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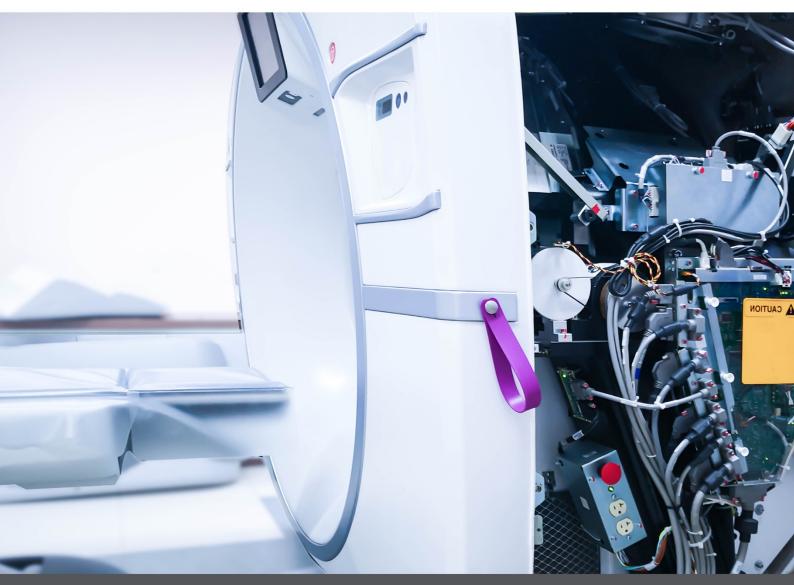
Australian Radiation Protection and Nuclear Safety Agency



Australian Radiation Incident Register

Annual Report

Incidents occurring January to December 2019



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Preface

The Australian Radiation Incident Register (ARIR) is a repository of radiation incident information from Commonwealth, state and territory radiation regulators. It is intended to raise awareness of radiation safety and to facilitate the sharing of lessons learnt from radiation incidents across Australia.

Schedule 13 of Radiation Protection Series 6 (RPS 6), *National Directory for Radiation Protection* (NDRP) specifies the types of incidents that must be reported to the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) for compilation in the ARIR. These reporting arrangements are agreed to by all jurisdictions through the Radiation Health Committee (RHC) and the Australian Health Ministers endorsed NDRP. The NDRP outlines the common requirements for reporting of incidents to the ARIR. Reporting of other radiation incidents is encouraged, including minor events, near misses and other opportunities which could lead to valuable learnings. More information on the RHC and ARIR can be found on the ARPANSA website <u>arpansa.gov.au</u>.

This report was prepared in 2020 including consultation with professional bodies and state and territory regulators and approved for publication in December 2020.

Purpose and scope

This report is a summary and analysis of data submitted to the ARIR for incidents that occurred in 2019.

The purpose of this report is to raise awareness of the risks associated with common tasks, share the learnings identified as the result of incidents, and assist in the identification of topical areas where safety efforts may be focused to improve radiation protection. Therefore, the focus of this report is on the causes of incidents and on recommendations or remedial actions taken as a result.

Geographical or personal data that may lead to the identification of individuals or organisations is not included in an incident report and does not form part of this analysis.

Source of the incident reports

Incidents are reported to regulators by users of radiation in their jurisdiction. The regulator submits incidents to the ARIR based on the user reports received. The specific requirements for incident reporting vary between jurisdictions. Due to the differences in legislation, and differing levels of promotion for reporting of incidents, some jurisdictions report more than others. For example, some jurisdictions do not regulate some types of non-ionising radiation and so do not receive incident reports related to these types of sources. Some jurisdictions require reporting of certain events, such a high fluoroscopy dose, which are not considered incidents in other jurisdictions.

Incidents are typically investigated by the reporting organisation and, where applicable, the local regulator. The reports identify the direct cause and contributing factors that led to the incident as well as recommendations or preventive actions implemented to avoid recurrence. No additional investigation is undertaken as part of the preparation of this report. However, additional information may be requested to help categorise incidents and to ensure learnings can be shared.

Throughout the report, individual incidents that occurred in 2019 are summarised and highlighted. These provide an insight into the circumstances of the incident and will include the lessons to be learnt which are typically identified by the reporter or in some instances by the submitting regulator. As such, the learnings may not represent the views of ARPANSA and may not be appropriate for all situations. Similarly, the reporter-estimated doses are based either on calculated individual dose or, where unavailable, on typical doses for that procedure.

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Summary of incidents occurring in 2019

Radiation is routinely used across Australia by more than 50,000 licensed users who perform millions of individual tasks each year. The incidents that occur and the nature of the resulting outcomes show that the use of radiation in Australia is generally very safe. However, unexpected events occasionally occur even with safety controls in place. Where such events meet the criteria in the *National Directory for Radiation Protection* (NDRP) they are required to be reported to the Australian Radiation Incident Register (ARIR). The register is managed by ARPANSA. We analyse the submitted incidents and publish the results to raise awareness of common hazards and to identify and promote practices which could prevent future incidents.

The number of incidents reported in 2019 decreased by 21% from the previous year. We believe that a factor in this decrease can be contributed to lower reporting through regulators in jurisdictions affected by COVID-19 response. It should be noted that regulators may submit reports until July the year following the incident. This is to allow for quality control and regulatory investigation where required. While some regulators report on incidents promptly, some regulators typically submit most of their incident reports close to the July deadline at which time this year many regulators' resources were being impacted. In the longer term we expect a return to the general upward trend of incidents reported that we have seen over the last five years but with possible short-term variations due to the impacts of the COVID-19 response. The upward trend is indicative of increased awareness and positive reporting culture which we have been actively promoting.

Human error was the primary cause identified in the majority of reported incidents in 2019 which is consistent with previous years. This year's report includes a focus on equipment-related incidents.

While an incident will typically have one primary (initiating) cause, incidents generally have a number of contributing causes, for example, time pressures, labelling issues, or various reasons for not following procedures. Often if one of these contributing factors had not existed, the incident would not have occurred. However, reports do not always identify the contributing factors that may have been present.

Ongoing improvements to the ARIR have made it easier to identify and share recommendations and learnings. These learnings are generally identified by the incident reporter or, in some cases, the relevant regulatory body.

Below are some highlighted lessons to be learnt or recommendations identified from this year's incidents:

- Equipment should be managed and evaluated throughout its effective life. This should include regular servicing and maintenance, applying upgrades to software/firmware as appropriate, and considering the impact of these actions on service delivery and staff knowledge.
- Equipment failure should be part of planning. Effective strategies such as arrangements to use alternate equipment or recovery and spill plans can reduce the severity of incidents. As these may only be rarely used, effective training in recovery operations (such as training drills) is key to ensuring that the appropriate steps are taken during incidents.
- Effective training and supervision for students and staff undergoing professional development is essential. This is especially relevant when there have been changes to equipment, work practices, and/or in the rotation of staff.
- It is important to follow procedures, for example, performing current patient/procedure matching processes. Where this does not occur, the reasons for non-adherence should be explored to understand why. For example, task familiarity may drive complacency which can lead to a slip or 'lapse in memory'.



Number of incidents reported

There were 575 incidents reported in 2019 which is 20% less than the previous year.

This reduction largely reflects reduced reporting from some jurisdictions whose regulatory resources were impacted by COVID-19 response activities, and no reports being received from one jurisdiction (South Australia). Many of the reports are submitted by regulators around July the year following the incident.

The overall trend remains one of increased reporting in many jurisdictions which is expected to continue over the medium-long term. To support this trend, ARPANSA has been raising awareness and promoting the Australian Radiation Incident Register as a resource, and its potential since 2012 including the upgraded web portal for regulators in 2016. ARPANSA is currently engaging in further projects to encourage increased reporting including an enhanced national reporting system for radiation oncology. Detailed national incident and event trend analysis is not possible without stable and consistent reporting practices.



Number of incidents reported to the register over time

Estimated doses received as a result of incidents

Doses in this report refer to the effective dose in millisievert (mSv) reported as received typically by the patient (averaged over the whole body). Where relevant, absorbed dose in gray (Gy) is used for organ doses or dose to a specific region.

Distribution of effective doses as the result of reported incidents

Effective dose received by patient	Percentage of incidents
Less than 0.1 mSv	45%
0.1 – 1 mSv	8%
1 – 10 mSv	38%
10 – 100 mSv	9%

The effective dose received by patients as a result of incidents is generally low. Of all reported incidents, 53% are below 1 mSv which is the less than the average annual natural background radiation. This includes the 45% of all incidents which resulted in no exposure or less than 0.1 mSv, including near miss events.

Types of incidents reported

The table below shows the number of incidents by category over the previous five years. The largest category continues to be medical imaging. This is expected as medical imaging, which includes general X-rays and computed tomography (CT) scans, represents one of the largest uses of radiation in Australia. More than 15 million medical (diagnostic) imaging procedures involving radiation were carried out in 2019 according to Medicare Benefits Schedule (MBS) information – see note below.

	20	19	20	18	20	17	20	16	20	15
Incident category	No.	%								
Medical										
Medical - Diagnostic Imaging (All)	533	92	691	96	532	93	352	91	320	95
+ Diagnostic Radiology (CT)	(208)	(36)	(264)	(37)	(212)	(37)	(143)	(37)	(135)	(40)
+ Diagnostic Radiology (Plain Film/RX)	(143)	(25)	(247)	(34)	(164)	(29)	(110)	(28)	(91)	(27)
+ Nuclear Medicine	(141)	(24)	(131)	(18)	(114)	(20)	(73)	(19)	(84)	(25)
+ Diagnostic Radiology (Interventional)	(36)	(6)	(45)	(6)	(34)	(6)	(22)	(6)	(9)	(3)
+ Diagnostic Radiology (Dental)	(5)	(1)	(4)	(1)	(8)	(1)	(4)	(1)	(1)	(0)
Medical - Radiotherapy	23	4	17	2	21	4	16	4	8	2
Non-medical/industrial										
Contamination	4	<1	3	<1	5	<1	1	<1	1	<1
Transport of radiation material	3	<1	2	<1	0	<1	1	<1	1	<1
Imaging (inc. Industrial Radiography and XRF)	1	<1	2	<1	1	<1	3	1	1	<1
Found/lost/stolen	6	<1	1	<1	4	<1	15	4	1	<1
Non-Ionising Radiation (inc. laser)	2	<1	1	<1	1	<1	1	<1	3	1
Irradiator/accelerator	0	<1	0	<1	1	<1	1	<1	1	<1
Other	3	<1	6	1	10	2	0	0	12	4
Total	57	′5	72	23	57	75	39	90	33	86

Overall ARIR statistics for 2019 compared with previous four years

Note: percentages are rounded

About Medicare statistics

Medicare statistics, available online (http://medicarestatistics.humanservices.gov.au/), only include the number of procedures for which Medicare payments are made. As such, the true number of procedures undertaken is higher than that indicated by Medicare statistics because state-operated (public) hospitals receive operational funding to perform imaging services which are not rebated against Medicare.



It is often difficult for a user to predict exactly when equipment failure will occur, but it is not hard to predict that it will occur. Equipment failure and deficiencies can have significant and varied impacts including financial, safety, and clinical impacts. For example, a patient's medical diagnosis or treatment can be impacted in addition to the impact of receiving an increase exposure due to repeated imaging.

The chance of equipment malfunction can be greatly reduced by managing equipment over its entire life cycle. Equipment selection, regular servicing, effective maintenance and regular evaluation are all essential for the prevention of equipment failure. There should be a plan to replace or dispose of equipment as required.

Design of equipment and workplaces as well as appropriate management oversight are key in the prevention and mitigation of equipment errors and failure. This includes considerations such as equipment design and manufacturer improvements over time, how equipment failure will be recognised and dealt within the organisation and ensuring that the workplace is suited to the equipment (such as through reliability/usability testing).

Equipment is designed for a specific use. Looking for potential issues and reporting faults through a quality management system is important to reduce equipment failure, predict issues and reduce consequences. Issues should be raised with suppliers/manufacturers, even when the factors that led to the failure may not be apparent or within the control of the operator. This may result in advisories or software/firmware updates to address the issues raised. Advisories and updates were highlighted in some incidents in 2019.

Workplaces should be designed with the potential of equipment failure in mind. This could include putting in place recovery procedures, ensuring the availability of alternate equipment, and providing effective training. In the real world there are many unexpected factors that are outside of the original equipment design. Sometimes human action causes the error, for example, when a patient moves during a scan or incorrect settings were used. Other times humans can mitigate the consequences. Human-led correction relies on the operator having the requisite knowledge, skills and ability to act. Some case studies featured in this report have demonstrated that some incidents could have been prevented if the operator was aware of key information such a limitation in the equipment.

The <u>Institute of Safe Medication Practices Canada</u>, a key partner in the Canadian medication incident reporting and prevention system, have proposed that the most effective interventions for mitigating medical incidents are systems-based, followed by standardisation and then training and policies. In the context of equipment failures, forcing functions/constraints, automation and standardisation of equipment design are more effective in reducing hazards than human-based prevention techniques such as setting rules, policies and training of equipment practices.

Summary of equipment-related incidents from 2019

Of this year's 575 incidents, 114 reported equipment failure or deficiency as the initiating cause.

There were no trends or common modes of failure identified from the data received. This suggests that the faults were not due to systemic issues such as the supply of products with manufacturing defects which could be subject to a recall.

Category	Medical Imaging – Nuclear Medicine	Medical Imaging – CT	Medical Imaging – Other	Radio- therapy	Other	All
Repeat exposure due to equipment failure	13	28	36	0	0	88
Higher dose due to equipment failure	1	8	11	1	0	10
Radiopharmaceutical administered but scan not performed (no benefit)	9	n/a	n/a	n/a	n/a	9
Defective batches of radiopharmaceuticals	1	n/a	n/a	n/a	n/a	1
Spill/leak	1	n/a	n/a	n/a	n/a	1
Other	0	0	2	0	3	5
Total	25	36	49	1	3	114

Equipment related incident statistics

Patients requiring repeated imaging due to equipment failure was the most common equipment-related incident reported. Equipment failure and the need for repeated exposure can occur due to the complex environment in which it is operated. There is reliance on many devices interacting with each other, with users, and with patients. Many of the incidents in 2019 do not consider equipment failure/deficiency to be the primary factor; however, it is identified as a contributor to the incident occurring. For example, ergonomic or equipment setup was reported as the cause in some incidents involving nuclear medicine preparation.

Equipment life management

Reliable equipment needs to be managed over its life including its initial design, use and maintenance. ARIR reports show that equipment reliability and safety are closely related because of the need for repeat exposures after a malfunction. It is therefore important to select the right equipment based on business needs and maintain it so that it remains reliable to the end of life.

Regular servicing and effective maintenance (in line with manufacturer requirements) are both important in ensuring that equipment remains reliable.

Equipment selection

Selecting the right equipment that will also perform reliably requires careful consideration of factors such as worker competencies, service requirements, and commonality and compatibility with other equipment. The <u>Device Usability Evaluation Handbook</u> published by the NSW Clinical Excellence Commission may be a useful resource in considering these factors.

Example case: microwave

During routine preparation of technetium (Tc^{99m}) sestamibi, a vial containing approximately 9.7 GBq of Tc^{99m} and its plastic holding container broke in the hot lab microwave while being heated causing contamination of the microwave and the adjacent hot lab area.

(Effective dose, for 4 staff: less than 0.1 mSv.)

Learnings:

The hospital evaluated the use of heat blocks for heating, as well as the requirements for a new microwave for preparation of radiopharmaceuticals that require heating.

The need for initial testing and commissioning of this equipment with non-radioactive liquids was also highlighted in a report.

Equipment limitations

Equipment used beyond its capability or capacity may result in failure. They may be used this way because staff are unaware of these limitations. In such a case the equipment deficiency can also be human error.

Example case: equipment limitation

A patient unnecessarily received 2 four-dimensional CT (4DCT) scans as part of radiotherapy planning. A 4DCT scan series consists of approximately 10 repeated CT scans taken over the same scanning range to provide views throughout the breathing cycle. The first scan exceeded the number of reconstructed slices allowed in the treatment planning system. The scan was subsequently repeated with a smaller scanning range.

A new step has been introduced which requires radiographers to confirm the number of images being taken is less than that accepted by the 4DCT reconstruction software. Radiology staff were also made aware of this limit.

(The effective dose from unnecessary scans: ~90 mSv.)

Learnings:

This incident highlights the need to take equipment limitations into account. Staff need to be trained to ensure they understand equipment limitations and that the limitations change.

End of life

The end of life of equipment should be planned for. As equipment ages, the range of errors that can occur often increases. This can make repair and maintenance more difficult. Additionally, new equipment can have enhanced clinical or safety features outcomes such as reduced scan time or new reconstruction techniques. This has both safety and economic considerations for owners of equipment.

When should diagnostic imaging equipment be replaced?

Diagnostic imaging equipment is allocated life ages for Medicare benefits purposes. This is known as 'capital sensitivity' which is intended to encourage practices to regularly upgrade or replace equipment, as appropriate. Medicare benefits are no longer payable for diagnostic imaging services rendered on equipment that has exceeded its effective life age or maximum extended life age unless the practice has an exemption. For more information see <u>Medicare website</u>.

Example case: equipment nearing end of life

A patient attended for a PET/CT whole body scan. During the PET image acquisition, an error occurred with the scanner's timeclock, affecting decay corrections for all data collected between the shoulders and the upper thighs. Due to normalisation of the data on the screen, the problem was not identified during acquisition but only after reconstruction. The resulting images showed almost no uptake between the shoulders and upper thighs and therefore were undiagnostic. The study was repeated on the department's other PET-CT scanner.

Following a previous similar incident, engineers replaced a circuit board in the scanner's computer; However, the error recurred and remained under investigation. A factor in the error was thought to be the ageing machine as it was due for replacement.

(Effective dose from first CT scan, which was performed without benefit to patient: 10.2 mSv.)

Learnings:

This incident highlights the importance of maintaining equipment with regular servicing and timely decommissioning or replacement. It also highlights the importance of equipment availability such as another scanner. See the section on Recovering from equipment failure.

Equipment design and failure detection

Equipment failure is a risk that can usually be anticipated and managed even if it cannot be avoided entirely. The design of the equipment, and the active detection and reporting of equipment issues is an important part of maintaining equipment safety.

Detection of equipment failure

Some equipment failure results in a higher than normal dose to the patient. This can occur when using a higher than necessary exposure setting or where an imaging field extends beyond what was intended. This type of incident can be more difficult to detect as there may not be an immediate effect in comparison to a piece of equipment not working and may only be discovered in review or when using specific tools.

Example case: higher dose due to equipment failure – fluoroscopy

Following a cardiac angiographic procedure, it was noted that the radiation dose recorded by the X-ray unit's dose tracking system did not match the dose recorded by the in-built dose-area product chamber.

Investigation revealed that one of the collimator leaves was not working. It was subsequently determined that this problem had occurred in two previous procedures. These two patients were irradiated beyond the selected fields of view. A new collimator module was ordered and installed by hospital engineers.

(Skin entrance dose for these two patients: 3 Gy and 4.5 Gy - instead of typically 1 Gy and 2 Gy.)

Learnings:

This incident highlights:

- the effectiveness of having the multiple independent systems installed to track performance of the equipment which is how the error was identified
- that medical equipment needs to be serviced regularly.

Equipment testing and audits

Testing of radiation equipment is important to confirm that it is operating as expected. This includes ensuring that the radiation output is in accordance with selected settings. This type of error is often difficult for an operator to detect which is why proper testing is important. Testing can include internal checks, third-party compliance testing of diagnostic medical imaging devices, and audits such as those conducted by ARPANSA's Australian Clinical Dosimetry Service (ACDS) for therapy equipment. One such ACDS audit revealed that a planning system had incorrectly assigned the density of air for a patient's CT slices. The audit identified that any patients treated in a specific manner would be over-treated by 5–8% of the planned dose.

Reporting equipment failure

Once equipment fails, it is important to ensure that the fault is properly reported and investigated and that any potential patient impact is also investigated. Where possible, test images using a phantom should be carried out following an equipment failure.

For example, general equipment communication errors can be due to a wide range of issues, such as loss of the connection between the (wireless) image plate and the unit due to a low battery. This may make it difficult for the user to determine the exact cause of the incident. However, it is important to report to manufacturers as such information may be used to improve equipment design. For example, systems can be designed that are self-limiting –the equipment automatically minimises the impact of any error which could lead to an increase in exposure. A further example of this is the design of systems that do not initiate an exposure where low battery levels are detected.

Reporting of equipment-related incidents to the manufacturer and regulatory agencies is important so that solutions can be implemented in software/firmware updates or as part of new product development and approval.

Example case: equipment failure

Thirteen incidents involved mammography detector communication dropout (red tile) during an exposure. This is a reduction from the previous year in which 39 such incidents were reported. In each instance the error did not reappear after equipment was reset.

(Average effective dose: ~0.3mSv, average glandular dose: ~1.3 mGy.)

Learnings:

This incident highlights the importance of appropriate maintenance and error reporting. Other similar incidents highlight where manufacturers had issued a product advisories or supply software/firmware patches in response to incident notifications from hospital staff.

Operational design and resilience

Equipment design cannot anticipate and prevent every possible occurrence of malfunction. Given this, procedures and workplace practices should take into account the potential for equipment failure. While human action (error) may trigger an equipment malfunction, human action can also prevent, identify, mitigate or recover from equipment malfunctions.

Recovering from equipment failure

Where a scan fails to complete or images are not captured, data can often be recovered to reconstruct the image. In the case of hybrid imaging failure, the CT component can sometimes be reused rather than repeated saving the patient from the additional exposure.

What is hybrid imaging?

Hybrid imaging refers to when two types of images/scans are combined, for example a SPECT/CT. The SPECT (Single Photon Emission Computed Tomography) uses a gamma camera and an injected nuclear medicine tracer to obtain functional images of the body part, while the CT scan provides images of anatomical features. The two scans are combined to make a single 3D image.

Example case: nuclear medicine – hybrid imaging

A patient was referred for bone SPECT/CT. The CT scan of the thorax was completed normally but the following SPECT scan halted at 62% with a spurious orbit error. The scanner was reset and the scan was performed from scratch.

(Effective dose: 3 mSv.)

Learnings:

A bypass process was adopted for scans which fail during SPECT acquisition so that the CT component does not need to be repeated. This requires the auto-body contour subsystem to be bypassed once the scanner error manifests with a manual (elliptical) orbit specified instead.

Supporting equipment and staff

Equipment failure is not limited to radiation emitting devices, such as the scanner or the pharmaceuticals used. If any piece of critical equipment malfunctions, the result can be a scan that is not clinically beneficial.

Example case: infusion pump failure

During a myocardial perfusion scan, an infusion pump failed to administer the correct amount adenosine which is needed to ensure the required blood flow for successful imaging. The technologist was instructed by the supervising doctor to administer the radioisotope regardless. The technologist questioned this 3 times and indicated that the adenosine syringe system appeared to still be loaded. The patient was sent home after being administered with 1,396 MBq of Tc^{99m} terofosmin and receiving no diagnostic benefit from imaging performed.

(Effective dose: 11 mSv.)

Learnings:

This incident highlights the importance of effective communication between clinical staff. The site Radiation Safety Officer concluded that the doctor should have taken into account the experience of the nuclear medicine technologist and understood that the resultant scan would not be of diagnostic quality.

Recovery plans

Large sources of radiation are sometimes used in mining and other industrial applications where equipment may be subject to significant forces and be used in environments that can cause significant corrosion and wear. The radiation source in a soil density probe for example, can become stuck or detached. These detached sources have resulted in some very serious incidents, including one in 2014 that was highlighted in past ARIR reports.

The mining industry is another area where it is important to consider the range of potential equipment malfunctions and these considerations should be included in risk assessment, procedures, staff training and equipment maintenance schedules.

How do soil density probes work?

Measurements can be taken by lowering a tool that contains both a radiation source and detector down a hole and based on the radiation scatter determine characteristics such as density, moisture content and composition. The depth can range from a few centimetres (for small hand portable equipment used on construction sites) to very deep boreholes in the mining industry. These often rely on measurements using both neutrons and X-rays, which can be either from an electrical source or, more commonly, from radioactive material.

Example case: density probes

A malfunction occurred during use of a neutron probe that resulted in the source tube and the probe's electronic assembly separating from the cable and dropping to the bottom of the bore hole. The source tube separated and was retrieved a few days later. As this device contained an electronic source of neutrons rather than radioactive material there was no radiation risk associated with a failed recovery.

(No additional dose to operators.)

A density tool with a radioactive source was unintentionally released into an uncontrolled descent from 32–134 m. The wire line parted and the tool was unable to be immediately recovered using conventional methods. The tool, including the source, was later recovered.

(No additional dose to operators.)

An exploration vertical hole was drilled to 102 m. The next day, a geophysical technician had run a dummy tool to 27.3 m, where it held up in the hole. Then a magnetic susceptibility tool was run to a depth of 29.3 m and returned to surface without any problems. The technician then ran the gamma-gamma density tool to a depth of 28.3 m and proceeded to record data. The technician noticed after 2 m a strange density response. Examination of the recorded data confirms that the source became detached 2 m into the assent. The hole was demarcated and the client, operations managers and company Radiation Safety Officer were informed. The following day a video survey was conducted and was able to get to 73 m where the hole was blocked. Due to poor visibility, the source bullplug (containing 2 cobalt-60 sealed sources) could not be identified. Borehole gamma survey confirmed the presence of the source in the borehole at approximately 72 m from surface. The source had not been removed at the time of reporting, and further recovery attempts are planned to be made.

(No additional dose to operators.)

Example case: density probes

Learnings:

- As this is a foreseeable type of incident, the recovery process should be covered by a risk assessment along with a specific procedure. This should be captured as part of the Job Safety Assessment (JSA) or similar.
- Previous incidents have highlighted corrosion of wire or joints as a contributing factor to this type of incident. The corrosion is sometimes concealed under tape or bindings making inspection more difficult.

Equipment not available when required

There were 11 incidents where nuclear medicine was administered to a patient but due to equipment malfunction the subsequent scan was not performed in time and so no clinical information was collected.

Why timing is important in nuclear medicine?

In nuclear medicine radioactive material is injected into the patient. Once the material accumulates in the area of the body under examination, imaging can be performed. The imaging needs to be carried out before too much of the radioactive material decays or is discharged by the body. The specific window of time for successful imaging varies with the procedure. A 2 to 4-hour window is typical for common bone scans.

In some cases, such as a cardiac stress tests, a patient normally must complete physical exercise during this time (such as running on a treadmill) to ensure the desired uptake of the radionuclide. However, if physical exercise is not possible a pharmaceutical substitute (such as adenosine) may be used to cause similar heart functions.

Example case: radiopharmaceutical administered, no scan performed

A gamma camera collimator system at a medical imaging practice developed a fault. The error could not be resolved in time to put the system back into clinical practice that day. However, 8 patients had already received an injection, of Tc^{99m} hydroxymethylene diphosphonate (HDP) with activities ranging from 786–861 MBq, for bone scans scheduled later in the day. All 8 patients had to be rebooked for another day.

(Effective dose: ~4 mSv each.)

The PET/CT scanner bed became nonresponsive after a patient (~105kg) pushed themselves on the bed to move during patient positioning. At the time of the malfunction 3 other patients had already been injected with PET radiopharmaceuticals.

It was possible to organise for two of the patients to be imaged at another hospital. Two patients had to be rescheduled for a new scan.

(Effective dose for patients not scanned: ~7 mSv each.)

Example case: radiopharmaceutical administered, no scan performed

Learnings

- Where possible, a second scanner or an agreement with a nearby imaging practice should be put in place. This allows the scanning of patients in the case of equipment malfunction without the need to readminister the radiopharmaceutical. However, this is not always possible particularly in regional settings and where specialist equipment such as a PET scanner is required.
- Procedures should be in place to avoid excess force on the scanner bed.
- Highlights the importance of:
 - Daily quality control checks on the gamma camera that should be carried out prior to injecting the first patient. However, it is noted that these checks cannot detect all possible issues.
 - Effective equipment servicing to minimise this type of occurrence.

Other factors

Incidents such as spills can occur for a wide range of reasons including containers breaking from impact, incorrect equipment selection, or failure of syringes and injecting equipment. These incidents are further discussed in <u>Spills of radiopharmaceuticals</u> in this report. These types of incidents often highlight the connection between human, technological and organisational factors in incidents. For example, a broken vial could be the result of being dropped (with human error being the proximal cause), but other factors that could have contributed to the incident include the piece of equipment itself that malfunctioned/broke and how it was used (the design of the system). As highlighted in ARIR reports, often the remedial actions to this type of incident include equipment changes (the use of bubble wrap or soft absorbent liners to reduce the chance of a breakage) or changes to the organisational procedure (better storage, supervision or the elimination of distractions).



Direct causes of incidents

Across all incidents reported in 2019, human error was identified as the direct cause in 61% (352) of cases. This is consistent with previous years. However, the direct, or initiating, cause should not be seen as more important than other contributing factors. Addressing the contributing factors may be as effective in preventing the incident or reducing negative outcomes.

Incidents by primary cause



Human error refers to something has been done that was not intended, was not desired by a set of rules, or that led the task or a system outside of acceptable limits. It should not be confused with a person being at fault but only that the outcome of human actions was undesirable. For more information on human error and elements that lead to human error see the <u>ARPANSA Website</u> and <u>Holistic Safety Guide</u>.

Equipment malfunction includes software and hardware failures. This can include incidents like breaks, glitches, or power failures. Malfunctions may be caused by human error in the design, manufacturing, operation and maintenance of equipment. In contrast, **equipment deficiency** is where the equipment used was not suitable for the task or failed to perform as expected. Equipment-related incidents are discussed further in *Feature topic: equipment-related incidents* in this report.

Patient factors outside operator control include where the patient becomes unwell or suffers anxiety (for example claustrophobia) or self-discharges.

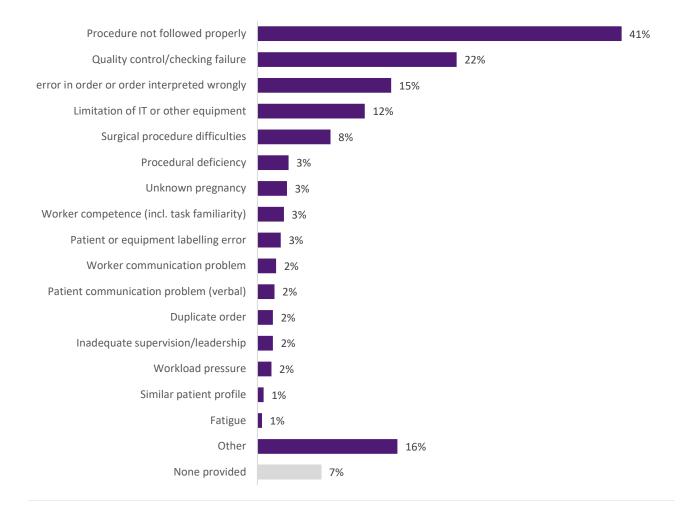
Medical procedure complications can result in a higher than normal dose being received by the patient. For example, during a complex surgery, a significant fluoroscopic dose may be delivered if the procedure takes longer than is typical. This is reportable as an incident in most jurisdictions.

Contributing factors of incidents

An incident will often have a number of contributing factors. However, these factors are not always identified in the reports submitted to the ARIR. In instances such as medical complications during a procedure or equipment failure, these factors may not be readily apparent. In 7% of incidents, no information on contributing factors was provided. Analysis of the contributing factors, such as why a procedure was not followed, can have a wider benefit in exposing underlying vulnerabilities that could result in other incidents.

Typically, there are multiple contributing factors involved in incidents and it is quite possible that the incidents would not have occurred if one of the contributing factors had been prevented. This is the basis for the 'Swiss cheese' model of safety where an incident or accident occurs only where there is an alignment of vulnerabilities. This demonstrates the value of the 'defence in depth' approach to radiation safety, where a number of independent controls contribute to safety. With effective monitoring of these controls, it is possible to detect deviations, positive or negative, from the expected outcomes. This can lead to issues and improvements being identified early which can reduce the likelihood of incidents with significant outcomes occurring.

The most common contributing factor this year was 'individuals not following procedures'. This was identified as a factor in 41% of incidents. The next biggest factors were errors in quality control, and issues related to orders or referrals. This is consistent with previous year's findings.

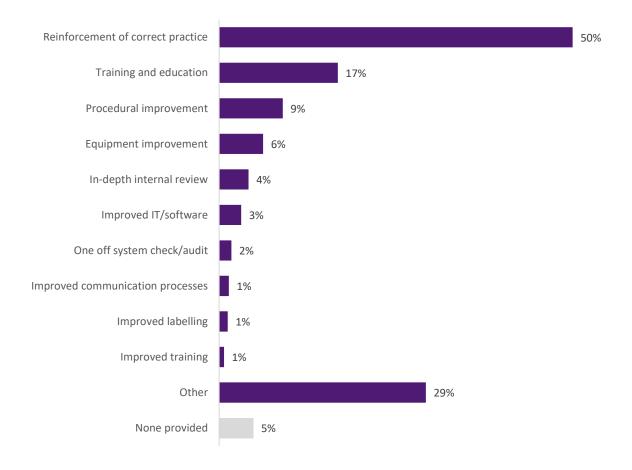


Contributing factors identified in 2019 incidents

Summary of controls and preventive measures implemented

Preventative measures are actions taken as a result of an incident to prevent recurrence. The preventative measures taken were identified in most reports. Examples of when no actions were identified include where equipment faults could not be reproduced, unforeseen patient complications, and unknown pregnancies.

Reinforcement of procedures and reminders of good practice remain the most common actions taken after an incident. In 2019 such actions were taken in 50% of incidents, which is consistent with the previous year. This remedial action may not be effective in the long term if used in isolation from other measures such as improved equipment and regular system checks.



Remedial actions taken to prevent recurrence in 2019



Medical – diagnostic imaging

This category covers medical imaging performed using X-ray apparatus and diagnostic nuclear medicine.

Overall statistics for diagnostic imaging incidents, by modality

Modality	Number of incidents reported	Effective dose per incident Note: does not include skin or critical organ doses.			
		Average	Range		
Computed tomography (CT)	208	6.0 mSv	0–61 mSv		
General X-ray	143	0.5 mSv	0–17 mSv		
Fluoroscopic/interventional	36	1.4 mSv	0—27 mSv skin doses up to 15 Gy		
Dental	5	0.03 mSv	0–0.1 mSv		
Nuclear medicine	141	4.6 mSv	0–68 mSv		

Overall statistics for diagnostic imaging incidents, by description

Туре	No. of incidents	Percentage	Effective dose per incident Note: does not include skin or critical organ doses.			
	reported		Average	Range		
Unnecessary scans	295	55%	4.7 mSv	0–56 mSv		
Equipment failure	94	18%	3.1 mSv	0–61 mSv		
Medical procedure complications	33	6%	0.2 mSv	0—5 mSv (skin doses up to 15 Gy)		
Unknown pregnancy	25	5%	3.1 mSv	0–28 mSv		
Incorrect radiopharmaceutical / dose	20	4%	10.1 mSv	0–69 mSv		
Extravasation of radiopharmaceuticals	28	5%	2.0 mSv	0–13 mSv		
Spills / contamination	6	1%	0.2 mSv	0–0.2 mSv		
Other	32	2%	3.4 mSv	0–20 mSv		
Total/average	533		3.9 mSv	0–70 mSv		

Equipment failure or deficiency is covered in the <u>feature topic</u>.

Unnecessary scans or scans not as intended

The most frequent type of incidents in the medical category were procedures carried out that were not as intended by the referrer. This means the benefit the referrer intended was not realised. In 2019 these included:

- incorrect region/procedure (46%)
- repeated imaging (36%)
- imaging the wrong patient (18%).

These incidents have the potential to significantly affect patient outcomes, for example if this is not picked up and wrong clinical decisions are made based on this imaging. Where incidents are detected and patients rescanned, it is not only resource and time consuming for both the medical imaging practice and the patient, but the patient also receives extra radiation exposure from the repeated imaging.

Example cases: incorrect procedure

A 70-year-old patient presented for a CT Right Hip (pre op). A CT examination of the right hip was undertaken by the medical imaging technologist (MIT). After the examination, the patient's wife indicated that the patient had knee surgery booked and not hip surgery. The MIT confirmed with the requesting doctor that details on the request form were incorrect and the hip CT was not needed.

(Effective dose: ~6 mSv.)

Example cases: incorrect settings

A hospital patient presented for a fluoroscopy guided defecating proctogram (DPG). The radiology registrars and radiographers involved incorrectly performed the imaging using 'acquisition mode' instead of 'fluoroscopy mode'. The use of acquisition mode greatly increased the radiation exposure to the patients. The use of the correct mode was reinforced at this practice.

(Effective dose: ~27 mSv.)

Example cases: wrong patient

A patient underwent a follow up CT coronary angiogram imaging of lung nodules as requested by the lung nodule clinic of the hospital. On reviewing the angiogram, the reporting radiologist indicated that no nodules were evident. The request for the follow up imaging was generated based on the CT coronary angiogram that another patient had previously undergone. The report for the first angiogram had been filed under the records of the incorrect patient. This occurred when the record was being transferred manually from one radiological information system to another. Changes to systems, such as a PACS, may help to minimise the possibility of such incidents in the future.

(Effective dose ~ 9.2 mSv.)

A hospital patient underwent a CT scan of the abdomen and pelvis with contrast that was intended for another patient. The radiographer involved used closed questions in identifying the patient.

(Effective dose: ~6.5 mSv.)

Two requests were submitted for 2 different patients at the emergency department – both for CT brain & C-spine and X-rays of the pelvis; for one patient an additional X-ray of the left hip, the other patient additional chest X-ray. Patient A was imaged without incident. A patient was then brought to ED Imaging by a wardsman and escorting nurse. CT Radiographer confirmed patient details with the escorting nurse and thought they had looked at the wristband. CT Imaging performed. Patient transferred to X-ray room, where radiographer performed X-rays, without confirming patient ID. Imaging showed fracture of left femur. Error was discovered following day when Patient B was sent for pre-op X-rays which showed no fracture. Investigation showed that Patient A was re-imaged as Patient B, with Patient B not imaged. A new pick up slip document and process has now been developed.

Learnings:

The previous <u>ARIR Report covering incidents in 2017</u> contained a feature topic on CT including a section on unnecessary scans, highlighting the importance of time-out procedures and ensuring correct patient, correct site/side, and correct procedure.

This category includes incidents involving the wrong patient or where scans are recorded against the wrong record. The importance of having the correct patient information when making clinical decisions was highlighted in an international case occurring in 2019.

International example case: incorrect image selection

In March 2019 at a hospital in England, a doctor in the accident and emergency (A&E) unit discharged a patient after mistakenly viewing the wrong CT scan results. This was detected two days later and the patient was readmitted but died shortly thereafter following a cardiac arrest due to a ruptured aortic aneurysm. The patient had Marfan syndrome and had been awaiting heart surgery.

An inquest into the death found that the patient was discharged when a previous CT image was looked at by mistake. A contributing factor in this was that current systems were described as 'not user-friendly' and 'unwieldy'. The doctor stated that had he seen the CT report, he 'wouldn't have sent him home'.

Another potential contributing factor was fatigue, as the doctor finished his shift two-and-a-half hours later than scheduled. It was considered unlikely that he would have taken a break and likely that he was under time pressure as, due to local hospital rules that limit shift length, he was required to finish his shift before midnight.

Since the incident, the radiology department has changed its procedures and will upgrade the Picture Archive and Communication System (PACS) which stores the scans and reports. A new procedure was implemented. When abnormalities are found, radiologists must now phone the doctor who requested the CT scan, instead of asking administrative staff to do so.

Learnings:

This incident highlights:

- the importance of clinical decisions being made on the basis of imaging. Where the decision is based on incorrect imaging, the consequence can be significant.
- the importance of effective communication between professionals.
- that computer systems need to effective and easy to use, particularly in a busy emergency department setting.
- that fatigue, shift length and shift restrictions can be a factor in performance.

Incorrect radiopharmaceutical/dose

A number of incidents included workflow issues, where the correct procedure was not adhered to, leading to incorrect radiopharmaceuticals or incorrect dose being administered. While human error (not following a procedure) is often the proximal cause of an incident, the underlying contributing factors play a large part.

How are radiopharmaceuticals made?

There are two components that come together in nuclear medicine. The radioactive material that the cameras pick up, and the pharmaceutical agent that determines where in the body the radioactive material will go (uptake organ).

For example, where Tc^{99m} is combined (cleated) with mercaptoacetyltriglycine (MAG3) and is injected into the patient, the resulting imaging can reveal how the kidneys and renal system are functioning. Without the MAG3 the Tc^{99m} would not be taken up by the kidney.

The radioactive material generally originates in a reactor or accelerator that is offsite. The pharmaceutical agent is usually supplied in the form of a 'cold kit' to which the radioactive material is added. The combination can take place within the nuclear medicine department, or at a dedicated radiopharmacy which then supplies individual 'unit doses' (in a syringe) or a bulk dose (in a vial). This determines which quality assurance (QA) steps are undertaken where.

The final radiopharmaceutical is commonly referred to as 'a dose' and has an activity measured in becquerel (Bq). This indicates how much radioactive material is present and this varies for each patient depending on their size and needs. This quantity is different to the effective dose, measured in Sv, which is a measure of exposure and relates to potential harm.

Example case: administration of incorrect amount of radiopharmaceutical

A patient attended for a PET-CT whole body scan. At the time of booking, the patient's height and weight had been entered into the database as 152 cm and 80 kg. The nurse weighed the patient in the waiting room and escorted the patient to the prep room but forgot to update the patient's weight in the database.

The injecting Medical Radiation Scientist (MRS) prepared and injected 500 MBq F¹⁸ FDG, based on the data in the system. After escorting the patient to the scanning bed the MRS noted that the patient looked quite small for the set scanning time. The patient was weighed again and found to be 148 cm and 42 kg. It was determined that the corresponding administered activity should have been 293 MBq.

A contributing factor was distraction of the nurse by the patient's son which led to the nurse forgetting to update the patient's weight in the database.

(Excess effective dose: 3.9 mSv.)

Learnings:

- The use of electronic tablets could be introduced so that data can be entered at the patient's side at the time of the measurement rather than writing it down and then entering it on the computer at the nursing station. This would reduce the risk that data entry is neglected and of transcription errors.
- Checklists can be effective at assisting people carrying out sequential task.

Example case: wrong pharmaceutical/binding agent

A patient attended for renal scan with Tc^{99m} MAG3.Due to supply issues of Tc^{99m} generators, the Tc^{99m} the MAG3 dose had been ordered from a radio-pharmacy. The dose label, packing list and syringe label all stated Tc^{99m} MAG3. However, following administration, uptake was consistent with unbound Tc^{99m}.

(Effective dose: 2.8 mSv.)

A patient booked for a lung scan Tc^{99m} MAA was incorrectly administered a radiopharmaceutical used for imaging the kidneys (Tc^{99m} MAG3). Based on the presence of radioactivity in the kidneys, it was suspected that the technologist had incorrectly dispensed a patient dose from the vial Tc^{99m} MAG3 that was housed in a lead pot adjacent to the Tc^{99m} MAA vial, having misread the label on the vial.

(Effective dose: 1.2 mSv.)

A patient had a bone scan demonstrating abnormal bone uptake along with cardiac, biliary and bowel uptake. The patient returned to the department for a repeat scan to determine if the uptake was physiological. The repeat bone scan demonstrated only normal skeletal uptake. The uptake on the bone scan suggests that both MDP and MIBI were introduced into the syringe used to administer the radiopharmaceutical. The skeletal uptake on the initial scan was significantly more that would be seen in a patient had they only received MIBI.

(Effective dose: 4.9 mSv.)

Learnings:

• All the pots containing reconstituted radiopharmaceuticals are to be kept in a lead box on the opposite side of the room so that only one pot (radiopharmaceutical) is behind the dispensing shield at a time.

Example case: wrong pharmaceutical/binding agent

A number of incidents that highlight the use of technology, and human factors (including the use of obvious identifies such as colour labelling) are discussed in the feature topic on nuclear medicine in the <u>ARIR report covering</u> <u>incidents occurring in 2016</u>.

Spills of radiopharmaceuticals

Six incidents involved the spill of radiopharmaceuticals. Small spills can typically be cleaned up without significant dose to persons and clean-up is often made easier by the relatively short half-life of medical isotopes. However, if contamination is not detected, it could lead to exposure to people including from ingestion or inhalation of radioactive material. Material which comes into close contact with the skin can also lead to significant skin dose particularly material used for PET scanning.

Example case: spills

During the administration of lutecium (Lu¹⁷⁷ PSMA) radiopharmaceutical the advanced medical trainee did not secure the cap on the used syringe. This fell on the floor contaminating the room. The technologist present in the room picked up the cap and disposed of it. The medical trainee and the technologist did not realise the syringe contained radioactivity and had contaminated the floor. Contamination was discovered by the medical physics specialist around an hour after the accident occurred. The technologist, the medical physics registrar and the patient had contaminated shoes. The contamination was spread in the room and at its entrance.

The shoes were double bagged and stored in the radioactive waste store, and the patient was moved to a different room making sure not to further spread contamination. Contamination level was assessed and the room was locked, radiation signs were put on the door and a physical barrier used to prevent people entering it until the material had decayed (days).

A vial containing ~23 GBq of fluorine (F¹⁸ FDG) was cracked in a dispensing apparatus and aqueous radioactive material split onto the shielded dispensing area. The vial was in a protective shield and was accidentally dropped onto the hard surface of the shielded structure where the work was being undertaken. Aqueous contents started dripping out of the protective shield. Soft absorbent material was placed at the base of the unit to catch any future drips.

A student was drawing up 2 ml of technetium (Tc^{99m} pertechnetate) under the direct supervision of a qualified technologist. During a moment of inattention, the student selected a 3 ml syringe rather than the recommended 5 ml syringe. The syringe was overdrawn and the plunger popped out the back, along with ~10 GBq of Tc^{99m} .

Some contamination was found on the floor and the soles of the student and the technologist's shoes. No contamination was found on skin or other clothing.

Learnings:

- Soft absorbent material should be placed on the bottom of dispensing (shielded) areas to reduce the chance of the vial cracking and facilitate clean-up.
- Syringes/hot consumables should only be handled in a designated area with minimal movement (across room).
- Syringes should be selected that have at least twice the desired draw-up volume when preparing or dispensing radionuclides.
- The importance of adequate immediate supervision of students when handling regulated material.

Supervision in the medical industry

New staff, students, and recent graduates undertaking their professional development year are required to undergo a period of supervision. During this time the student may not hold a licence, or hold a limited licence which restricts their operation, until such a time as they are deemed competent. This depends on the jurisdiction. Their licenced supervisor is responsible during this time. Over the supervision period, students typically progress from immediate close supervision to general supervision. The supervision arrangements during this time need to be carefully considered and monitored to ensure effectiveness.

Example case: supervision

During theatre procedure for spinal surgery the radiographer undertook a c-spine level check with a fluoroscope. The radiographer misheard the surgeon and initiated the exposure whilst the surgeon and other medical support staff were working on the patient.

Prior to the exposure the surgeon reprimanded the radiographer for turning up late and was described as 'quite rude' throughout the procedure. This added to a high-pressure environment and inhibited clear professional communication.

The radiographer was a student who was required to hold a student licence and be under supervision of an experienced radiographer. However, the regulatory agency investigation found that neither of these were in place. The medical imaging provider was directed to create a training manual specific to student radiographer training and supervision.

(Effective dose of all staff: less than 0.02 mSv.)

Learnings:

- The importance of adequate immediate supervision of students, when handling regulated material or operating equipment.
- Each radiation practice must have documentation that covers student training if they have students. This includes clear requirements and responsibilities for the supervisor.
- Licencing of students is different across the jurisdictions and radiation practices must educate themselves to the requirements in their jurisdiction.
- Abrasive behaviour inhibits clear communication and can lead to adverse outcome.

Shielding

Why is PPE needed?

The use of shielding is an important control for radiation protection. In most cases shielding is constructed so that staff can be in a shielded location when operating equipment. However, in interventional situations, staff performing surgery on a patient must be next to the patient being actively X-rayed. In this case personal protective equipment (PPE), such as lead gown/glasses, are a primary defence against exposure.

Example case: fluoroscopy PPE

A doctor (urology registrar) did not wear PPE during an interventional procedure.

When the radiographer arrived at the operating theatre the Registrar was scrubbed with gown completely tied up, and everyone else was wearing their lead gown. The Radiographer asked to confirm if everyone had PPE on before commencing the procedure. The Registrar did not respond. It was only when they removed their sterile gown that it was noticed that the Registrar had forgotten to wear the lead gown. The Registrar involved was informed of the estimated radiation exposure and of the legal requirements.

Learnings:

Highlights the importance of PPE in interventional settings, and vigilance in ensuring requirements are in place and followed. Asking a question to the room such as 'is anyone not wearing PPE?', is not always effective as memory can be unreliable for ensuring all steps are followed in a complex environment. Important steps should to be brought to conscious memory through a variety of tools (e.g. team checks, integration with procedures, visual reminders, verbal protocols, checklists). This could also include gestures and visual or tactile feedback, which can be effective at directing attention to important controls.

Interventional, higher dose

Example case: fluoroscopy skin exposure

A patient was referred by his GP to a private surgeon who attempted a skin graft. Following this the patient was referred for corrective plastic surgery. The plastic surgeon identified injury due to a high skin dose from an interventional fluoroscopy procedure (embolisation of a splenic artery aneurysm). However, the patient had not been informed that a high skin dose had occurred.

(up to approximately 15 Gy peak skin dose.)

Learnings:

A high skin dose is not always avoidable and may be medically required for life-saving procedures, but protocols must be in place when there may be a radiation injury, including communication with the patient and reporting within the hospital and externally.

Radiotherapy

Radiotherapy is the use of radiation as treatment, often for cancer. This was the feature topic of the <u>ARIR</u> <u>report on incidents occurring in 2018</u>.

Doses in therapy

Radiotherapy doses are different from diagnostic imaging doses. A very large dose is delivered to a specific area for a clinical benefit. Other surrounding areas receive a smaller dose. Rarely the high dose might not be delivered to the correct site. As the absorbed dose (measured in Gy) is concentrated on a specific area, this is hard to compare with an effective dose (Sv) for the whole body.

Radiotherapy incident statistics

Category	Number of Doses reports		
Treatment site	11	Ranged from 3 to 10 Gy additional, with an average of 5 Gy	
Patient positioning	6	Additional does to non-target areas ranged from 0.001Gy to 1 Gy	
Planning CT	4	Ranging from 25 to 90 mSv, average dose 25 mSv effective dose	
Treatment dose	1	12% less dose delivered	
Other	1	10 Gy to treatment site	
Total	23		

One incident relates to equipment malfunction and is discussed in the <u>feature topic</u>. Additionally, one incident related to <u>transport of a source</u> used for radiotherapy.

Treatment site

Misalignment or targeting the wrong site can occur for a variety of reasons. Mismatching using the spine or skin markings were reported in several incidents.

How is the treatment targeted?

Usually, planning images (CT) are taken of the patient in the same position as the treatment will be delivered. Patients generally attend several times for a course of treatments. Each time the patient is treated, the patient and the machine must be aligned precisely. This is done by aligning the position of anatomical features (e.g. the location of the spine, ribs etc) in the X-ray or using surface marks such as tattoos. Example case: incorrect treatment site – anatomical misalignment

Patient undergoing palliative radiotherapy was prescribed treatment to thoracic vertebrae 3–5 (17.5 Gy, 5 fractions). Pre-treatment imaging was performed, and the image was matched to the incorrect vertebral level, resulting in 1 fraction of treatment being delivered to T4–T6. The error discovered on the weekly chart check.

(Under dose of T3 [14 Gy delivered instead of 17.5 Gy intended] and increased dose of T6 [4.3 Gy delivered instead of 1.3 Gy intended].)

Incidents were identified at different stages in planning, during treatment or verification. Typically, if picked up earlier, such as during planning, the impact to the patient can be minimised or prevented.

Example case: incorrect treatment site – marker alignment

The patient was setup incorrectly to a freckle rather than the tattoo, a difference of 2 cm inferior and 1 cm left of the intended treatment isocentre. The pre-treatment cone beam computed tomography (CBCT) scan picked up and corrected for the error; however, the move required was greater than the department's verification imaging policy tolerance so an additional CBCT was required to verify the patient shift was correct. Therefore, the patient received an additional CBCT to verify the isocentre position prior to treatment.

(Nil from treatment, 6.8 mSv from pre-treatment CBCT.)

Incidents which are picked up in post-treatment review help to improve practices and identify learnings. These incidents can be more effective at identifying opportunities for improvements as any subsequent independent reviews are not subject to factors such as time pressure prior to treatment commencing.

Example case: incorrect treatment site – post-treatment review

Geographic miss detected during post-treatment quality assurance of radiation therapy treatment.

The patient attended for the treatment for the third fraction of the 5 prescribed fractions (4 Gy). Patient identification and setup was completed correctly, and online pre-treatment image verification was undertaken. Orthogonal images were acquired and analysed online by two Radiation Therapists. It was noted by the treatment Radiation Therapists that although it was difficult to obtain an absolute match in each of the image views, the match performed was the best fit of the day.

Upon the usual practice of retrospective review of the orthogonal images by an independent radiation therapist, it was observed that a shift of 1.5 cm inferiorly would result in a better overall match on ribs and vertebrae.

(The mismatch resulted in a slight reduction rather than an increase in dose, due to the angulation of the planned fields. No corrective action was requested by the Radiation Oncologist, and so no clinical consequence for the patient.)

Learnings:

- Before delivering treatment, staff need to be sure that they understood the treatment planning and patient anatomy match. Any uncertainty in the procedures should be discussed with others for correct treatment delivering.
- Where an issue is detected during treatment, it is important to promptly raise these. Further investigation can then inform decisions regarding adjustment to treatment if required.

Incorrect dose

The use of the incorrect settings can lead to increased or decreased doses.

Example case: incorrect dose

A patient received part of the treatment intended for one area to a different treatment area. The patient had been prescribed to receive treatment to the T-spine and left scapular. The patient was setup correctly to receive the T-spine treatment, but staff selected the scapula beam for treatment. The beam was interrupted when the mistake was realised (95 MU to the spine). The RT staff then delivered the remaining treatment which had been scheduled correctly. Incorrect vertebral level were registered in treatment planning. This is likely due to a mistake in planning which was not picked up.

(12.5% less dose delivered to the left scapular than that originally prescribed.)

Learnings:

Highlights the importance of double-checking parameters & calculations during pre-treatment planning.

Patient positioning

Patient movement should be avoided by providing effective stabilisation and clear instructions to patients and the staff positioning the patient. This is particularly important for extremities which can inadvertently enter the beam path.

Minimising patient movement

While the actual irradiation time is relatively short, the patient needs to be positioned accurately and remain still for an extended period of time, to ensure that the dose is delivered only to the area as intended and no other tissue is in the path of the beam. This setup is verified through imaging to confirm the position of the patient. To help reduce patient movement supports or restraints, such as masks (pictured), may be used.



Example case: patient positioning

A hospital patient was undergoing radiation therapy to the lower right leg. The prescribed absorbed dose to the limb was for 20 Gy in 10 fractions. After the seventh fraction of treatment, the patient reported discolouration on his left big toe. Analysis of all fraction images revealed that his left big toe was within the treatment radiation field for 2 of the 7 fractions.

(The dose to the toe was a maximum of 1 Gy. No clinical implications are expected from the positioning error.)

Patient imaging on fraction 5 for cancer of the cervix revealed patient had their arms down in the treatment field, when the setup instructions detail the patient to be positioned with arms up. On the image it was noted that the patient had her arms down, with elbows bent and hands clasped on her chest resulting in approx. 7.5 cm of at least one elbow being in the treatment field. All other setup imaging for the previous fractions showed the arms above the head.

A patient was undergoing external beam radiation therapy for treatment of oesophageal cancer. During one fraction the patient was observed via closed circuit TV to be partially sitting up during treatment of the upper chest. The radiation beam was immediately terminated. The patient did not alert radiation therapists to discomfort and pain during treatment. The patient was repositioned, and treatment continued, the importance of not moving during treatment was re-enforced.

(Tissues not intended to have been exposed received radiation dose of less than 1 mGy)

Example case: patient positioning

Patient was to receive 50 Gy in 20 fractions to the left nose using 9 MeV electrons, with custom-made wax bolus placed on the nose. As there was a gap between the patient's thermoplastic immobilisation mask and the custom-made wax bolus, a layer of tissue-equivalent material ('pink stuff') was also to be placed on top of the mask to fill the gap.

Instructions to the treatment team were provided in the electronic medical record used for daily set-up instructions as per current procedures. The initial treatment team overlooked this instruction and omitted the use of the pink stuff. There was subsequently no handover of 'pink stuff' instructions to the any of the team members involved in treatment fractions 1–9 (inclusive).

The issue was identified after analysing the thermoluminescent dosimeter (TLD) readings which showed an anomaly in dose being delivered compared to the expected planned dose. The pink stuff was correctly applied to the remaining prescribed treatment fractions (i.e. fractions 10–20 inclusive).

(The Radiation Oncologist has evaluated the effect of the missing pink stuff on the original dosimetry. Final plan was deemed to still be within ICRU guidelines and providing adequate treatment to the area.)

Learnings:

- Radiation therapists need to provide sufficient stabilisation for areas not being treated that are close to the area of treatment.
- Standardised set up for a procedure (e.g. gynaecology patients who typically have large field RT use arms above head position) reduces confusion and the risk of switching setup after a procedure commences.
- Handover instruction and communication between teams needs to be effective
- Highlights the effectiveness of TLD readings in highlighting dose discrepancies.
- Highlights the importance of imaging verification and good communication to ensure the patient remains in correct position during treatment

Laboratory and radiopharmaceutical production

Four incidents involved radioactive material in a laboratory or non-medical setting. This is in addition to similar <u>incidents within the medical space</u>. However, typically in a laboratory or production setting there will be a greater quantity of high-activity radioactive material. These sources pose a serious hazard to workers from direct contact. If contamination is not detected, it could lead to exposure of workers including from ingestion or inhalation of radioactive material. Detection of contamination can be made more difficult as this material may spread contaminate even where the volume of the liquid is too small to be visible.

What is a hot cell in nuclear medicine production?

In nuclear medicine production small quantities of highly radioactive material are processed. To avoid contamination and exposure to people, especially their hands, these processes are done in cells. This is a shielded box with a lead window. The operator uses manipulators that extend inside the box, rather than holding material with their hands. Once prepared the material is placed in a shielded container and 'posted' out of the cell through a locked chamber. This shielded container is usually free from contamination, unless something goes wrong.

Example case: spills and contamination

When exiting the facility, a production operator detected contamination on their face, shoulder and hair. The operator was involved in production of *I*¹³¹ in radiochemical cells, and contamination was detected on skin, personal protective equipment (PPE) and personal clothes.

The contributory cause of the personal contamination was the handling technique and vigilance of the staff member when posting materials for production into the radiochemical cells. These are administrative and PPE controls.

Follow up measurement of the thyroid showed there was no significant intake. It was conservatively estimated that the length of exposure was 3.5 hours and resulted in a small skin dose of approximately 16 mSv (which is 3% of the relevant dose limit).

A shielded container that was contaminated was being cleaned, which resulted in exposure of 3staff members. Two personnel exceeded their skin statutory dose exposure limits, with extremity doses of greater than 500 mSv, but did not result in any deterministic effects.

During the dispensing process, the manipulators accidentally touched the product bottle. As the contaminated manipulator touched other items, including the transport container, these also became contaminated. It was recognised that this could occur, which is why there was a detection and cleaning step. However, there was a failure to recognise the amount of radioactive material that could be transferred and thereby the potential hazard posed during cleaning of the pot after it was removed from the hot cell.

A glass vial containing 32GBq of Tc^{99m} sodium pertechnetate was dropped on the floor in the clean room laboratory as it was being transferred into the dose calibrator for measurement. The vial smashed upon impact with the floor, spreading Tc99m across approximately 2 square meters of the laboratory floor.

The spill was contained to the clean room. The broken glass was removed from the area and disposed of as radioactive waste. The area was covered with absorbent wipes which were then discarded as radioactive waste. The area was covered with significant amounts of lead shielding to reduce the dose rate within approximately 5 minutes of the spill occurring. Contaminated over gowns and over boots were placed in a bag and isolated within the laboratory. Contamination survey of the general laboratory area (immediately outside the clean room) showed that there had been no transfer of contamination.

Example case: spills and contamination

Unexpected radioactive contamination was identified on various items in a radiopharmacy. A radiochemist contaminated their gloves while working with Lu¹⁷⁷ possibly during high performance liquid chromatography (HPLC). They failed to check their gloves and several items in the lab got contaminated. This included reagent bottles, mouse/keyboards, pipettes, floor, main door handles, transfer sliding doors, and the handles of a transport trolley. Production was halted and contamination cleaned-up; staff were re-trained.

Learnings:

- Highlights the need for clear protocols/procedures for cleaning up spills and ensuring that staff are suitably trained.
- Highlights the importance of contamination checks, even on objects and surfaces where contamination is not expected. These controls are highlighted in Radiation Protection Series 14.2 and AS/NS 2243.4:2018.
- Where a task is regularly performed but there is no adverse result, people can become complacent about the magnitude of the risk. This is particularly important where administrative practices, technique, or PPE are important controls. Time pressures can also affect how closely people follow proper techniques and practices. Processes should be reviewed to ensure people understand the worst-case risks and that engineering controls are implemented were applicable. People should also be well trained in what to do in unexpected, incident or emergency situations. As reactions in an incident can differ from plans, this type of training should include practical or simulated components (drills).

These types of high-consequence low-probability events within laboratory settings were discussed in the previous two <u>*ARIR reports.*</u>

Other incidents

Lost, stolen or unauthorised disposal of sources

Six incidents involved lost or stolen sources, or sources disposed of without authorisation.

Example case: lost/unauthorised disposal

A hospital reported that a handheld dental apparatus was missing. It was due for disposal but could not be found. It did not appear to have been stolen for use as the two power packs (batteries) were not taken. If the apparatus was destroyed in regular waste, this would not pose a hazard.

The store in which it is kept is large and full of material. A search was made but the dental X-ray apparatus could not be found. Poor record keeping could not identify if the apparatus had been sent for disposal.

A company reported the loss of a small (185 kBq) caesium (Cs¹³⁷) check source. A stocktake of the radionuclide inventory within the source safe revealed that the check source was not in there. Subsequent searches of the company's premises as well as equipment kits failed to locate the source. Due to the low activity nature of this small check, it does not present a significant hazard.

Eight ultraviolet (UV) sources were unaccounted for and most likely disposed of during a recent laboratory refurbishment. All eight were in storage at the time of the refurbishment, and each apparatus contained an ultraviolet radiation source. Approval to dispose of the sources had not been obtained, nor was there any documentation that the disposal had occurred.

During a routine audit 5 portable pulsed X-ray generator units could not be found while 5 new portable pulsed X-ray generators were located. These generators are for use in non-destructive testing/ imaging. The new units were not registered with the regulatory body. It is assumed that the 5 missing X-ray units were replaced by the 5 new X-ray units. However, records relating to disposal and acquisition could not be located. These units each require a unique key, and the security practice requires the key of each unit to be securely stored separately from the apparatus itself. The keys for the missing units remain in storage.

Learnings:

- Effective inventory control and periodic confirmation of the inventory are important controls. This is particularly relevant for disused sources or items in storage.
- Items requiring disposal authorisation should be clearly labelled to avoid accidental disposal.

Example case: stolen source

One portable soil moisture and density gauge (which contains radioactive material) was stolen from a utility vehicle. The vehicle was stored at the residence of a technician who had finished on-site in the afternoon and was due to go to a job close to their home the next morning. The gauge was padlocked and secured to the rear of the tray of the utility. The police were informed of the theft and conducted an investigation.

Learnings:

Where possible, gauges should not be stored on utility vehicles overnight. A store area should be used if the gauge is being kept at a private residence.

Transport

The transport of radioactive material is routinely carried out across Australia, mostly without incident. Unlike on-site movement, transport can involve material moving through areas that are not under the direct control of a licence holder.

What are the transport requirements for radioactive material?

All shipments of radioactive material must be carried out in accordance with the *Code for the Safe Transport of Radioactive Material 2019 (<u>RPS C-2</u>). The code sets out requirements such as signage and permitted container types. Under the code, different requirements apply depending on the type of material, ranging from exempt and low-level material to shipments of high-activity radioactive material.*

Example case: radiotherapy source transport

On completion of a radiation oncology eye plaque procedure a ruthenium (Ru¹⁰⁶) low activity (16.2 MBq) source was not returned to proper storage.

The attending nurse placed the plaque in the emergency pot instead of the normal storage pot which is also used for transportation. Medical physicists then arrived and transferred the source within its carry case via trolley, to the properly placarded car and returned it to another hospital where it is kept. It was assumed that the source plaque was in the pot, which was placed behind a lead shield and then locked in the hot lab.

The source was discovered in the unshielded transport box the following day, having fallen out of the emergency pot (presumably during transportation). The source was then placed in shielded container, capped and stored properly. Another medical physicist had been working in the vicinity for approximately 3 hours.

(Effective dose: 0.015 mSv.)

Learnings:

- Task familiarity/training are important; in this case the nurse may have been unfamiliar with the different lead pots.
- Procedures should include adequate verification step to ensure the correct pot is used. For example, a checklist could be used post procedure and/or at final storage.

Example case: vehicle collisions

A vehicle being used to transport a moisture/density gauge was involved in an accident which caused the vehicle to roll over. The gauge was secured inside a metal transport container which was bolted to the vehicle tray and further protected with a 'roll bar'. Police, fire services and ambulance attended, as well as the Radiation Safety Officer (RSO) of the licence holder.

The RSO determined from a radiation survey and visual inspection that the gauge was intact and undamaged. The RSO then transported the gauge back to the site.

Fatigue was identified as a contributing factor in the accident. The company has amended the travel arrangements to permit additional rest periods for technicians involved in transporting gauges to the site.

A truck carrying mineral sands was involved in a collision. The mineral sand in the truck was ilmenite that had a specific activity of 0.86 Bq/g. As such, this naturally occurring material is considered exempt under the Code for the Safe Transport of Radioactive Material (RPS C-2). The spilled material was cleaned up and returned to the originating site. A survey of the road was carried out and no elevated levels were recorded.

Learnings:

The incidents highlight the need for effective controls such as secure transport and rest periods for drivers, which help mitigate transport risks.

Non-ionising radiation

Only incidents that are covered by radiation protection legislation in the jurisdiction where they occur are reported to the ARIR. This may include the use of cosmetic lasers and industrial applications of lasers. Two incidents involved non-ionising apparatus, both in the hair removal industry.

Example cases: lasers

A machine fault appeared on the screen of the laser. This prompted the technician to turn off the machine and recalibrate. While the technician set the energy level (16J), the reset caused the previously selected wavelength to rest to 755nm. The operator did not notice this change when the laser was reset. The client received burns, for which care was provided.

A client received second degree burns during laser treatment for hair removal on her legs. The laser clinic manager checked and re-calibrated the machines and advised that all the settings were minimal and within the guidelines. Following a complaint made by the client, the service provider checked with distributors to see if they were aware of similar incidents.

Learnings:

These incidents highlight that familiarity with equipment and training to ensure that appropriate settings are selected, and appropriate actions are taken, by the operator are important factors for safety.

Borehole logging

Three incidents involving borehole logging were reported. These have been covered in the <u>feature topic</u> <u>section of this report</u>.

Non-medical imaging (industrial radiography)

Industrial radiography has a high potential for exposure to workers as it often involves the use of large radiation sources in locations that are not designed for exposure, for example, in the imaging of pipes that are installed in a factory. During imaging significant amounts of radiation can be present and therefore access to the area must be strictly controlled to ensure safety.

Example case: non-destructive testing/imaging

Two staff were likely exposed as a result of industrial radiography. Industrial radiography in a workshop was scheduled to occur during the lunch break when personnel had left the area. On completion of the first of 3 separate exposures, the radiographers were approached by two employees who thought they may have been inside the exclusion zone whilst the exposure was being conducted.

The investigation revealed that the two personnel did not vacate the workshop when all other workers left for lunch. They did not recall being told of the impending radiography at the pre-start meeting and they did not hear any of the PA announcements. On investigation while the 2 personnel were unexpectedly inside the workshop, they were not inside the exclusion zone. Measurements of dose rates taken after the event show that the location where they reported they were working was well below the acceptable level ($25 \mu Sv/hr$).

(Effective dose: less than 0.025 mSv.)

Learnings:

Exclusion zones need to be controlled and confirmed prior to exposure.