.

**Group 3:** includes fuel cycle or radiopharmaceutical processing facilities with an off-site consequence. There is currently only one facility – ANSTO ANM in this group.

Group 4: includes Australia's only operating research reactor – the OPAL Reactor

The risk level indicators are included in the matrix cells in Table 3. Note non-linearity of the risk level as it best matches the range of licensed facilities.

TABLE 3: DETERMINING NUCLEAR INSTALLATION (NI) REGULATORY PRIORITY

	Level of Control				
Nuclear Installation (NI) (type, complexity, potential hazard)	Very High	High 2	Medium 3	Lower 4	Limited 5
Very low NI - waste store, facilities of higher category but under P or C, siting, or construction licence	1	3	6	9	12
2. Low risk NI - waste processing, radio pharm processing with no off-site effect	3	6	9	12	15
3. Medium risk NI - fuel cycle or radio pharm processing with off-site effect	5	9	13	17	21
4. High risk NI - research reactor	9	13	17	21	25

## Determining the level of control of a Nuclear Installation

Appendix 1 is used for determining the level of control of NIs. Additional aspects specific to assessment of NIs are included in that table.

### Determining the inspection schedule for Nuclear Installations

Similar to the determination of the PRF inspection schedule format, the NI inspection format presented in Table 4 is based on the POC module cycle length, number of inspections in a POC module cycle and inspection depth defined by the number of POC modules per inspection. ARPANSA maintains a threeyearly inspection schedule for nuclear installations and provides this to licence holders.

TABLE 4: DETERMINING NUCLEAR INSTALLATION (NI) INSPECTION SCHEDULE FORMAT

		POC module cycle	Inspecti	H = f =	
Reg priority	Risk level indicator	length (years)	# of inspections in POC module cycle	Depth (# of POC modules)	# of quarters between inspections
NI Very Low (VL)	1-2	2-3	1	8	8-12
NI Low (L)	3-4	2	1	8	8
NI Med-Low (ML)	5-8	2.5	2	4-8	5
NI Med (M)	9-11	2	2	4	4
NI Med-High (MH)	12-13	2.5	4	2	2-3 (e.g. 3, 3, 2, 2)
NI High (H)	14-17	2	4	2	2 (every second quarter)
NI Very High (VH)	18-25	2	8	1	1 (every quarter)

In case of RP amendment, the start of the next POC cycle is to be selected in such a way that POC modules are rotated periodically. Alternatively, the Lead Inspector may alter the sequence of the POC modules for the next period so it better fits the result of the control assessment and the aspects of determining the level of control. For example, POC BM2 may be selected for the next inspection if a NI facility had a noncompliance such as in the change control system within the last 12 months. This adjustment in the POC module sequence can be made irrespective of when the facility was last inspected on BM2. However, the POC sequence alteration may not be the best option if that non-compliance occurred before the previous reassessment (presuming 12 months ago) and the POC was altered at that time.

If the next inspection is already overdue due to a dramatic increase in RP the next inspection should be carried out as soon as possible. This may happen for example if the RP of a NI currently assessed as a 'low' and last inspection was conducted 9 months ago increases to 'high'. When the priority is updated the inspection frequency is already overdue as the last inspection was completed 9 months ago and the new frequency requires inspection every second quarter. In that case the Lead Inspector should consider conducting a reactive inspection instead of a scheduled one as that kind of inspection can better focus on problematic areas. Consequently, the next scheduled inspection should be organised for the quarter following the reactive inspection. Alternatively, a scheduled inspection is conducted as soon as possible (within the current quarter) with a suitable POC module selection.

It may be more practical for some facilities to conduct multiple inspections with fewer modules than the inspection schedule proposes, e.g. F0260 that comprises many buildings and processes. The RO's discretion should be applied provided the inspection cycle is maintained.

The inspection schedule for all facility licence holders may be adjusted to balance the numbers of inspections per individual, the number of inspections over each quarter, and the geographical location of the facility. Therefore the final facility inspection schedule may be relatively adjusted from the specific licence inspection frequencies established by the prioritisation process within a range of ±1 quarter.

### Review of regulatory priority of facilities

The RP of facilities is reviewed at least annually; RP is usually reviewed after an inspection, following changes to a facility, or after an accident or incident. The flow chart in Appendix 1 shows the review process.

#### **Regulatory priority of sources** 1.7

Table 5 provides the RP and inspection frequency for sources. Inspection effort is based on regulatory priority, complexity of licence holder activities, and on site/geographical considerations and constraints. Table 6 shows the number of inspectors based on these factors.

Where appropriate, an inspector may conduct a source inspection alone taking into account the location and complexity of the source/dealing. To ensure efficient use of resources, source inspections may be conducted within a time window and be considered to have met the inspection schedule. Inspection of RP1 or RP2 sources may vary around the scheduled date by ± one quarter year. Inspections of RP3 - RP6 sources may vary around the scheduled date by ± two quarters. Inspections may be scheduled before the time window if warranted.

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 of its sources.

TABLE 5: REGULATORY PRIORITY & INSPECTION FREQUENCY FOR SOURCES

Hazard Level <sup>a</sup>	Items from Section 4 of Regulations	Regulatory Priority (RP)	Maximum Inspection Interval (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	5 <sup>b</sup>	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	6 <sup>b</sup>	6

- a. Based largely on hazard grouping in section 4 of the Regulations
- b. A simplified approach is suitable (e.g. e-inspection, limited scope inspection, review of licence holder quarterly or biannual reports)

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 Safety and Security.

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.

The performance of the licence holder will determine whether inspection frequency should be increased for poor performance or whether a simplified inspection approach such a limited scope inspection has been earned for consistently high performance - see Table 6.

TABLE 6: REGULATORY PRIORITY & INSPECTOR NUMBERS

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

a. A simplified inspection approach may be used (e.g. e-inspection, limited scope inspection)

ARPANSA maintains a 6-yearly inspection schedule for sources that is reviewed annually. Licence holders are given access to their inspection schedule.

## > Inspection of sources across 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, Australian Federal Police sites or regions or other licence holders as appropriate.

### 1.8 Types of Inspection

### > Scheduled, reactive and unannounced inspections

Inspections are usually scheduled according to the frequency described in section 1.7. Reactive inspections may also be conducted. These reactive (or unscheduled) 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 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

b. Triggered by but not limited to poor inspection results, notifications, incidents, accidents or other significant compliance issues

embassy. This inspection method may also be used under special circumstances when core regulatory functions are disrupted and inspectors cannot attend licence holder premises.

## 1.9 Performance objectives and criteria

### > Facility inspections

Facility inspections will focus on one or more of the eight functional areas or objectives in Table 7, which reflect the Regulatory Guide: Plans & arrangements for managing safety.

### > Source inspections

Source inspections should address all of the performance objectives.

TABLE 7: PERFORMANCE OBJECTIVES FOR INSPECTIONS

1	Effective Control
2	Safety Management
3	Radiation Protection
4	Radioactive Waste
5	Ultimate Disposal or Transfer
6	Security
7	Emergency Plans
8	Protection of the Environment

## 1.10 Inspection process

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 and may include photographs
- 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 (see Appendix 3 Radiation monitoring equipment)

The inspection procedure is modified appropriately for e-inspections.

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 operator should be asked to assist. At no time should tests conducted by inspectors place the facility or source in an unsafe condition or contribute to risks of any kind.

In addition to verifying compliance with regulatory requirements, inspectors should be aware of issues including human and organisational factors that are indicators of safety performance. Common performance indicators to be aware of are:

- housekeeping
- financial stability
- staffing including staff turnover
- record keeping and retrieval systems
- investigation levels set by the LH and procedure to be followed if these levels are exceeded
- training and effectiveness of training retention
- occupational exposures for the type of facility or source
- recurring failures of structures, systems and components important for safety
- unavailability of structures, systems and components
- response to areas for improvement, recurrent themes and incidents
- frequency of breaches or enforcement action
- demonstrated ability to learn from past incidents and/or near misses
- preventative actions undertaken, e.g. drills.

### 1.11 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. They provide an opportunity for inspectors to extend their understanding of the managerial, engineering and operational aspects of the facility or activity. 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 advise 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 licence holder management/personnel during the visit.

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.

NOTE: This approach should only be taken after conferring with the section director or Chief Regulatory Officer (CRO). If an identified non-compliance is significant to safety then more immediate action should be considered such as an improvement notice.

The inspector must record site visits in RAD.

### 1.12 Review of the 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:

Post-inspection review after complex inspections to assess the process and identify any lessons learned.

- Review of resourcing to ensure the inspection program continues to meet its objectives and is consistent with the branch plan.
- Review of the inspection schedule following any significant inspection findings to determine whether a reactive inspection is required. This is undertaken by the Lead Inspector.
- Survey sent to the licence holder annually. The survey results are analysed to identify any improvements to the inspection program or process. Licence holders can also provide feedback anonymously through the ARPANSA website at any time.
- Quarterly review of inspection outcomes is available via RAD.
- Annual review of inspection findings, emerging trends, significant issues, compliments, complaints and quality audit findings.
- Periodic review of Lead Inspector assignment (see paragraph 1.4)
- Review of this manual on a 3-yearly cycle as required by the IMS 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 procedures or identified improvements is managed through the corrective action program established under the agency's Integrated Management Systems (IMS).

### 1.13 Special circumstances

In the case of disruptions affecting society or specifically affecting ARPANSA's ability to deliver in accordance with its mission, ARPANSA's regulatory functions may be significantly hindered or interrupted. A variety of scenarios are possible including those experienced over the 2011-2020 decade, for example the nuclear accident in Japan following the 2011 earthquake and tsunami which significantly affected ARPANSA staff for a period of several months and the COVID-19 pandemic where lockdowns, quarantine, physical distancing and travel restrictions impeded agency activities.

Under such circumstances RSB will be guided by the Business Continuity Plan and the decisions of the CEO and the Business Continuity Group and will consider alternative arrangements to maintain effective regulatory activities.

In the specific case of the pandemic, alternative arrangements may include:

- Only conducting physical visits to medium-high risk facilities and sources, including reactive inspections or investigations in response to safety and security events
- Carrying out virtual inspections including the use of video facilities for interviews, photographs and videos taken by the licence holder and collecting information electronically for review
- Introducing additional reporting requirements such as self-assessment of compliance with regulations and licence conditions and conducting a desktop review of information submitted by licence holders
- Maintaining regular communication with licence holders during any lockdown period to understand any changes in the risk profile and offer guidance where required.

It is expected that licence holders will consider operational disruptions in their risk assessments and develop appropriate management plans.

International best practice relevant to inspection:

- 1. IAEA Organization, Management and Staffing of the Regulatory Body for Safety, GSG-12 (2018)
- 2. IAEA Functions and Processes of the Regulatory Body for Safety, GSG-13 (2018)
- 3. <u>IAEA Leadership and Management for Safety GSR Part 2 (2016)</u>
- 4. IAEA Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards GSR Part 3 (2014)
- 5. <u>IAEA Notification, Authorization, Inspection and Enforcement for the Safety and Security of</u> Radiation Sources, TRS 1002, 2022
- 6. JAEA Inspection of Radiation Sources and Regulatory Enforcement TECDOC-1526 (2007) (Supplement to IAEA Safety Standards Series No. GS-G-1.5) [GS-G-1.5 has been superseded by GSG-12 and GSG-13 and, although superseded, TECDOC-1526 contains useful information and sample checklists for a variety of sources and facilities]
- 7. Office of Nuclear Regulation Guidance on Mechanics of Assessment, NS-TAST-GD-096 (Issue 1.2), 2022

# 2. Inspection process

NOTE:

- 1. The Lead Inspector is responsible for implementing this procedure unless otherwise indicated
- 2. Some parts of this procedure may not be applicable to e-inspections

## Planning & preparation

## 2.1 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 inspection modules or objectives set out in the POCs; these are used to aid inspection planning and conduct.

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

### 2.2 Inspection file (optional)

The RAD system will create a document location (this will also be mirrored as an inspection file in the licence holder's CM container) where all records relating to the inspection should be maintained (see Record Keeping in paragraph 2.14). Access to all inspection records should be via RAD as the CM file is only updated once per day.

### 2.3 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 or sources 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.

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 under subsection 15(2) of the Act, and the obligation of all staff carrying out inspections on behalf of the CEO, 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.

### 2.4 Inspection planning

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:

- relevant codes & standards and international best practice
- endorsed security plan or other specific security considerations relevant to RPS 11
- regulatory requirements relating to the source or facility and conditions of licence
- relevant performance objectives & criteria (POCs)
- findings and any unresolved issues from previous inspections including areas for improvement
- any enforcement actions
- past correspondence relating to the inspection area including any recent applications for changes
- recent site visits if relevant
- safety assessment report, operational limits and conditions, and other safety documentation on design and operation of the facility or source
- policies/plans/procedures/source inventory
- the licence holder's management system
- compliance reports & performance history
- reports of accidents or incidents, including abnormal occurrences or near misses
- any other information made available to the Lead Inspector, including self-reported information or third-party reports

### 2.5 Timetable

An inspection plan should be drafted which provides 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.

### 2.6 Notification

In the case of an unannounced inspection the notification email must be authorised by the CRO or delegate and provided to the licence holder prior to entry.

For scheduled and reactive 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. A template is provided within the RAD system for this notification.

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.

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

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. For sites frequently visited the licence holder may be asked to confirm known risks via e-mail instead of completing the checklist each time. Workplace hazard identification checklists or confirmation of risks should be saved in the relevant inspection folder via RAD.

The Lead Inspector must update RAD with details of the inspection when the notification is sent.

Following completion of the inspection, if any hazards were encountered by inspectors which had not been identified beforehand, these should be reported to the ARPANSA WHS Manager and recorded appropriately.

## 2.7 Logistics

Relevant checklists should be prepared and any equipment identified. For example: radiation detection equipment (see Appendix 3), 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 RSB. Approvals are sought as necessary.

## Conducting the inspection

### 2.8 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, the inspection notification letter (signed by the branch head) is shown to the licence holder
- identify specific areas within a facility/sources to be seen & arrange for appropriate personnel to be present. It may not be necessary for all requested personnel to be present for the duration of the entire inspection.
- reiterate inspection criteria (including POCs)
- explain the role of inspectors
- review relevant site safety and emergency procedures for the inspection team (review hazard notification form if necessary)
- address management of inspector's access to areas with restricted access
- determine the approximate timing for the exit meeting and draft report distribution

In some cases an introduction to ARPANSA and its regulatory functions may be appropriate.

The inspector must record all attendees. The appointment function in RAD can be used or the Record of Meeting template may be used for this purpose and should be saved in RAD post-meeting.

### 2.9 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.

Note: Inspectors must NOT use their personal phones for taking photos during inspections. To ensure compliance with the Protective Security Policy Framework only ARPANSA-issued devices such as mobile phones, tablets or RSB digital cameras are to be used.

Facts and relevant observations should be recorded and filed in the relevant inspection record. Good practices should be acknowledged. Non-compliances and AFIs should be noted. Inspectors should look for underlying causes where weaknesses have been identified as this may point to more systemic issues with human and organisational factors. Inspection records should demonstrate the scope of the inspection which was carried out even where aspects of the inspection are not recorded in the final inspection report.

Note: Inspector Powers do not extend to any technical advisors supporting the inspection team. Those powers can only be applied by people formally appointed an ARPANSA Inspector and who carry a valid ARPANSA Inspector Card.

### 2.10 Inspector review

Prior to the exit meeting the inspection team meets to review the facts relating to the scope of the inspection to ensure information is adequately recorded. Preliminary conclusions and recommendations are made based on an analysis of the information available at the time of inspection. All statements should be clear and substantiated; agreement amongst team members is important.

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.

NOTE: 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 CRO must be notified as soon as reasonably practicable. Issuing an improvement notice may be appropriate under certain circumstances - see <a href="Compliance Manual">Compliance Manual</a>.

### 2.11 Exit meeting

An exit meeting is held with licence holder representatives to outline observations and preliminary findings and reach agreement on the facts. The timing of the exit meeting can be negotiated with the licence holder and will depend on whether there is additional documentation to review that may affect the inspection findings. The meeting may be held by phone or video conference if necessary. If there are outstanding issues or complex matters to resolve that will delay the exit meeting the inspector may consider a reactive inspection.

Licence holder representatives should be informed of the timeframe that the inspection report will be made available for verification of technical accuracy, and that as from March 2025 the final report will no longer be published on the ARPANSA website but may still be accessed under FOI provisions, subject to security and commercial considerations.

Where the report identifies areas for improvement the licence holder should be made aware that they are expected to be addressed in a timely manner and within three months where possible. Licence holders are expected to report on the progress of AFIs in their quarterly reports while Lead Inspectors are responsible for tracking progress on AFIs (see Section 2.17).

Non-compliance such as failure to comply with a licence condition is more significant. Although the inspection team may describe a finding as a non-compliance, only the CEO (or delegate) can decide whether it is a breach. Should a 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 breach as soon as reasonably practicable.

Ensure a record of attendees is made; the RAD appointment function or <u>Record of Meeting</u> template may be used for this purpose.

## Reporting inspection outcomes

### 2.12 Inspection report

The Lead Inspector prepares an inspection report using the appropriate template to record inspection findings and document the assessment of licence holder performance. This should be using the template generated from RAD after entering the relevant information including the inspection outcomes.

The purpose of the inspection report is to:

- record the results of inspection activities with safety or regulatory significance
- record an assessment of the licence holder's safety & security performance
- record the outcomes of relevant discussions held with licence holder's staff & management
- inform the licence holder of the inspection findings, any non-compliance, and good practice
- record any findings or conclusions reached by inspectors
- provide a means of sharing of inspection findings with other regulatory staff, stakeholders and other interested parties
- contribute to maintaining regulatory history.

The report should be factual and concise and should focus on the inspection scope. It should not identify any security arrangements or reveal any commercially sensitive information such as intellectual property. There should be a clear link to international best practice for all areas for improvement identified. There must be evidence (elements of proof<sup>2</sup>) to support any alleged non-compliance.

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.

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 that are outside the scope 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, in addition to the report being signed by the Lead Inspector.

### 2.13 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)

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<sup>&</sup>lt;sup>2</sup> See <u>Appendix 4 Report writing guide</u>

### [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 where possible.

## [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:

- Correct template has been used
- Observations address the scope of the inspection and provide sufficient detail and evidence to support findings
- Areas for improvement, non-compliance, and good practices are appropriate
- Consideration is given to common cause and extent of condition when defining areas for improvement or non-compliance
- Findings are described clearly and accurately and are within scope

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 quality review from Safety Systems (SS). The SS 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 non-compliance or a specific legal question
- [6] Independent review only required when there is an inspection of ARPANSA's sources or facilities. The Lead Inspector will seek the views of an independent radiation regulator (e.g. an inspector or other staff member of a State or Territory regulatory body) for independent verification purposes.

### 2.14 Approval and issue

The final report is signed (electronically) by the Lead Inspector. Other inspectors should sign the report to indicate that they have read and agree with the contents. The lead Inspector and any other Inspectors signing the report must be appointed Inspectors that possess a current, valid Inspector Card.

Where there is no non-compliance the relevant section director may approve, provided he/she was not part of the inspection team. The final report should be issued within 20 working days. This period includes steps 1–4 (and 6 where relevant) in paragraph 2.13.

Where non-compliance is identified the report is signed by the CRO. The final report should be issued within 40 working days. This period allows for review steps 1-5 (and 6 where relevant) in paragraph 2.13.

The Lead Inspector should consider any information sharing that may be relevant under an MOU with another agency such as Comcare or ASNO.

The Lead Inspector should consider the classification of the report, particularly if it contains any security or commercially sensitive findings. The Lead Inspector should consider if the report needs to be brought to the Minister's attention. In such cases the OCEO should be advised to allow sufficient lead-time to prepare talking points, briefs, etc.

The final report is converted to a pdf and emailed to the nominee and licence holder representatives using the appropriate email template. This is via the RAD system and may include processing by the LAO.

NOTE: Because the inspection report is agreed with the licence holder prior to its issue the need to reissue a report is unlikely. However, in the rare case that it should be required, the reason for reissue should be clearly documented and the same approval process followed. The report should be marked as an amended report.

### 2.15 Record keeping

The report must be saved in RAD within the inspection document space.

All documents associated with preparation, performance, reporting and follow-up of the inspection must be saved in the appropriate RAD space (which will record it in CM); this may include scanned checklists or handwritten notes, photos and/or electronic recordings.

Relevant information must be entered into RAD. Compliance outcomes (areas for improvement and noncompliances) must be entered.

Any required actions against any non-compliances or areas for improvement should be recorded, and these should be updated before it is closed.

## **Review & Follow-up**

### 2.16 Review of facility regulatory priority

The regulatory priority for facilities should be reviewed and updated where required and RAD updated accordingly.

#### Follow-up areas for improvement and non-compliance 2.17

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 RAD. Inspectors are required to follow-up on inspection findings within three months and actions recorded as appropriate in RAD.

In the case of non-compliance, the Lead 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 Manual.

Compliance status and areas for improvement are published on the web. The Lead Inspector must ensure relevant follow-up information is provided to close out items on the web.

### 2.18 Feedback & lessons learned

After complex inspections inspectors should review the process and identify any lessons learned. These should be recorded in the Opportunity for Improvement Register.

Feedback from the annual survey and AFIs from inspections are regularly collated and analysed by Safety Systems.

An analysis of inspection outcomes is periodically published on the ARPANSA website.

Outcomes from inspections and licence holder feedback should be discussed at section meetings and are evaluated during review of the inspection program described in paragraph 1.12.

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# Inspector health, safety & security

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

### 3.1 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 on site. 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 ARPANSA 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 ARPANSA 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 WHS incident form should be completed.

### 3.2 Travel safety and security

All inspectors must follow the Travel Procedure that covers all levels of travel and for official travel overseas this includes the requirement to download and regularly check-in using the International SOS (ISOS) App. 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 or Safe Work Australia remote or isolated work may be useful resources for the risk assessment.

# 4. Glossary

Area for improvement (AFI) means 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.

**Breach** means a violation in the performance of, or a failure to perform, an obligation required by the Act, the Regulations or a licence condition without justification. A non-compliance will only be declared a breach by the CEO of ARPANSA after affording the licence holder natural justice and after taking into account all information relating to the non-compliance. (Refer to the <u>Compliance Manual</u> for information on the management of non-compliance).

**Controlled person** is defined in section 13 of the Act as

- (a) a Commonwealth entity
- (b) a Commonwealth contractor
- (c) a person in the capacity of a Commonwealth contractor
- (d) a person in a prescribed Commonwealth place

**e-inspection** means 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. Such inspections may also be conducted during special circumstances as described in <u>paragraph 1.13</u>.

**Good practice** means 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.

NOTE: Good practice should be expressed as a clear 'stand-alone' statement so it is self-explanatory when extracted for the website – preferably around 80 words or less.

*Inspection* means the act of assessing licence holder performance to determine whether controlled a material, a 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 means 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 conducts and/or dealings authorised under the particular source or facility licence, which is reflected in their regulatory priority. The inspection schedule defines the minimum number of inspections to evaluate licence holder performance over a specific period. Additional reactive inspections may be conducted in response to specific circumstances.

*Inspection team* means 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 means 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.

Instrument calibration files means the paper/CM files containing all the documentation associated with the testing and calibration of the radiation monitoring instruments.

Instrument register means the list of instruments (including when the instrument is due for recalibration).

**Instrument store** means the secure room on Level 3 of the Miranda office.

Instrumentation officer means the officer appointed to manage the calibration and maintenance of instruments and associated records.

Lead Inspector means 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.

Non-compliance means the situation that exists when facts indicate to an inspector that requirements in the Act, the Regulations, or one or more licence conditions have not been met.

RAD means the Regulatory Administration Database, which forms part of ARPANSA's management system.

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.

This also includes health effects and health risks associated with acute or prolonged exposure to nonionising 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.

Reactive inspection means an inspection that is outside the established inspection schedule; usually in response to a regulatory event such as an accident or incident, relevant change or non-compliance.

Safety for the purpose of this manual refers to all factors that contribute to protection of people and the environment from harmful effects of radiation which include radiation protection and safety, nuclear safety, waste safety, transport safety, physical protection and security, and emergency preparedness and response.

Site Visit means 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.

Technical/Scientific Advisor means a technical/scientific expert requested to provide advice or scientific services or to participate in an inspection.