



**Queensland  
Government**

# **Radiation Safety Act 1999:**

## **Strategy to Achieve Compliance**

May 2013

Radiation Health  
Health Protection Unit

## Preface

Although the use of radiation offers many benefits in health care, industry, and research, it is recognised that radiation can be detrimental to our health and the environment. In view of the adverse health risks associated with radiation, effective and appropriate regulation, education, monitoring and enforcement strategies are necessary to ensure protection of people and the environment.

Queensland's radiation safety legislation, the *Radiation Safety Act 1999*, places strict controls on those activities that may result in unacceptable exposure of persons to radiation or may result in detriment to the environment. It provides the legislative support to the system of radiation protection within which Queensland's health and non-health related industries operate through strict licensing controls and safety standards, and stringent requirements over the transport and disposal of radioactive substances.

The conduct of legislative compliance activities is an integral part of the administration of the Radiation Safety Act. In this way we can form a view about the extent to which the Act is being implemented and whether the regulatory system is appropriately cast to efficiently and effectively protect people and the environment. Compliance assessment is therefore a fundamental activity within radiation protection and is the primary way of assessing compliance with legislation, standards and dose limits, and of identifying areas requiring improvement. This is consistent with the aim of the Health Protection Unit is to protect public health by ensuring legislative compliance.

This strategy outlines how the Health Protection Unit will assist or otherwise ensure radiation-related activities comply with the Radiation Safety Act. It sets out the framework for the risk based selection of radiation-related activities undertaken by the Unit and provides the basis for its management and implementation, and is consistent with the Health Protection Unit's *Regulatory Principles Statement and Operating Framework 2011 – 2015*. These activities are detailed in the extant *Compliance Plan*.

**Executive Director  
Health Protection Unit**

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# 1 Introduction

## Purpose and scope

This document explains the framework for the risk-based selection of radiation-related activities that are to be audited and provides the basis for the management of the Department of Health's compliance strategy, which includes handling of complaints, enforcement decisions, education and both scheduled and adhoc compliance activities.

Scheduled compliance activities constitute the planned investigation of persons and their dealings with radiation sources, leading to an assessment of the levels of radiation safety and recommendations for improvement if necessary. These compliance monitoring activities may, in some cases, lead directly to investigations and inspections and consequent enforcement activities when clear breaches of the Radiation Safety Act have been identified.

For the purpose of this document, radiation-related activities, irrespective of what they are, have been given the generic term "radiation practices". Also, for the purpose of this document, an inspection is a formal regulatory function which may only be conducted by an inspector appointed under the Act. Inspectorial activities should be consistent with, but not limited by, this strategy.

This document is to be reviewed every five years.

## Regulation of radiation practices in Queensland

In Queensland the regulation of radiation practices is achieved through the *Radiation Safety Act 1999*. The Act was developed in the light of an extensive review process, which was influenced by research and development work at State, national and international levels. The review took into account the recommendations of the peak national and international radiation advisory bodies in relation to the adverse health effects which may arise from exposure to different types of radiation and the measures that may be taken to prevent or minimise these effects.

The objective of the Radiation Safety Act is to protect persons and the environment from the harmful effects of particular sources of ionising radiation and harmful non-ionising radiation. The administration of the Act is conducted by the Radiation Health, Health Protection Unit within the Department of Health. Radiation Health also has a role under the *Environmental Protection Act 1994* in those matters where the environment is, or could be, affected by radioactive material.

In part, the objective of the Radiation Safety Act is achieved by:

- establishing a licensing system to regulate
  - the possession and use of radiation sources
  - the transportation of radioactive substances
- establishing a framework to ensure radiation sources and the premises at which they are used, and the premises at which radioactive substances are stored, comply with radiation safety standards
- establishing an approval process for the acquisition and relocation of radiation sources
- imposing restrictions on the disposal of radiation apparatus and radioactive material
- requiring possession licensees to have an approved radiation safety and protection plan that describes the radiation safety measures in place to deal with the radiation hazards in their practices
- requiring possession licensees who possess a security enhanced source to have an approved security plan in place that describes the security measures in place for the source
- requiring persons transporting a security enhanced source to have an approved transport security plan in place for the transport of the source

In addition to ensuring that minimum radiation safety standards are achieved, the Act also states that one of the principles guiding the achievement of its objectives is that doses of radiation should be kept as low as reasonably achievable, economic and social factors being taken into consideration (the ALARA principle).

The Act also provides for the appointment of inspectors and establishes a framework within which compliance, investigative and enforcement activities, may be undertaken.

### **Explanation of terms**

The following terms used in this document have the specified meaning:

*Compliance* – the goal that businesses, with public health obligations, and agencies aspire to achieve in their efforts to ensure that personnel are aware of and take steps to comply with relevant laws and regulations.

*Enforcement action* – the implementation of investigative processes, the initiation of remedial actions by inspectors, and legal activities to address non-compliance with legislation and policy.

*Investigation* – an investigation is an objective enquiry and assessment of an act, omission, situation or event with a view to establishing the facts and ascribing responsibility for that act, omission, situation or event. The evidence on which this assessment is based must be obtained within the confines of established rules and principles of law.

## 2 Compliance Activities in Queensland

There is an industry and community expectation that the department will adequately enforce the radiation safety legislation and properly monitor the level of compliance with the legislation by persons carrying out radiation practices. A compliance strategy coupled with appropriate enforcement and behaviour modification strategies to ensure optimal levels of radiation safety contributes to public confidence about radiation safety and also meets the public's expectations regarding the regulatory system.

### Objectives of the compliance activities

By implementing a compliance strategy, the Health Protection Unit is seeking to:

- achieve full compliance with Queensland's internationally based radiation safety standards and principles so that unacceptable behaviour is not seen at all
- identify and promote best practice behaviours and a satisfactory level of radiation safety in all activities involving radiation
- encourage the development of a culture which has the goal of continual improvement in levels of radiation safety
- maintain familiarity with industries and their radiation practices so that the Department of Health may have an informed and practical basis on which to formulate policy, standards and guidelines at both the State and national levels
- ensure outcomes achieved through the regulatory processes are appropriate for industry and the public
- ensure that the department is complying with its own legislated administrative responsibilities.

### Strategies used to meet the objectives

The goal of ensuring radiation safety is facilitated through the development of responsive and cooperative relationships between the department and its clients and creating an environment supportive of sound radiation safety principles and behaviours.

Strategies used to achieve compliance include:

- documenting and assessing complaints
- providing educational information and tools to assist licensees in meeting the legislative requirements, which may be downloaded from the website
- maintaining a routine compliance monitoring program which is a mix of assessing
  - a risk based sample of radiation practices intended to give a picture of a whole industry sector
  - certain types of radiation practices identified as focus areas
- monitoring compliance across the full range of radiation practices in urban, rural and remote locations throughout the State by appropriate sampling methods
- focusing on activities where compliance is poor or where health or environmental risks due to non-compliance are significant
- evaluating the effects of changes to the legislation or standards
- maintaining cost efficient and informed compliance monitoring activities
- developing a supportive environment to help foster a statewide radiation safety culture
- maintaining and enhancing Radiation Health's understanding of the contemporary business requirements and activities of licensees
- undertaking investigative and enforcement action when appropriate.

## **Compliance strategy to be risk based**

Activities involving radiation sources cover a wide range of industries including health related and non-health related activities in the public and private sector. The use of radiation sources in each of these radiation-related activities poses different degrees of risk to the users of the radiation sources, other people and the environment. In addition, there are national security issues relating to certain radiation sources.

Amongst other things, compliance activities are based on the health and environmental risk posed by a radiation practice as well as its security risk. This results in a greater proportion of higher risk radiation-related activities being monitored each year than those for which the risks have been assessed as being lower. The compliance program also assists the department in its role in assuring the security of radiation sources.

Radiation-related activities have been classified as low, medium or high risk depending on their public, occupational health or environmental risk. The risk is based on the extent of radiation exposure that could occur during the normal conduct of a radiation practice, the potential for adverse effects in the event of an incident, and on the likelihood of incidents occurring.

The radiation-related risks associated with the conduct of a radiation practice have been divided into four risk categories:

- ***Direct exposure risks***

These are the risks of adverse health effects to a person due to radiation exposure as a result of:

- direct exposure to the radiation from radiation sources
- ingestion or inhalation of radioactive substances
- poor operational skills
- substandard techniques or procedures (resulting in a high dose procedure or the need to repeat the procedure)
- malfunctioning or substandard equipment (for example: a shutter mechanism that does not completely close to the “off” position).

- ***Indirect risks***

These are the risks of adverse effects resulting from circumstances associated with the use of a radiation source but not involving direct exposure to sources of radiation. These risks include:

- poor quality or inappropriate radiography leading to misdiagnosis or disorders being overlooked or the overuse of radiation for a particular procedure
- poor quality industrial radiography not detecting flaws in high pressure gas pipelines leading to catastrophic ruptures
- inadequate instream chemical analyses due to faulty industrial gauges leading to the disposal of many tonnes of product produced in commercial processes.

- ***Environmental risks***

These are the risks of environmental harm or health effects subsequent to the disposal of radioactive material due to:

- deliberate inappropriate disposal of radioactive material to the environment
- accidental release of radioactive material into the environment.

Activities involving the use of radioactive substances pose an ongoing hazard because there is always a potential for the release of the substances into the environment.

- ***Security risks***

There are certain radioactive substances which have been identified internationally as sources that might be of interest to persons with malevolent intent. Australia has, nationally, decided that special precautions need to be taken to ensure the physical security of such sources.

### 3 Enforcement in Queensland

An implicit part of the radiation safety compliance program is that licensees are audited to assess the extent of compliance with their radiation safety and protection plans, security plans and transport security plans, as well as for the purposes stated in the compliance plan. During these on-site activities, there are instances where individual licensees are found to be performing in an unacceptable manner. These circumstances are investigated through the existing inspection arrangements provided for by the *Radiation Safety Act 1999*.

It is also possible that the performance of a whole industry sector is found to be unacceptable in a particular aspect of its operation. In this unlikely circumstance, strategies to remediate the deficiency across the sector will be planned, developed and implemented in a manner consistent with the department's business planning processes.

In the Health Protection Unit, the enforcement process is applied by:

- investigating non-compliance and determining the level of risk of the matter which is the subject of the complaint/audit/other intelligence source
- identifying the enforcement options following each investigation using a risk based enforcement tool to determine and record the most effective and consistent means of rectifying identified non-compliance with the legislation
- commencing the decided enforcement option
- reviewing decisions as part of an on-going improvement strategy.

The following provides auditors with a tool to guide consistent and supported enforcement actions to rectify identified non-compliance with the *Radiation Safety Act 1999*. Over the next few years, this tool will be refined to better target the actions required for particular practice groupings. The guidance will be reviewed in the light of information collected in MAPLE including; practice type, details of regulatory action, offence type, action completed within timeframes.

#### Enforcement Guidance Tool

		Consequence - Impact on human health (Actual or potential)				
		Level 1	Level 2	Level 3	Level 4	Level 5
Likelihood of non-compliance (Based on compliance history, willingness and capacity to comply)	<b>Category A</b> High compliance	Advice/education	Advice/education Warning letter	Warning letter Improvement Notice/seizure	Improvement Notice/seizure Show Cause Notice	Prohibition Notice/seizure Prosecution
	<b>Category B</b>	Advice/education Warning letter	Advice/education Warning letter	Warning letter Improvement Notice/seizure	Improvement Notice/seizure Show Cause Notice	Prohibition Notice/seizure Prosecution
	<b>Category C</b>	Advice/education Warning letter	Warning letter Improvement Notice/seizure	Improvement Notice/seizure Show Cause Notice	Prohibition Notice/seizure Prosecution	Prohibition Notice/seizure Prosecution
	<b>Category D</b>	Warning letter Improvement Notice/seizure	Improvement Notice/seizure Show Cause Notice	Prohibition Notice/seizure Prosecution	Prohibition Notice/seizure Prosecution	Prohibition Notice/seizure Prosecution
	<b>Category E</b> Low compliance	Improvement Notice/seizure Show Cause Notice	Improvement Notice/seizure Show Cause Notice	Prohibition Notice/seizure Prosecution	Prohibition Notice/seizure Prosecution	Prohibition Notice/seizure Prosecution

The following provides information about the meaning of the categories/levels referred to in the above tool.

**Likelihood of non-compliance**

Likelihood Category	General Descriptor
A	Rare likelihood of non-compliance – No previous known occurrences of non-compliance Good demonstrated awareness and capacity to meet regulatory requirement Regulated entity has a reasonable and cooperative attitude to compliance
B	Unlikely likelihood of non-compliance – Few previous known occurrences of non-compliance Questionable awareness and capacity to meet regulatory requirement
C	Possible likelihood of non-compliance – Numerous previous known occurrences of non-compliance Little or no demonstrated willingness or capacity to meet regulatory requirement
D	Likely likelihood of non-compliance – Wilful violation of regulatory requirements Little or no demonstrated willingness or capacity to meet regulatory requirement
E	Almost certain likelihood of non-compliance – Wilful violation of regulatory requirements Little or no demonstrated willingness or capacity to meet regulatory requirement Hindering or obstructing a departmental officer Refusing to provide required information Intentionally providing false or misleading information

**Consequence**

Consequence level	General Descriptor	Nature of offences
1	Very low consequence – <ul style="list-style-type: none"> <li>• Non-compliance that does not result in any immediate human health impact</li> <li>• Minor administrative non-compliance</li> <li>• No organisational and regulatory scheme risk</li> </ul>	Failure to – <ul style="list-style-type: none"> <li>• provide information or produce documents</li> <li>• renew licence on time</li> <li>• advise of change of contact details</li> </ul>
2	Low consequence – <ul style="list-style-type: none"> <li>• Non-compliance resulting in a minor, temporary threat to human health</li> <li>• Moderate administrative non-compliance</li> <li>• Failure to meet a Critical Control Point and/or a Critical System failure</li> <li>• Negligible organisational and regulatory scheme risk</li> </ul>	Impersonate an inspector or accredited person Failure to – <ul style="list-style-type: none"> <li>• obtain a certificate of compliance</li> <li>• keep, or make available, certain documents</li> <li>• appoint a radiation safety officer</li> <li>• report a dangerous event</li> <li>• comply with an improvement notice or a direction</li> </ul>
3	Moderate consequence – <ul style="list-style-type: none"> <li>• Non-compliance resulting in a moderate, temporary threat to human health</li> <li>• Major administrative non-compliance</li> <li>• Moderate organisational and regulatory scheme risk</li> </ul>	<ul style="list-style-type: none"> <li>• Use of non-compliant sources or premises</li> <li>• Non-authorized requesting or prescribing of diagnostic or therapeutic procedure</li> <li>• Transport non SES or use without licence</li> <li>• Acquire, relocate or supply without approval (non SES)</li> <li>• Possession, use or supply of banned source</li> <li>• Possession without licence (non SES)</li> </ul>
4	High consequence – <ul style="list-style-type: none"> <li>• Non-compliance resulting in a significant threat to human health</li> <li>• Significant organisational and regulatory scheme risk</li> </ul>	<ul style="list-style-type: none"> <li>• Causing unauthorised radiation exposure of people or environmental harm</li> <li>• Failure to comply with a prohibition notice</li> <li>• Failure to take reasonable steps to ensure health and safety (non-compliance with RSPP, standards)</li> <li>• Unauthorised access to security plan, or use or transport of SES</li> <li>• Not taking reasonable steps to ensure security of SES (non-compliance with security plan)</li> </ul>
5	Extreme consequence – <ul style="list-style-type: none"> <li>• Known or likely human health impact that is severe in effect (e.g. hospitalisation and/or chronic health problems)</li> <li>• Extremely high organisational and regulatory scheme risk</li> </ul>	<ul style="list-style-type: none"> <li>• Possession, use or transport of SES without licence</li> <li>• Acquisition, relocation or supply of SES without approval</li> <li>• Non-approved disposal or abandoning of source</li> <li>• Causing significant unauthorised radiation exposure of people or significant environmental harm</li> </ul>

## 4 Radiation Safety Act: Compliance Plan

### Radiation Safety Act: Compliance Plan

Standards of radiation safety should be the same throughout Queensland regardless of the location at which the radiation practices are carried out. To help ensure this, the compliance monitoring program involves the assessment of practices across the State, including those in rural and remote areas.

This is particularly beneficial in rural and remote areas because the compliance monitoring program allows local personnel direct contact with radiation safety professionals who would otherwise be unlikely to venture into such locations.

Full and proper implementation of the Radiation Safety Act requires the department to have in place a program to conduct radiation safety monitoring of persons having dealings with radiation sources. However, the implementation of a compliance monitoring program does not detract from the ultimate responsibility for radiation safety and protection being borne by the persons carrying out radiation practices.

Every year the current *Radiation Safety Act: Compliance Plan* must be reviewed. This plan includes a rolling three year strategy and annual goals. This document is maintained by Radiation Health in liaison with a group convened for this purpose. This group is the Health Protection Unit – Compliance Working Group (Radiation Safety Act 1999).

Before implementation, the plan is endorsed by the Health Protection Compliance Committee which provides strategic oversight of the compliance activities in the Health Protection area to ensure coordinated and integrated implementation of the compliance activities associated with public health legislation across the State. Information in relation to the membership and conduct of both the compliance working group and the compliance committee may be found in their respective Terms of Reference.

The compliance plan consists of a mixture of activities involving:

- the compliance monitoring of a sample of the practices in Queensland (the “sampled audits”) and
- the more detailed compliance monitoring of certain types of practice for which specific outcomes are intended to be achieved during the period of the compliance monitoring plan (the “focused audits”).
- ***Sampled audits***

Sampled audits are essentially a random sample of radiation practices stratified on the basis of the health and environmental risk they pose. The reason for sampling a range of radiation-related activities is to maintain knowledge about those activities and, more broadly, the state of radiation safety within Queensland. Licensees involved in each of these activities have equal likelihood of being selected for compliance monitoring purposes, however efforts are made to ensure individual licensees are not selected unreasonably frequently.

The number of licensees within each years sample for each type of radiation practice to be audited is dependent upon the risk posed by the conduct of the type of activity. As mentioned earlier, practice types which pose a greater risk will have a greater proportion of licensees subject to audit than those which pose less of a risk. To facilitate this process, practice types have been classified according to the risk they pose. There are three broad classifications which, for the purpose of this document are called risk categories. The sample size chosen to represent licensees in high risk categories is proportionately greater than the sample size chosen to represent licensees in the low risk categories.

The percentage of the radiation practices, in particular risk categories, which are to be audited is specified in each revision of the compliance plan.

#### *Desired outcomes*

The goal of sampled audits is to:

- Investigate the general level of compliance with the Act
- assess whether persons or types of radiation practices are achieving minimum acceptable levels of radiation safety
- identify common problems.

As a result of these sampled audits, it is expected that:

- strategies will be developed for ensuring licensees comply with the basic requirements of the Act and improve on these basic levels of radiation safety
- the department will maintain and develop familiarity with each of the types of radiation practice and get a measure of the overall level of radiation safety in Queensland
- feedback from persons undertaking compliance monitoring will be used to review the compliance monitoring program
- radiation-related activities which might require focused attention in coming years will be identified.

- ***Focused audits***

Focussed audits of specific radiation-related activities are performed because these activities, or elements of the activities, have been identified as having a particular problem that needs to be investigated or rectified, or is one about which additional knowledge is required.

Examples of this are:

- there has been a change in policy which impacts on a particular type of radiation practice and uptake of the policy is being examined
- circumstances suggest that licensees involved in a particular type of radiation practice have been conducting themselves in a manner which is sub-optimal or unsafe as far as radiation safety is concerned
- a particular type of radiation source has been found to be unsafe.

#### *Desired outcomes*

The goal of focused audits is to:

- thoroughly investigate, within certain types of radiation practice, processes and procedures required by the Act, policy, standards or codes of practice
- develop a position identifying minimum and optimal levels of radiation safety within the type of radiation practice
- investigate the extent to which radiation-related activities of the type to be investigated are achieving the identified optimal levels of radiation safety
- identify desirable and feasible changes in the types of radiation practices investigated to achieve the identified levels of radiation safety.

As a result of these focused audits, it is expected that:

- specific strategies will be developed to ensure clients comply with the basic requirements of the Act and achieve optimal levels of radiation safety
- the Unit will maintain and develop an in-depth knowledge of the practical achievement of radiation safety in these types of radiation practices
- feedback from persons undertaking compliance monitoring will be used to review the Unit's radiation safety assessment tools and produce new tools such as activity specific checklists, template reports and reference sheets
- the quality and appropriateness of the Act Instruments issued, agreed or approved under the Act will be verified or, if concerns are raised, recommendations for change will be made
- programs of work will be developed to implement the specific strategies; for example –
  - convening industry-specific forums to discuss and remedy consistent failures and find an acceptable solution
  - developing proposals for research projects to investigate particularly difficult issues in specific types of radiation-related activities
  - initiating reviews of the legislation as it relates to particular types of radiation-related activities
  - investigating the effect or consequences of regulatory action.
- the relevance of the legislation itself will be reviewed and, where necessary, recommendations for change will be made.

In these instances, informed by the additional information provided by performing the focused audits, the Health Protection Unit will develop strategies to identify and rectify the specific concerns through its specific program area activities. Subsequently, but separately from the scheduled compliance activities, the Unit will implement the strategies across all relevant radiation-related activities to ensure the concerns are rectified. These strategies, and any consequent work, might be significant projects and, if so, will be planned and funded in accordance with the department's business planning processes.

### **How will the Radiation Safety Act: Compliance Plan be developed**

The compliance plan is to contain a statement of three year objectives that will:

- identify who is to be the subject of routine compliance monitoring via the sampled audits
- identify focus groups and who is to be the subject of compliance monitoring via the focused audits
- describe what elements of these licensees or activity types need to be investigated
- describe the key deliverables for the compliance monitoring program
- set out management systems to support the compliance monitoring program.

The development and implementation of each year's revision of the compliance plan to achieve the overarching objectives are to follow project and business planning methodologies with each discrete body of work being developed, implemented and completed as a project.

The compliance plan will also be provided to the Radiation Advisory Council for information. Similarly, the outcomes of each year's compliance monitoring activities will be provided to the Radiation Advisory Council for information.

### **Who is to implement the compliance plan**

Radiation Health has specific responsibility for implementing the compliance plan and enforcing compliance with radiation health standards and radiation safety goals. A primary role of Radiation Health is to administer Queensland's radiation safety legislation, the *Radiation Safety Act 1999*. Radiation Health

monitors and ensures compliance with radiation-related health and safety and environmental protection standards by formulating policy, standards and guidelines relevant to radiation health and safety and implementing a statewide compliance monitoring program.

### **Scheduling activities under the plan**

The compliance plan will contain a schedule of the planned activities expected to be conducted during the year. This also includes an assessment of the level of compliance in the department's administration of the Act to provide evidence that the department is properly managing its portfolio accountabilities.

However, arrangements for these planned activities may be varied if enforcement activities and planned activities overlap and there are cost savings to be made. For example, routine compliance monitoring scheduled for Cairns in October may be performed in August if enforcement activities are required in Cairns in August, as there would be cost savings in both time and travel.

Where there is a conflict between the need to conduct a planned routine audit and an enforcement activity, it is to be resolved by the Director, Radiation Health. At no time will any constraint provided by this document prevent an inspector from conducting an inspection in a way the inspector believes is necessary.

### **Reporting**

An annual report detailing the outcomes of the annual compliance activities will be produced. The particular items reported will vary from year to year but may include details such as:

- a report on the level of compliance with legislation
- a report on investigations and ad hoc activities (i.e. unplanned compliance activities conducted during the term of the plan)
- an investigation into whether the behaviours within a type of radiation practice type are typical
- an evaluation of whether the law is appropriate for industry and the public
- recommendations for future program objectives.

The report will be considered by the compliance working group and provided to the Health Protection Compliance Committee and to the Radiation Advisory Council for information.

## 5 Handling Complaints

Complaints may be received within the Unit which may be both internally or externally related. Internally, they may be about licensing criteria, application forms, conduct of officers, timeframes for processing applications or information received.

Externally, a person may complain about the conduct of a licensee, or 'dob in' a person who may be in possession without a licence, or not be implementing a radiation safety and protection plan, or have general concerns about the radiation safety status of a practice.

While these complaints may be dealt with individually, as a whole, they can provide an important tool in assessing the compliance status of radiation practices in Queensland. It is therefore imperative that the information is captured and analysed to apply an informed approach in improving compliance.

Records of complaints are required to ensure that the information derived from the data can be used. The mechanism for entering and maintaining data is through the MAPLE system.