Australian Government
Australian Radiation Protection and Nuclear Safety Agency

arpansa

REGULATORY SERVICES

INSPECTION MANUAL

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

ARPANSA-GDE-1119WEB v5

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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) *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:

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

Summary of changes to this version of the manual:

- Expanded guidance based on IAEA TRS 1000[1] and IAEA GSG-13[2]
- Removed section on inspector competence & training and added link to Inspector Training & Competence Manual in paragraph 1.2
- Revised the methodology for determining regulatory priority of facilities
- Included paragraph on *Special Circumstances* to describe regulatory considerations in situations such as a pandemic when regulatory functions may be hindered or interrupted

[1] IAEA Technical Report 1000 *Notification, Authorization, Inspection and Enforcement for the safety and security of radiation sources,* Draft 2020

[2] IAEA General Safety Guide GSG-13 *Functions and Processes of the Regulatory Body for Safety*, 2018

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[3]
- 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 ARPANSA-GDE-1765 *Inspector training & competence manual.*

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.

1.3 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.

[3] 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.

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* (AIMS-AAI-COI-1). Guidance on conflict of interest is available at: http://isaac.arpansa.local/Governance/Accountable_Authority_Instructions/Pages/Conflicts-Of-Interest.aspx

1.4 Assignment of inspectors

A lead inspector is 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 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 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: PRF RISK GROUPING

PRF (type, complexity, potential hazard)	Level of Control				
	Very High 1	High 2	Medium 3	Lower 4	Limited 5
1. Low risk PRF - waste store, linac, general irradiator, accelerator	1	2	3	5	6
2. 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

Reg priority	Risk level indicator	POC module cycle length (years)	Inspection format		# of quarters between inspections
			# of inspections in POC module cycle	Depth (# of POC modules)	
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 licence holder. 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 RO 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 the RO 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 NI risk*

The risk grouping is based on the emergency planning categorisation 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 considered to be 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 possess or control, siting or construction licence. This group includes the HIFAR defueled 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 NI REGULATORY PRIORITY

NI (type, complexity, potential hazard)	Level of Control				
	Very High 1	High 2	Medium 3	Lower 4	Limited 5
1. 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 NI*

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 NIs*

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 three-yearly inspection schedule for nuclear installations and provides this to licence holder.

TABLE 4: DETERMINING NI INSPECTION SCHEDULE FORMAT

Reg priority	Risk level indicator	POC module cycle length (years)	Inspection format		# of quarters between inspections
			# of inspections in POC module cycle	Depth (# of POC modules)	
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 RO 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 non-compliance in e.g. 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 RO 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 facility geographical location. 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.

1.7 Regulatory priority of sources

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 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[a]	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	5[b]	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[b]	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
5[a]	1	5
6[a]	1	6
Complex Sites	2 or more	3
Augmented Inspections	As required	0[b]

a. A simplified inspection approach may be used (e.g. e-inspection, limited scope inspection)
b. Triggered by but not limited to poor inspection results, notifications, incidents, accidents or other significant compliance issues

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

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 Tables 7.

TABLE 7: FACILITY POC 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.

➢ *Source inspections*

Source inspections focus on the expectations in the Performance objectives and criteria for source licence holders. The objectives are shown in Table 8 and reflect the *Regulatory Guide: Plans & arrangements for managing safety*. The cross-cutting elements from Table 7 are integrated into the criteria and sub-criteria under each objective.

TABLE 8: PERFORMANCE OBJECTIVES FOR SOURCE 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 licence holder 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 to 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 eg. 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 LAD as they would for an inspection.

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 after each inspection. The survey results are analysed on a six monthly basis 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 circulated to all inspectors and published on the website.
- Annual review of inspection findings, emerging trends, significant issues, compliments, complaints and quality audit findings.
- Any self-assessment of ARPANSA's regulatory performance in accordance with the Government Regulator Performance Framework. Reports are available via the website.
- Periodic review of lead inspector assignment (*see paragraph 1.4*)
- Review of this manual on a two-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). Information on the outcomes of such reviews is published on the ARPANSA website.

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:

- Limiting physical visits to facilities and sources with medium-high radiological risks 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
- Maintain 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 guidance 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. IAEA Management *and Leadership for Safety GSR Part 2 (2016)*
4. IAEA *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards GSR Part 3 (2014)*
5. IAEA *Notification, Authorization, Inspection and Enforcement for the Safety and Security of Radiation Sources,* TRS 1000 (Advanced draft October 2020)
6. IAEA *Inspection of Radiation Sources and Regulatory Enforcement TECDOC-1526 (2007)* [although superseded contains useful information and sample checklists for a variety of sources and facilities]
7. Office of Nuclear Regulation *Guidance on Mechanics of Assessment*, 2020

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 POC; 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 lead inspector may ask the Licence Admin Officer (LAO) or $ARPANSARecords@arpansa.gov.au to create 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). Where there is not a dedicated inspection file records should be saved in the licence file in CM.

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, 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.

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 RPS11
- regulatory requirements relating to the source or facility and conditions of licence
- relevant performance objectives & criteria (POC)
- 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 workbook
- 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

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.

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.

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 identification checklists or confirmation of risks should be saved 'alternatively within' CM container M2014/00435 for WHS purposes.

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

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 (as per paragraphs 1.13 - 1.14).

➢ 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 POC)
- 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. Record of Meeting template may be used for this purpose and should be saved in CM 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.

Facts and relevant observations should be recorded. Good practices should be acknowledged. Non-compliance and AFI 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.

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 Compliance Manual.

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 the final report will be published on the ARPANSA website. There may be circumstances where the report is not published or redacted due to security/commercial reasons and this is discussed during the exit meeting.

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 Record of Meeting 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.

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[4]) 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 which 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 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.

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)

[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.

[4] See Appendix 4 Report writing guide

[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:

- Use of correct template
- 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 potential 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 (eg 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.

Where there is **no non-compliance** the relevant section director may sign 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 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 OCEO should be advised to allow sufficient lead-time to prepare talking points, briefs etc.

The final report is sent to the LAO[5] who converts it to a pdf and emails it to the nominee and licence holder representatives using the appropriate email template.

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.

[5] If the LAO is not available, the inspector may send the pdf report to the licence holder but must send a copy to the Licence Admin mailbox.

2.15 Record keeping

The report must be saved in CM 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 CM 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 non-compliances or areas for improvement should be recorded before it is closed. Non-compliances must also be entered into LAD.

2.16 Publish report & request post-inspection survey

The LAO removes the addendum and sends a request to the 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 organise a post-inspection survey.

➢ Review & Follow-up

2.17 Review of facility regulatory priority

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

2.18 Follow-up areas for improvement and 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. Inspectors are required to follow-up on inspection findings within three months and actions recorded in the appropriate CM file and LAD.

In the case of 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 Manual.

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

2.19 Feedback & lessons learned

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

Feedback from the online 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.

3. 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.

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 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 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 incident form should be completed.

3.2 Travel safety and security

All inspectors must follow the WHS Travel Procedure that covers all levels of travel and includes the requirement to download and regularly check-in using the 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 Safework 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, Regulations or 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 Compliance Manual for information on the management of non-compliance)

Controlled person is defined in the Act as

(a) a Commonwealth entity
(b) a Commonwealth contractor
(c) a person, in the capacity of a Commonwealth contractor
(d) a person an 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 paragraph 1.13.

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.

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.

Inspection means 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 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.

Instrument store means the metal cabinet located in the secure room of the Miranda office.

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).

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

LAD means the Licence Administration Database

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.

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.

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.