Australian Government



Australian Radiation Protection and Nuclear Safety Agency



# Australian Radiation Incident Register

## **Annual Report**

Incidents occurring January to December 2018



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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 No.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 by the Radiation Health Committee (RHC), which includes representatives from radiation regulators of each Australian jurisdiction. Reporting of additional 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: arpansa.gov.au.

This report was prepared in 2019, and published in early 2020, following consultation with professional bodies and state and territory regulators.

#### **Purpose and scope**

This report is a summary and analysis of data submitted to the ARIR for incidents that occurred in 2018.

The purpose of this report is to raise awareness of the risks associated with common tasks, share the learnings identified as the result of an incident, and assist in the identification of topical areas in which 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 reports received. While the specific requirements for incident reporting vary between jurisdictions, the NDRP outlines the common requirements for reporting of incidents to the ARIR. Due to the differences in state 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.

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 2018 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 by category	14         14         15         15         16         17         18         19         20         21         22         22         22         22         22         22         22         24         25         26         26

## Summary of incidents occurring in 2018

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 strict 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 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 2018 increased by 26% from the previous year. ARPANSA expects this trend to continue, which shows increasing awareness and positive reporting culture rather than an increase in radiation incidents. We actively promote the benefits of reporting all incidents, including low consequence and near-miss events, through partnerships with regulators and industry professionals.

This year's report includes a focus on radiotherapy incidents. A number of these incidents focus on effective quality control and data matching. ARPANSA is actively working with relevant professional societies to enhance the collection and analysis of radiotherapy related incidents including near-misses.

Human error was the primary cause identified in the majority of reported incidents in 2018, which is consistent with previous years. While an incident will typically have one primary (proximal) cause, incidents generally have a number of contributing factors, for example, time pressures, labelling issues, or 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.

On-going 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.

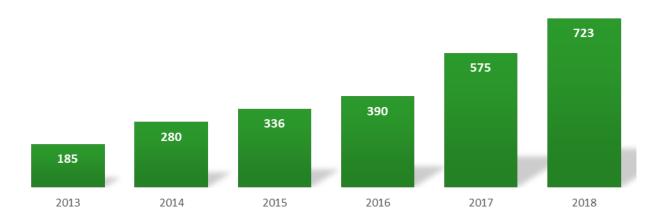
Below is a list of lessons to be learnt from or recommendations identified in reports:

- It is important to follow procedures, for example, performing current patient/procedure matching processes. These procedures should be clear and regularly evaluated for effectiveness.
- The need for effective training, including regular training and training on new equipment (e.g. applications training) or non-routine procedures.
- Effective supervision needs to be in place. This includes of medical students and Professional Development Year (PDY) staff. The supervisor should always ensure sufficient oversight is provided that is commensurate with the assessed task specific competency of the person being supervised.
- Where equipment failure occurs, equipment should be tested using a phantom to confirm the issue is resolved, and correct notification and reporting requirements (including internal, manufacturer and regulatory) should be followed.
- The appropriate use of technology can reduce human error. This includes avoiding manual calculation steps and using a referral system with alerts and confirmations, rather than faxes and paper request forms.
- Monitoring should be in place to detect, record, and periodically evaluate deviations to a process. Operators should not be relied on to always perform actions as intended, instead there should be active monitoring to confirm that the controls are in place and effective. Similarly, other critical controls, human or technological, should be monitored.



#### Number of incidents reported

The number of incidents reported continues to increase. In total, 723 incidents were submitted that occurred in 2018, which represents an increase of 26% compared to 2017. The increase is considered to be due to an improvement in reporting practices. Detailed national Incident and event trend analysis will not be effective until reporting practices stabilise. To enhance engagement with ARIR, ARPANSA has been raising awareness and promoting the resource and its potential since 2012, including the upgraded database and web portal for regulators introduced in 2016.



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.

#### Dose statistics for incidents, not including beam therapy

Effective dose	Number of incidents	Fraction of total
<1 mSv	350	48%
1 mSv–10 mSv	291	40%
10 mSv–100 mSv	82	11%
>100 mSv	1	<1%

Note: percentages are rounded

#### **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 diagnostic radiology. This is expected as diagnostic radiology, which includes medical imaging procedures such as general x-rays and computed tomography (CT) scans, represents one of the largest uses of radiation in Australia. More than 15 million diagnostic imaging procedures involving radiation were carried out in 2018 according to Medicare Benefits Schedule (MBS)<sup>1</sup> information.

	20	18	20	17	2016		2016 2015		2014	
Incident category	No.	%	No.	%	No.	%	No.	%	No.	%
Medical - Diagnostic Radiology (All)	560	78	418	73	279	72	236	70	178	64
+ Diagnostic Radiology (CT)	(264)	(37)	(212)	(37)	(143)	(37)	(135)	(40)	-	
+ Diagnostic Radiology (Plain Film/RX)	(247)	(34)	(164)	(29)	(110)	(28)	(91)	(27)	-	
+ Diagnostic Radiology (Interventional)	(45)	(6)	(34)	(6)	(22)	(6)	(9)	(3)	-	
+ Diagnostic Radiology (Dental)	(4)	(1)	(8)	(1)	(4)	(1)	(1)	(0)	(3)	(1)
Medical - Nuclear Medicine	131	18	114	20	73	19	84	25	74	26
Medical - Radiotherapy	17	2	21	4	16	4	8	2	14	5
Medical - Non-Ionising Radiation (inc. laser)	1	<1	1	<1	1	<1	3	1	1	<1
Non-medical/Industrial – contamination	3	<1	5	<1	1	<1	1	<1	4	1
Non-medical/Industrial - Transport of radiation material	2	<1	0	<1	1	<1	1	<1	1	<1
Non-medical/Industrial - imaging (inc Industrial Radiography and XRF)	2	<1	1	<1	3	1	1	<1	6	2
Non-medical/Industrial - sources found/lost/stolen	1	<1	4	<1	15	4	1	<1	2	1
Non-medical/Industrial - irradiator/accelerator	0	<1	1	<1	1	<1	1	<1	0	
Other	6	1	10	2	0	0	12	4	18	6
Total 723 575 390		90	33	36	28	80				

#### Overall ARIR statistics for 2018 compared with previous four years

Note: percentages rounded

<sup>&</sup>lt;sup>1</sup> For more information on Medicare Benefits Schedule statistics visit <u>http://medicarestatistics.humanservices.gov.au/</u> Note: this does not include examinations that are billed under arrangements other than Medicare.

## Feature topic: Radiotherapy

Radiotherapy is the treatment of cancer, or the symptoms of cancer, using radiation. This area of medical speciality is referred to as radiation oncology. More than 2.3 million radiotherapy sub-processes are performed (including therapy planning, delivery, and verification procedures) to treat the more than 60 000 patients undergoing radiotherapy in 2018 (see 'The Radiotherapy Process' in the breakout box below). It is also worth noting that more than 3 000 therapeutic nuclear medicine procedures were carried out in 2018. The vast majority of all procedures were carried out without incident. However, incident reports indicate areas where performance could be enhanced.

Radiotherapy is used to deliver both therapeutic treatments delivered with curative intent, and palliative treatment delivered for disease control and pain mitigation. Therapy doses a usually delivered via multiple 2–3 Gy treatments, often to a total of 55–75 Gy to the tumour. The exact dose depends largely upon the tumour type. Palliative treatments are frequently a few fractions of 4–6 Gy each to the effected region. As the absorbed dose (measured in Gy) is concentrated on a specific area, there is no simple translation to an equivalent/effective dose for the whole body (Sv).

#### The Radiotherapy Process

From an ARIR perspective, it is important to recognise where in the patient treatment path incidents can occur and understand how these could impact on the patient. The approach used to quantify the number of processes is based on the <u>Medicare Benefits Schedule</u> items processed from January 2018 to December 2018. The 'T2 Radiation Oncology Group' provides a breakdown on the basis of modality, verification and computer planning. Using Medicare data assumes that each sub-group within the T2 group can be considered as an individual process and as a discrete function from an incident analysis perspective. Summing these sub-group items arrives at 2.3 million processes in which an incident could occur that, undetected, could impact on a patient and require reporting. ARPANSA recognises that individual clinics will perform the different sub-group operations in their own way and future development has been proposed to better categorise and analyse therapy incidents in terms of process flow. This will help to identify the causes and contributing factors and help target effective interventions in the clinical context. See the 'Learning from future incidents and events' section on page 10.

#### **Incidents from 2018**

#### **Radiotherapy incident statistics**

Category	Number of reports	Doses
Planning (CT)	3	Up to 30 mSv, average effective dose 12 mSv
Treatment site	9	Up to 40 Gy additional dose to healthy tissue, average dose 11 Gy.
Treatment dose	4	Doses varied from the intended dose to the treatment volume by up to 11 Gy. Note: this includes both where more than and less than the intended amount is delivered (over/under dosing).
Other	1	None
Total	17	

#### **Planning CT**

A CT image is required for the planning of the therapeutic dose, and is taken on dedicated equipment. This is typically referred to as a planning CT or CT sim (a 'simulation' of the therapeutic setup). These CT scans are about 1/1000th of the dose delivered during therapy treatment. However, incidents that are picked up during planning can often mitigate a more significant issue if not detected.

#### Example case: patient match in planning

A patient was scanned using the wrong patient setup. A patient was taken into a radiotherapy bunker ready for patient set up. A decision was then made to treat a different patient who was in severe pain first. Due to the urgency and patient's poor condition, the time out patient identification procedure was skipped. As a result, the fact that the first patient details were still loaded onto the computer was not picked up. When imaging fields were delivered as part of image-guidance and image matching, it was realised that the incorrect patient plan was loaded. The incorrect plan was closed, the correct plan was loaded and the second patient imaged and treated.

(Effective dose: 30 mSv)

#### Learnings:

*This incident highlights the importance of patient and procedure identification requirements.* 

#### Incorrect treatment site

Misalignment or targeting the wrong tissue occurred in nine incidents. A number of incidents involved incorrect matching of spine, and miss-identification of the lesion to be treated in superficial treatments. In a number of these incidents, training of staff for both routine and unexpected situations was highlighted as a learning. Regular training can reinforce requirements, including to query any inconsistencies or missing information.

#### Example case: mismatch with treatment site

A patient receiving stereotactic body radiation therapy for metastatic prostate cancer received a treatment dose to normal tissue for four out of 10 fractions (50 Gy in 10 fractions).

#### Example case: mismatch with treatment site

This error was due to a combination of an unusually mobile nodal target volume site and difficulty in matching the cone beam CT (CBCT) to the planning CT. The latter problem was primarily due to artefact from the presence of bowel gas on the CBCT in addition to the low contrast between target and surrounding tissue.

(The dose to healthy tissue was approximately 20 Gy)

#### Learnings:

- *Refresher training should be provided for treatment staff members in appropriate matching.*
- This incident highlights where a complication from planning contributed to the wrong tissue being exposed.

#### Example case: mismatch with treatment side

A patient was administered a palliative radiation treatment of 14 Gray (Gy) in four fractions incorrectly prescribed to the right side of the tongue. This patient in fact had a histologically-proven diagnosis of a locally advanced squamous cell carcinoma, arising in the sublingual region of the left oral cavity invading the floor of the mouth and lateral tongue. The booking form did not include site and laterality of tumour, this was not queried by the radiotherapist.

(The dose to healthy right side of tongue was approximately 14 Gy)

#### Learnings:

- The hospital booking forms should always include site and laterality of tumour.
- Radiotherapists need to be trained regularly in correct patient and procedure matching procedures.

Further examples of incorrect treatment site and incorrect does are provided in 'Appendix A – Further radiotherapy example cases', these incidents are presented with more technical information on the events and subsequent actions which may assist clinicians in the review of the these incidents.

#### Incorrect dose

Patients received doses that were higher or lower than planned in four incidents. Where the dose is lower than intended, this can affect the clinical outcome, while excess radiation dose should be avoided. These incidents often highlight how a small error can propagate when not be picked up in quality control checks.

#### Example case: incorrect dose

A patient received less than the prescribed radiation dose to the treatment area.

The patient was to have five separate lesions treated with 20 Gray prescribed to each lesion over five treatment fractions. The methodology for computing the Linear Accelerator Output (MU), required to deliver the prescribed dose to each of these single fields, is via a manual calculation (look-up tables and calculation template).

The dose for electron treatments is generally prescribed to the 90% isodose line, as was the intent for this patient. In this instance instead of 100% of the prescribed dose at the 90% isodose line, the MU was manually calculated to deliver 90% of the prescribed dose to the 100% isodose line.

#### Example case: incorrect dose

The standard pre-treatment calculation checking procedures were undertaken and the switching of the percentages was not picked up. The resulting radiation exposure that was delivered due to this miscalculation was approximately 20% lower than that prescribed for two fractions. At the second fraction an experienced radiation therapist observed that the calculated MU was lower than they would ordinarily have expected. Treatment was halted until the MU was cross checked. At this point it was discovered that there had been an error in calculation.

The prescribing Radiation Oncologist was advised of the error and it was decided that the shortfall in delivered dose could be safely made up across the remaining treatment fractions.

(Effect: not significant as following identification of the error the patient received the prescribed total dose to all of the lesions. However, if undetected it may have impacted the treatment effectiveness.)

#### Learnings:

The incident highlighted:

- the need to make sure the calculations for radiation dose to a patient are correct and require to double check the calculations.
- vulnerabilities in manual calculation steps.
- the value of a questioning attitude of experienced staff when presented with unexpected results.

#### Other

#### Dosimetry

There are a number of controls for monitoring radiation exposure (dose) to workers including, measured barriers, radiation area monitoring, electronic dosimetry and dosimetry badges. Badges are worn for a fixed period, typically three months, and are then analysed to determine the total radiation exposure during that period. This is a very effective means of establishing actual exposure to each worker over a time period.

#### Example case: dosimetry

One incident involved leaving a dosimetry badge in a room while the equipment was being used. As this means the badge no longer represents an individual's exposure, the individual did not have an accurate measure of the period prior to the exposure.

(No additional dose received)

#### Learnings from previous years

Less than 20 radiotherapy incidents are typically submitted to the register each year. To accurately represent the range of incidents that can occur, and learnings identified, additional incidents from 2016 and 2017 have been summarised below.

#### Pregnancy

In 2017 an incident occurred where a patient became pregnant during a course of treatment, which resulted in a fetal dose of 37 mGy.

Reasonable steps must be taken to determine the pregnancy status of therapeutic patients prior to a procedure, and in the case of therapeutic nuclear medicine a biochemical test is required, under the *Code for Radiation Protection in Medical Exposure* (RPS C-5). However, a course of treatments can be delivered over an extended timeframe and pregnancy status should be considered over the full course of treatments.

#### *Error in order interpretation / quality assurance*

In 2017 one incident involved a patient receiving a whole brain dose for 5 fractions at 4 Gy each, rather than the planned 20 fractions at 1.8 Gy each. This was to be followed by treatment to the residual tumour. The error was picked up when the patient indicated they were expecting more treatments, after being informed that the next treatment would be to a reduced volume.

Also in 2017 an incident occurred where a patient was given twice the intended amount of radiation for 8 out of 10 fractions. The error of entering 30 Gy in 5 fractions, rather than across 10 fractions, in the treatment planning system was not picked up in the standard quality assurance procedures. The error was detected during the eighth fraction as part of an unrelated quality assurance program of the new linear accelerators.

The incident highlighted that:

- patients should be provided with a complete treatment course, and that details are confirmed with patient, on day one of treatment
- consistent and standardised policy for the Radiation Oncologist (RO) portal should be used to confirm prescriptions
- any changes in the patient treatment and care plan (e.g. changes to the number of fractions or dose per fraction) should be fully documented in the patient electronic record, the RO portal, and communicated to the patient
- consideration should be given to including course detail in the written consent process using the RO portal.

#### Wrong patient

In 2016 two patients were treated with the settings intended for a different patient, and a labelling issue resulted in a mix-up of treatments for two therapeutic nuclear medicine patients.

The incident highlights the need for effective control of 'Correct Patient, Correct Procedure, Correct Site' processes and resulted in the increased use of bar code scanners throughout that particular radiotherapy department - used by patients to check themselves into the department by their individual bar codes and scanned before a patient is treated. One incident also suggested that alerts in the electronic medical record system should be used when patients with the same or similar name are being treated at the same time.

The use of labels in nuclear medicine was discussed in the 2016 ARIR report, while patient identification is further discussed in the 2017 report.

#### Data processing

An incident in 2016 occurred during the import of the plan data into the treatment software (RayStation to Mosaiq). Sections of the data transfer process were not fully understood by staff which resulted in overwriting of the correct iso-centre during data transfer. This error was not picked up during quality checks.

The incident highlighted:

- a need for training to increase staff understanding of technically difficult apparatus, including the data-transfer process
- the need to review data-transfer checking procedure with a view to simplify and/or automate the process
- the benefit of reviewing the day one setup procedure to help determine whether any lack of similarity between day one and subsequent days are one-off issues or repeated issues
- that introducing a procedure that requires staff to document the justification for having a greater than 1cm shift should be considered (where practical).

#### Communication

In 2016 an incident occurred where a procedure was commenced that had been cancelled by the clinician. This highlighted communication issues. Specifically, that a protocol for appropriate channels of communication with clinicians in the event of any change of treatment course should be developed and implemented. This should include verbal and electronic protocols concerning the suspension or cessation of treatment. A similar incident in 2016 also highlighted communication issues where a patient moved from one jurisdiction to another and the initial treatment process was repeated.

#### **Controlled areas**

An incident occurred in 2016 where the last person out interlock switch was used and an exposure initiated, when another person was still in the room. However, the person did not receive any significant radiation dose. The incident recommended a visual inspection of the bunker prior to the use of the last person out, and an audible last person out alarm – which allows a person in the bunker to know that the last interlock in the safety chain has been activated giving them more time to react. The incident also highlighted the need for radiation therapy, medical physics and radiation engineering staff to communicate effectively when entering and exiting controlled areas.

#### Learning from future incidents and events

There are currently a large number of events that are not submitted to the ARIR but are recorded in hospital event reporting systems. These include 'near-miss' events and incidents that did not meet the reporting requirements to the ARIR, for example because they were picked up before affecting a patient. These events contain valuable data that could help to prevent future incidents if collected, analysed, shared, and acted on.

ARPANSA is currently pursuing opportunities for enhanced incident reporting in partnership with professional societies, including the Radiation Oncology Alliance members: The Royal Australian and New Zealand College of Radiologists (RANZCR), the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM), the Australian Society of Medical Imaging and Radiation Therapy (ASMIRT), and the Cancer Nurses Society of Australia (CNSA).

Through the national oncology reporting project, as part of ARIR, we will seek to collect incident and nearmiss information from hospitals across Australia and connect them in an integrated manner. Utilising modern technological innovations to drive the 'collect once, use many times' philosophy, we will utilise existing registers where possible and use web submission systems to reduce the burden associated with reporting. This system will intelligently deliver data to the relevant bodies, and assist in analysis, while ensuring strong security and privacy provisions are in place.

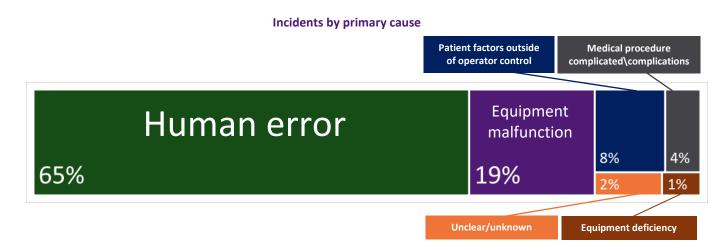
Leveraging the existing work on creating uniform reporting requirements and national harmonisation for radiation oncology incidents, we are now in the process of establishing rigorous roles and responsibilities for all parties, and ensuring effective governance. This will help to ensure protection of the privacy and confidentiality of data, as appropriate, and establish clear expectations around data collection, use and distribution. We will then build the technical infrastructure and data connections.

Through effective partnership with professional societies, this project will focus on delivering enhanced patient outcomes and staff safety. This project will also serve as a pilot for possible expansion into other fields and modalities such as nuclear medicine and other medical imaging.



#### **Primary cause**

Across all incidents reported in 2018, human error was identified as the primary cause in 65% (473) of cases. This is consistent with previous years.



**Human error** means that something has been done that was not intended, not desired by a set of rules, or that led the task or system outside its 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 this and on elements that lead to human error see the <u>our website</u> and <u>Holistic Safety Guide</u>.

**Equipment malfunction** includes software and hardware failures. This can include a range of incidents including breaks, glitches, or power failures. In contrast, **equipment deficiency** is where the equipment used was not suitable for the task or failed to perform as expected.

There were no trends or common modes of failure. 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.

**Patient factors outside operator control** include where the patient suffers from claustrophobia or selfdischarges.

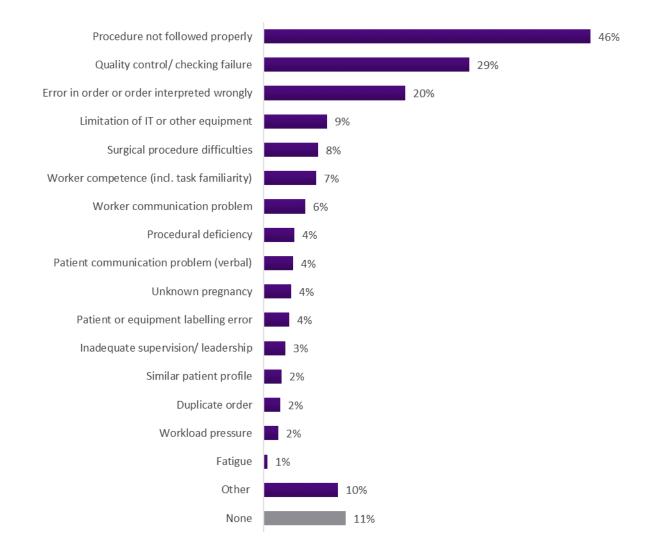
**Medical procedure complications** can result in a higher than normal dose. For example, during a complex surgery, a significant fluoroscopic dose may be delivered as the procedure takes longer than typical. This is reportable as an incident in most jurisdictions.

#### **Contributing factors**

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 some instances, such as medical complications during a procedure, or equipment failure, these factors may not be readily apparent. In 11% of incidents, no information on contributing factors was provided.

Typically, there were multiple contributing factors 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, which may result in significant reductions in the likelihood of an incident with significant outcomes occurring.

The most common contributing factor was 'individuals not following procedures', which was identified in 46% 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.

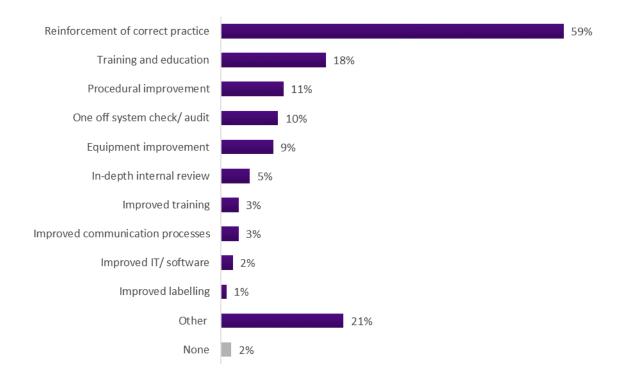


#### Contributing factors identified in 2018 incidents

#### Summary of controls and preventive measures implemented

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

Reinforcement of procedures and reminders of good practice remain the most common actions taken after an incident. In 2018 such actions were taken in 59% of incidents, which is consistent with the previous year. This remedial action may not be effective in the long term if used in isolation.



#### Remedial actions taken to prevent recurrence in 2018



#### Medical - diagnostic imaging

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

Modality	Number of incidents	Effective dose per incident Note: does not include skin or critical organ doses		
·	reported	Average (mSv)	Range (mSv)	
Computed tomography (CT)	264	6.7	0–44	
General x-ray	247	0.5	0–14	
Fluoroscopic/interventional	45	0.3	0—8 skin doses up to 15 Gy	
Dental	4	0.03	0-0.1	
Nuclear medicine	131	5.8	0–70	

#### Overall statistics for diagnostic radiology incidents, by modality

#### Overall statistics for diagnostic radiology incidents, by description

Туре	Number of incidents	Fraction of	Effective dose per incident Note: does not include skin or critical organ doses		
	reported	total (%)	Average (mSv)	Range (mSv)	
Unnecessary scans	400	58	4.2	0–44	
Equipment failure	131	19	2.7	0–34	
Medical complications	45	7	0.5	0—10 skin doses up to 15 Gy	
Unknown pregnancy	37	5	2.0	0–28	
Incorrect radiopharmaceutical / dose	37	5	9.4	0–70	
Extravasation of radiopharmaceuticals	25	4	4.2	0–10	
Spills / contamination	5	1	0.8	0–2	
Other	11	2	-	-	
Total/average	691		3.9	0–70	

#### **Unnecessary scans**

The most frequent type of incidents in the medical category, was procedures carried out that were not as intended by the referrer. In 2018 these included:

- incorrect region/procedure (23%)
- imaging the wrong patient (24%)
- repeated imaging (25%).

These incidents have the potential to significantly affect patient outcomes 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.

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

#### Equipment failure/deficiency

Equipment failure or deficiency was the cause of 131 incidents, which typically resulted in a higher dose or a repeat examination.

#### Example cases: equipment failure (mammography)

Failure of mammography equipment was identified in 39 incidents. The errors were commonly described as 'red-tile' communication error, detector unavailable error, or a system error. These resulted in unrecoverable images, or artefacts that rendered the image non-diagnostic. In most cases following a reset of the equipment diagnostic quality images could again be taken.

(mean glandular dose range is 1–3 mGy, average effective dose less than 1 mSv)

A patient received multiple exposures following a malfunction of a mammography machine. The machine had frozen after initial exposure. After a restart the machine froze again after the exposure, this was repeated five times (three times on right breast and twice on the left breast). In addition to the radiation exposure, this would have caused discomfort to the patient.

The multiple attempts was brought to the attention of the supervising radiologist, who asked the mammographer to stop and only expose with a test phantom. It was thought to be a power issue and an electrician was called.

After a change in power supply to the unit the test phantom was exposed and saved on the system. This resolved the equipment issue. While equipment failure was the initial cause for a repeat exposure, the subsequent repeated exposures indicate human error and a procedural deficiency.

(estimated mean glandular dose is 5 mGy; effective dose 0.5 mSv)

#### Learnings:

- Following equipment failure, the equipment should be tested using a phantom.
- Equipment failure should follow the correct notification and reporting requirements (e.g. failure notified immediately to lead radiologist / supervisor prior to re-examination of patients as well as any required regulatory or manufacturer reporting).

#### Example case: equipment failure (CT)

A hospital patient underwent a CT scan of the cervical spine, chest and abdomen. The scanner malfunctioned during acquisition of the image of the abdomen; the abdomen was required to be rescanned due to an artefact on the first image. The malfunction was due to a power drop out. Engineers replaced the power supply for the detector that was found to be faulty.

(Effective dose: first, failed, scan of the abdomen 12 mSv)

#### Learning:

This incident demonstrates the need for medical equipment to be serviced regularly including preventative maintenance and software updates. However, even with these systems in place it is not possible to prevent all cases of equipment failure.

At times there is a known issue or limitation to equipment which can result in higher doses if a specific situation arises, or if specific steps are not followed. These may be rectified through a software update, however these updates may be under development for a significant time and need to undergo stringent testing to reduce the risk of unintended consequences.

#### Example case: equipment deficiency

A paediatric patient at a hospital underwent unnecessary radiation exposure due to a known software malfunction that occurs when an anterior-posterior (AP) or PA topogram is completed before a computed tomography (CT) scan of the head.

The radiographer completed an AP topogram of the upper chest and head to plan for a CT angiogram. The radiologist then informed the radiographer that a CT scan of the brain was required before the CT angiogram. The CT brain was completed based on the AP topogram which resulted in a higher than necessary tube current and resulting unnecessary radiation exposure to the patient.

The manufacturer informed users (customer advisory notice) that the tube current modulation algorithm may select the maximum tube current for the uppermost part of the skull when an AP or PA topogram is completed. This error is dependent on the shape of the skull bone and does not occur when a lateral topogram is performed.

(Effective dose: 4 mSv)

#### Learnings:

All medical imaging technologists should ensure they complete a lateral topogram for CT scans of the head and review the tube current histogram on the CT scanner prior to scanning a patient.

#### **Referral system**

The referral system is also an important part of the medical process, ensuring that orders are correctly requested, approved and delivered.

#### Example case: referral system deficiency

An unauthorised electronic order was submitted for plain film x-ray imaging. The radiographer noted that the clinical information suggested imaging was required urgently despite the patient having been discharged from hospital weeks earlier. The radiographer contacted referrer to discuss, who advised that they had no knowledge of the patient and had not submitted the order. On further investigation the doctor discovered that the order, which was listed under the doctor's orders, had been entered by a nurse.

While certain plain x-ray examinations can be referred by a nurse practitioner, the ordered examination is outside the scope of the exemption. The system allowed the nurse to enter the order using the physician's provider number (rather than the nurse's) which made the system assume the request was approved by the physician.

*In this instance the referring doctor, on review of the information, agreed to the need for imaging and accepted the order. The imaging was then performed.* 

(Effective dose: none – near miss)

#### Learnings:

*Ensure systems only allow persons to authorise (order) tests they are allowed to order.* 

#### Example case: faxed referrals

A Positron Emission Tomography (PET)/CT was ordered by fax for a male patient, and performed as requested, but at a time other than intended. After the report was sent, the referring doctor queried why it had been performed in November and not January as he had requested. On investigation it turned out that whoever sent the fax accidentally cut off the bottom line of the request, which was a note stating that it was not needed until January. The request as received was perfectly normal and in keeping with the patient's clinical history. Useful clinical information was in fact obtained, although at the wrong time. The January scan will be rescheduled if still clinically indicated.

(Effective dose: 8 mSv)

#### Learnings:

Procedures can be designed to reduce or eliminate duplication/scheduling errors, such as verification of sent information back to the requestor and systems to prevent partial submissions. These processes are typically in place for electronic referral systems.

#### Shielding

The effective use of shielding is an important control for exposures in the medical setting. Care needs to be taken that installed and personal shielding is used wherever indicated.

#### Example case: Personal protective equipment (shielding)

A staff member (Resident Medical Officer [RMO]) entered the electrophysiology (EP) lab in cardiology without a lead gown during an exposure.

A cardiologist, radiographer, three nursing staff and two anaesthetics staff were in the room wearing lead gowns. A case had already been started and screening had taken place. The radiographer was moving the tube and getting equipment organised under the drape.

The RMO entered the room to talk to anaesthetic staff and give blood results without a lead apron on. When the Cardiologist was ready to screen again he stated he was doing so, and asked if everyone was 'leaded'. This was not strictly required as the case was already well under-way with screening already having occurred, and normally there would not be additional staff in the room. The nursing staff quickly

#### Example case: Personal protective equipment (shielding)

*identified the staff member in the room not wearing the lead gown and screening ceased until the staff member left the room. Dose to the staff member was very low, as the screening time was less than 5 seconds and the staff member was approximately 2 m from the source of radiation.* 

(Effective dose: <0.1 mSv)

#### Learnings:

Following a review, the following improvements were made:

- Increased signage was placed at the entrance of the cardiology suites at eye level to remind staff of lead personal protective equipment (PPE) requirements.
- Radiation safety information sheets have been distributed to new staff in cardiology as part of their induction pack.

#### **Unknown Pregnancy**

Unknown pregnancy was identified in 37 incidents. The *Code for Radiation Protection in Medical Exposure* (RPS C-5) requires that reasonable steps to be undertaken for any procedure which is likely to result in a radiation dose of more than 1 mSv to the uterus. This typically involves confirming with the patient, and may include additional tests or examinations. Biochemical tests are only required, by the code, prior to therapeutic nuclear medicine procedures.

#### Example case: pregnancy of patient

A patient underwent a CT KUB (kidneys, ureters and bladder), and despite the patient denying the possibility of pregnancy immediately before the scan, a possible early (approx. 2 weeks) pregnancy was subsequently identified by Beta human chorionic gonadotropin (β-HCG) test.

Noting that appropriate patient questioning protocol was followed by the radiographer in this instance, staff discussion has occurred emphasising the importance of documenting pregnancy status.

(Effective dose: 10 mSv)

Patient attended for CT abdomen. Patient stated on contrast form she was not pregnant. Radiographer verbally asked her of chance of pregnancy which she answered in the negative. Pregnancy not visible on scanogram.

After scanning it was observed the patient was pregnant. Doctor was advised and he contacted the referring doctor. After further discussion with patient she stated she had not had a normal menstrual period for 12 months. She had also been put on the oral contraceptive pill 2 months prior. Patient was informed of the incident and told to discuss the next step with her general practitioner.

(Effective dose: 28mSv)

#### Learnings:

Consider the use of pregnancy tests prior to certain imaging exams (e.g. abdo-pelvic CT), particularly where a patient may have some uncertainty, as patient testimony is not always reliable.

The maximum dose that can be delivered by a procedure should be considered. For example, interventional procedures, diagnostic angiography of the pelvis, hysterosalpingography, or standard-dose dual-phase CT protocols of the pelvis are examples of procedures where the American College of Radiology practice guidelines recommend that a pregnancy test may be required prior to commencement of the procedure unless medical exigencies prevent it. However, in some circumstances, the clinical history may be sufficient and pregnancy testing is not needed.

#### Example case: pregnancy of carer

A two year old child was referred to emergency department for a chest x-ray. She was held by her mother who was wearing lead apron and standing behind the child during the procedure. The radiographer forgot to ask the mother if she is pregnant and only discovered this after the x-ray was performed. In this instance neither the mother nor the fetus was exposed directly. As the pregnancy was unknown at the time of the procedure, the foetus would have received an unintended dose. The mother was standing about 30cm from the patient and received a small amount of scattered radiation.

(Effective dose: <0.01 mSv)

#### Learnings:

Ensure that a process is in place to check the pregnancy status of carers, where relevant. However it should be noted that this is not required for procedures which are not likely to give rise to any significant doses (including chest x-rays).

#### Training and supervision

It is important for staff to continuously train and keep up their skills in the medical industry. This is particularly important when there has been a change, such as new equipment or new operations.

#### Example cases: applications training

*Repeat x-rays had to be carried out as the wrong detector was selected for first projection. The machine was new and the radiographer did not receive applications training.* 

(Effective dose: 0.7 mSv)

Learnings:

Ensure staff have received applications training on all new pieces of equipment.

New staff, recent graduates undertaking their professional development year, and students, are required to undergo a period of supervision. During this time they may not hold a licence or hold a limited licence which restricts their operation until such a time as they are deemed competent. Over the supervision period students 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 cases: supervision

A student radiographer incorrectly imaged a patient without reading the referral. The doctor had requested images to be performed erect (standing up), however the imaging was performed supine (patient lying down). The images needed to be repeated.

While some onus is placed on the student for not performing the examination correctly, the responsibility lies with the supervising radiographer for not directly supervising their student.

The radiographer should have made sure the student had read and understood the referral before attempting the procedure. Students should tell the Radiographer exactly what views, and what positions they are going to use before attempting any procedure.

(Effective dose: 1 mSv)

Example cases: supervision

A patient booked for a dementia brain fluorine-18 fluorodeoxyglucose (F<sup>18</sup> FDG) PET/CT scan and was administered 248 MBq instead of the department's prescribed dose of 150 MBq.

On the day of the incident, there were three patients ready for injection in PET and two technologists working in the PET area, a senior and a professional development year (PDY) trainee technologist. The experienced technologist instructed the PDY to inject the FDG patient in uptake room 1 while they dispensed prostate specific membrane antigen (PSMA) doses and injected the first PSMA patient.

On checking that the FDG patient had been injected, and if there were any problems, it was noted that the dose record for the FDG PET patient on the dose administration machine showed an administered dose of 248 MBq, a deviation from the 150 MBq prescribed dose.

The trainee staff was not closely supervised for administration of the dose. Additional measures implemented or proposed:

- a list of standard FDG doses be displayed on the noticeboard in the PET control room
- staff reminded of the need to review the request form prior to injection, to complete the preinjection checklist (check blood sugar level, patient weight, indication and scanning protocol) and perform a 3C check prior to administration of any radiopharmaceutical - including double-check procedure prior to administration of radiopharmaceuticals in the PET suite.
- a bar code system for patient identification

(Additional effective dose: 1.9 mSv)

#### Learnings:

*Close supervision is required for students, prior to being deemed competent. Clear communication between the supervisor and student is required to ensure understanding.* 

#### Incorrect radiopharmaceutical/dose

Nuclear medicine involves the administration of a quantity of radioactive material, prepared as a radiopharmaceutical, which is commonly referred to as 'a dose'. The activity, measured in becquerel (Bq), indicates how much radioactive material is present. The radioactive material binds to a pharmaceutical agent which ensures the combined radiopharmaceutical goes to the correct organ/area (e.g. brain).

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, including the controls put in place, play a large part.

#### Example case: administration of incorrect amount of radiopharmaceutical

A patient was injected with a larger than intended amount of iodine (I<sup>124</sup>) in preparation for a Pre radioiodine-ablation thyroid positron emission tomography (PET) scan.

Following patient identification verification and preparation, a nuclear medicine technologist (NMT) selected a pre-calibrated syringe of I<sup>124</sup> from the lead container. The NMT read the label as containing 73.8 MBq of I<sup>124</sup>, which was consistent with the hospital protocol to use less than 100 MBq. The I<sup>124</sup> was then administered to the patient through an intravenous cannula. During the patient's PET scan, it was noted that the patient showed higher than usual uptake of iodine. The NMT realised that they had misread the label and that they had in fact selected the stock syringe, which contained 738 MBq of I<sup>124</sup>. An ink mark on the label had been interpreted as a decimal point. The NMT also failed to recalibrate the I<sup>124</sup> activity with the dose calibrator prior to administrating to the patient, which would likely have identified the error. (Effective dose to patient 70mSv)

#### Example case: administration of incorrect amount of radiopharmaceutical

#### Learnings:

- Nuclear medicine centres need to have clear labelling requirements for pre-dispensed syringes that include identification of the patient.
- Highlights the importance of the checks (dose calibrator) to be carried out to ensure the correct radiopharmaceutical and activity have been drawn up.

#### Example case: administration of incorrect radiopharmaceutical

Two patients were injected with the wrong dose. One patient attended for a brain scan. After administration of the tracer, imaging showed no uptake for the brain. The radiopharmacy confirmed that the tracer had passed QC at 98%. On investigation the activity in the pot was 1.6GBq in 1 ml rather than, the expected activity of 2.4 GBq in 2.4 ml. The initial assumption had been that the central pharmacy dispensed less as there was a lack of technetium on the day. However, when another site was contacted they noted that they had received 3 GBq in around 2.4 ml. The tracer they had ordered was for a renal patient, and so the scan of the other patient (who had received a brain tracer) was also non-diagnostic.

The immediate cause was human error when dispensing doses at central radiopharmacy, which led to the wrong doses being dispatched.

(Effective dose: one patient received 6 mSv and the other 7 mSv)

#### Learnings:

Any inconsistency in dose/volume should always be discussed with provider, regardless of circumstances.

The management systems should be set up to reduce the likelihood of human error. For example, in some institutions the dose calibrator is connected to the patient management system in a manner to confirm that the reading taken is consistent with the expected patient isotope and activity. In other institutions manual adjustment of the calibrator is required for different isotopes, followed by a record kept in a log book, which is prone to human errors - such as the technician seeing the dose they expected (e.g. 73.8 instead of 738 MBq), or of justifying an unexpected result to themselves. For example in an incident the operator assumed that 'it must be due to shortage', or 'they must have sent us double so it will be fine if we just use half'. Additionally, the consideration of human factors in the design of labels, use of colours, and choice of vial can reduce the likelihood of this type of error.

A number of incidents that highlight the use of technology, and human factors are discussed in the feature topic on nuclear medicine in the ARIR report covering incidents occurring in 2016.

#### Spills of radiopharmaceuticals

Small spills can typically be cleaned up without significant dose to persons, which is 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

A spillage of fluorine(F<sup>18</sup>) fluorodeoxyglucose (FDG), used for PET imaging, occurred in a patient injection room of a hospital due to a loose connection on the automated injector line. Associated working surfaces were also contaminated.

(Effective dose to staff < 0.01 mSv)

Spillage of gallium (Ga<sup>68</sup>) prostate-specific membrane antigen (PSMA) occurred due to a loose connection. A patient was cannulated ready for Ga-PSMA PET/CT injection, which is performed on the PET scanner to enable a dynamic uptake scan. The patient had a low-dose CT scan (for attenuation correction and localisation). The Nuclear Medicine Technician (NMT) then connected a line to a three-way tap for injection but did not ensure a positive lock. When the injection was performed the connection failed. Approximately 60% of the prescribed activity was injected; the remaining 40% was deposited on the bed, gantry and NMT.

(Effective dose to staff <0.01 mSv and patient (effective dose due to CT scan 6.3 mSv, skin entrance dose approximately 20-120 mGy)

#### Learnings:

- Use checklist for adherence to protocol.
- Perform check of connections immediately prior to injection (timeout), confirming positive lock on Three-way tap prior to applying pressure, and flushing with saline prior to activity injection

#### **Other incidents**

#### Radiopharmaceutical production

During the production of nuclear medicine high-activity and low-volume radioactive material is handled. This concentrated material is combined with a binding agent to form a radiopharmaceutical which is administered to patients. Prior to this, a number of quality control steps must take place to ensure the quality of the diagnostic or therapeutic products.

#### Spills and contamination

High-activity solutions are handled in the manufacture and quality control of radiopharmaceuticals. 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.

#### Example case: spills and contamination

A vial containing radioactive material was dropped during disposal and smashed on the floor of the cleanroom. The incident occurred at the end of production, with an elute of less than 12 GBq of technetium ( $Tc^{99m}$ ).

One staff member had radioactive material spilt on their cleanroom gown and overshoes, they spent approximately 15 minutes in a radiation field measured up to 0.03 mSv/h.

#### Example case: spills and contamination

Measurement and a radiation survey was conducted of other staff members. Contamination was found on over gowns and overshoes, which were placed in a bag and isolated in clean room. Staff member's cloths and shoes were monitored and found to be clear of contamination. Contamination survey undertaken of the anteroom found a small area of contamination. Anteroom and clean room were placed under restricted access until the material decayed.

(Effective dose <0.1mSv)

The wheel of the trolley used to transport quality control samples between laboratories unscrewed and detached from the trolley resulting in a spill of liquid.

The trolley tilted on losing a wheel and this caused the lead pot containing a closed vial to fall from the trolley and spill the vial contents on the floor. The analyst quickly recovered the pot and placed it back on the trolley (contrary to procedure for a dropped vial). Minor contamination was detected on the worker's personal protective equipment (e.g. gloves), however the worker's skin was not contaminated and no abnormal external or internal dose was received. The spillage was cordoned off for investigation. The spillage was then cleaned and the contaminated items were left to decay in isolation.

A number of contributing factors were identified:

- The transfer of radioactive samples within the building did not have sufficient requirements or guidance on the process.
- Human factors were not considered, specifically for the process design covering sample transfers on trolleys. The trolley had a short wheel base with a high centre of gravity, guard rails only went around three sides. This made it unsuitable to transport this material.
- The business area responsible for the trolley was not clear, and so the associated maintenance of the equipment was not appropriately defined.
- There were no adequate procedural checks to ensure the equipment was in a suitable condition.
- A questioning attitude by staff and management could have led to an assessment of the adequacy of the trolley, however it was used for a long period of time.

(Effective dose <0.1mSv)

#### Learnings:

This incident highlights the importance of the considering unexpected but predictable events which can occur in the workplace, including during transport and disposal. Potentials for contamination should not only be considered on implementation of the process, but regularly evaluated in the workplace. In addition to potential radiation exposure these incidents can significantly affect production/dispensing of medicine as the area may be inaccessible while the material decays.

#### **Process deviations**

Within a laboratory setting there is a strong focus on following, often complex, procedures and policies. These contain instructions, advice, warnings, and other information that help people to understand the risks and hazards associated with these tasks. Therefore, they need to be clearly and effectively communicated, as well as monitored and reviewed. Where a process is deviated from this can affect both the quality of the final product and the safety of workers. For this reason, the critical controls should be actively monitored, and all deviations from processes or outcomes recorded and investigated appropriately.

#### Example case: process deviation

During quality control sample testing, a higher than required radioactivity was provided.

A sample was dispensed and provided for testing. The paperwork accompanying the sample did not indicate any deviations from the procedures. On further investigation it was found that two dilution steps to achieve the required radioactive concentration of the sample were missed in the process. This resulted in approximately nine times higher radioactive concentration than required.

No actual spillage of the sample occurred and no abnormal doses were received. However, the higher activity concentration presented a greater hazard than expected for the analyst receiving the sample.

The work as intended (in the procedure) had deviated from the work as performed (in practice). Procedures were updated and clarified, and now includes a dose-rate meter used as the sample leaves the hot cell port to confirm that the sample is below a set limit.

(No increased effective dose)

#### Learnings:

This incident highlights the need for detection of deviations from a process. Rather than relying on operators to always perform actions as intended, there should be active monitoring to ensure that the controls are in place.

In this instance the control (dilution) was not monitored (e.g. via a dose-rate meter) to detect a potential changed outcome (activity of sample). Instead there was an over-reliance on operators to perform all steps, which were countersigned by a second operator.

#### Lost, stolen or unauthorised disposal of sources

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

#### Example case: unauthorised disposal

A landfill site detected radiation in a general waste consignment. The truck was halted at the weighbridge and the local regulatory agency responded and attended site. The shipment was isolated in a secure area of the landfill and later retrieved. The source dose-rate was measured at 15 mSv/hour.

The source was old and did not match details from the current systems for tracking of radioactive material. Following further investigations, the origin of the material was identified. However, the incident is still under investigation and further lessons may be identified.

#### Learnings:

This incident highlights the benefit of having radiation detection equipment (portal monitors) on all landfill weigh bridges. This also highlights the need for reliable tracking and management of sources of radiation that are no longer in use.

#### Example case: stolen source

One portable soil moisture and density gauge (with contains radioactive material) was stolen from a utility vehicle. The vehicle had radiation warning signs displayed and the gauge was locked in a metal tool chest that also had a chain wrapped round it. The chain was cut, and the tool chest was broken into to access the gauge. Nothing else was taken from the vehicle. The NSW police have been informed of the theft and are investigating.

#### Example case: stolen source

#### Learnings:

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

#### Transport

The transport of radioactive material is routinely carried out across Australia. All shipments must be carried out in accordance with the Code for the Safe Transport of Radioactive Material 2019, RPS C-2. The code sets out requirements such as signage and permitted container types. Under the Code, different requirements apply based on the type of material, ranging from exempt and low level material to shipments of high-activity radioactive material.

#### Example case: transport

A movement of a shipment was undertaken in a manner not consistent with RPS C-2. The shipment was between two sites of the same organisation in the same city. The requirements of RPS C-2 apply to all shipments on public roads regardless of who is doing the transporting or the distance travelled.

The courier as well as the dispatching area were unaware of the exact nature of materials being transported. An assumption was made that the material was below the exemption limits and that additional requirements were not required. In this instance the shipment exceeded the exemption limits. However as the shipment was a drum with a low surface dose rate (0.030 mSv/hr) the safety implications, including foreseeable accident scenarios, are minor.

As the package was incorrectly classified, the shipment did not comply with additional requirements of RPS C-2, including: hazardous goods declaration, labelling on the package, and it should have been contained within a secondary container to create two levels of protection from the liquid in the drum.

An investigation was conducted by the operator and found a number of issues at the site where the shipment originated:

- This site routinely deals with exempt radioactive material but in this instance the shipment was not exempted material. There was some complacency and staff did not question if this shipment was exempt, instead they just treated it the same.
- Poor training was identified as a contributing cause. The awareness on the requirements of the transport code were low, due to infrequent shipments from this site.
- There was a lack of equipment to categorise the contents prior to transport, support from the receiving location should have been sought.

(Additional effective dose: none)

#### Learnings:

- Ensure clear lines of responsibility in the transfer of materials, and arrangements are properly documented.
- Documentation should make explicit where particular responsibilities lie for critical steps in safety-related procedures.
- Have effective communication between different business units with regular meetings to ensure best practices are being followed.

#### Non-ionising radiation

Only incidents that are covered by radiation protection legislation in their jurisdiction are reported to the ARIR. Depending on the jurisdiction this may include the use of cosmetic lasers and industrial applications of lasers.

#### Example cases: lasers

Nurse walked into an operating theatre while a laser procedure was in progress. The nurse was unaware the laser was in use. Of the three entrances to the theatre, one had a working red light, one entrance had a broken light on the door, and the other door did not have a light. There was also no eye protection available for the nurse at the door.

Following the incident, the hospital provided training for all theatre staff around radiation safety. The hospital also reviewed the use of a laser log and updated the safety checklist to include checking the laser safety lights.

Employees in a beauty salon were practicing using cosmetic laser apparatus by using the equipment on each other. One employee reported burning and tingling sensation in their hands. Investigation by the regulator found poor practices, poor training oversight, and insufficient licensing.

#### Learnings:

- Ensure that adequate training is provided
- Routine checks of safety equipment should be performed

#### **Borehole logging**

One incident involved an inspection tool containing a radiation source that is lowered down a borehole. In this instance the tool was stuck more than 600 m underground and the team was unsuccessful using all available methods to retrieve radiation source. Following regulatory approval the source was disposed in place.

#### Non-medical imaging (industrial radiography)

Industrial radiography has a high potential for exposure to workers as it often involves the use of radiation source in locations that were not designed for exposure. For example, in the imaging of pipes that are installed at an industrial site or aircraft components attached to an aircraft. The source remains shielded, or off, when not imaging and is briefly deployed during imaging. During this time period significant amounts of radiation can be present in the area and therefore the access to the area must be strictly controlled.

#### Example case: non-destructive testing/imaging

Technicians were performing radiography, and had established barriers to ensure there were no persons in the area as per procedure. The all clear was given from all four levels of the structure, and two sentries controlled the access points. The radiographer in charge and assisting radiographer noted some issues with their radios. The radiographer started the imaging without positive notification from both sentries. One of the sentries moved up a level to communicate with radiographer as his radio wasn't working, when his survey meter alarmed. He was present for 10 seconds and left the area immediately. The second sentry confirmed boundaries were set. This incident was considered a near miss, the sentry or another staff member could have accessed an area with higher radiation while the sentry was not at their post. (Effective dose: <0.01 mSy)

(Effective dose: <0.01 mSv)

#### Example case: non-destructive testing/imaging

#### Learnings:

Positive communication checks should always be used prior to exposures. Especially where issues arise preventing the normal communication process, clear and agreed communication protocols should be in place.

## Appendix A – Further radiotherapy example cases

These incidents are presented with more technical information on the events and subsequent actions, which may assist clinicians in the review of these incidents.

#### Incorrect dose radiotherapy incidents in 2018

Treatment type	Description	Actions taken
Electron boost	A patient was prescribed with a breast photon tangent treatment and an electron boost. Electron boost was prescribed for 16 MeV for 8 fractions. Of the 8 fractions, 6 were delivered with a lower electron energy of 6 MeV. At the prescribed point, the patient received approximately 54.4 Gy (due to the 6MeV beam) compared to the prescribed dose of 65.8 Gy (16 MeV). Therefore, the dose received at the prescription point is 11.4 Gy less than planned, without taking into account the change in dose distribution due to different electron energies.	The radiotherapy staff involved were reminded to ensure that the correct beam energies have been selected before treatment.
Electron	The patient has 5 separate lesions being treated with 20 Gy prescribed to each lesion over 5 treatment fractions using electron radiation therapy ranging from 6 MeV to 12 MeV. The methodology for computing the linear accelerator output (MU) required to deliver the prescribed dose to each of these single fields is via a manual calculation, look-up tables and calculation template. The dose for electron treatments is generally prescribed to the 90% isodose line, as was the intent for this patient. That is, the intent was to deliver 100% of the prescribed dose to the 90% isodose line in order to adequately cover each of the targeted lesions The calculation for each of the fields was incorrectly made. The MU was manually calculated to deliver 90% of the prescribed dose to the 100% isodose line.	The prescribing Radiation Oncologist was advised of the error and it was decided that the shortfall in delivered dose be made up across the remaining treatment fractions for each of the sited. Calculations were completed to show correct MU and daily dose to ascertain the safety of delivering the additional monitor units across the remaining fractions. It was decided by the Radiation Oncologist that it was safe to make up the shortfall in dose over the remaining scheduled fractions. The patient received the prescribed total dose to all of the lesions.

Treatment type	Description	Actions taken
SXRT	Incorrect filter used for a Superficial X-ray Radiation Therapy (SXRT) treatment. Started to treat field 1DIR1 (RT forearm) but scab over treatment area had to be removed first. Whilst waiting for the nurse to come radiation therapists went on to treat field 1DIR2 (Rt hand/thumb), whilst the Rt forearm field was downloaded on Mosaiq, hence the incorrect filter was used. The final checks were done on exiting the treatment room, incorrect field was loaded. Both areas receive the same dose (3.5 Gy). On discussion with physics and planning it was found that at a PDD of 90% there was a difference of 1.5 mm, and at 80% 2 mm, however the dose was as prescribed. This incident occurred for 1 of 13 fractions.	Investigated incident and it essentially occurred as a result of a failure to conduct the 'time out' procedure. Discussed the importance of this again with the staff involved. Also discussed the open disclosure policy and the fact that RTs can openly disclose an incident but they must be capable of also discussing the implications and how the error is going to be corrected. RO did disclose incident in this instance and patient is accepting of error.

#### Wrong treatment site radiotherapy incidents in 2018

Treatment type	Description	Actions taken
Palliative Spine	Patient was prescribed palliative radiotherapy of 20 Gy in 5 fractions to the L4-Sacrum (inclusive) spine region, treated with a single Posterior to Anterior Field. On fraction 2 of 5, patient was attended to and set up as per treatment plan. A pre-treatment kV electronic portal image was taken (daily image guidance radiotherapy with online correction is standard at this hospital) and the image indicated a 0.5 cm move Superiorly and a 1.6 cm move to the Right was required, but the two treatment Radiation Therapists did not action the required moves before beaming on for treatment and hence the treatment field was misaligned approximately 0.5cm inferiorly and 1.6 cm laterally to the left for that one treatment fraction. The error was noticed after the patient's treatment was completed on the day.	Remove imaging fields from the treatment fields when using the Auto Field Sequence (AFS) feature during radiotherapy. In this instance, the software pre- loaded the treatment field after the imaging was done. By removing imaging fields from AFS, after an image is taken, staff are forced to acknowledge that they want to move to the treatment field/s. It is thought that this extra prompt might mean it is less likely that staff forget to review images.

Treatment type	Description	Actions taken
Palliative Spine	A patient was prescribed radiation therapy to the chest and lumbar spine for advanced lung cancer with symptoms of bone pain in her lumbar spine. The prescription was for 20 Gy in 5 fractions to both chest and spine. On the second day of treatment, the lumbar spine was treated incorrectly, with the radiation delivered 8 cm inferiorly from where it should have been delivered. The error occurred because the patient was positioned from the wrong reference point. The procedures to verify the patient's position prior to treatment were not complied with, including confirming the correct reference point and verifying the couch position. The incorrect positioning was realised when the patient was repositioned for the chest treatments. The absorbed dose to healthy tissue was 4 Gy.	A refresher session was held for radiation therapy staff at the hospital. All radiation therapy staff members at the hospital were required to read and sign an email sent to them to remind them of the treatment policies and procedures.
Brachy- therapy	A patient underwent intra operative radiation therapy following surgical excision of a tumour within the pelvis. A Freiburg flap applicator was positioned over the treatment area by the radiation oncologist and the patient prepared for radiation therapy. The radiation oncologist prescribed a radiation dose of 10 Gy at the surface of the applicator. The applicator consisted of 10 channels, and the plan was to use four of these channels. This would provide adequate treatment of the planning target volume. As part of the plan, the radioactive source was not to be positioned in the superior right and left corners of the applicator (channels were off weighted) to protect blood vessels. The plan was made by a radiation therapist and approved by the oncologist. During treatment, the oncologist noted that the off weighted corners of the applicator did not correspond to the off weighted corners intended. One channel was over dosed by 100% and the healthy tissue under that channel received an absorbed dose of 10 Gy.	A formalised brachytherapy timeout procedure (separate to the surgical timeout) was implemented which includes specific verification of the position of off weighted sections of the applicator. Any areas of the applicator that would be off weighted were to be physically marked on the applicator.

Treatment type	Description	Actions taken
Palliative Spine	Patient being treated for palliative spine (33 Gy/10#). Error was a discrepancy for fraction 1 and 2 with treatment being delivered 1 vertebra too inferior.	Dose assessment was performed to determine the dosimetric variation as a result of the incident. Negligible change to organ-at risk doses (remain within planned tolerance): i.e. spinal cord (inc PRV), heart, and lungs. No change to treatment. It was ascertained by the radiation oncologist that the impact was minimal. Recommendations include confirming position of secondary anatomical landmarks (e.g. carina and any other obvious features).
Palliative Sacrum/ Pelvis	A patient underwent a single fraction 8 Gy palliative treatment of the sacrum/pelvis with three fields. After offline review of the pre-treatment images, the charge radiation therapist noticed part of the right elbow was in the right lateral field. This was not picked up on the treatment machine and so the right elbow was partially irradiated unintentionally. The part of the right elbow inside the treatment field received a dose of less than approximately 5.7 Gy. The patient was reviewed following the incident. No erythema was noticed on the elbow and no clinical implications were expected.	The radiation therapist involved was advised that, if a part of the body is close to the area to be treated, specific instructions about this part of the body should be provided in the setup note.
SBRT prostate	A patient at a Melbourne hospital receiving stereotactic body radiation therapy for metastatic prostate cancer received a treatment dose to normal tissue for 4 out of 10 fractions (50 Gy in 10 Fractions). This error was due to a combination of an unusually mobile nodal target volume site and difficulty in matching the cone beam CT (CBCT) to the planning CT. The latter problem was primarily due to artefact from the presence of bowel gas on the CBCT in addition to the low contrast between target and surrounding tissue. The dose to healthy tissue as a result of this error was approximately 20 Gy.	Error was due to a combination of an unusually mobile nodal target volume site and difficulty in matching the cone beam CT (CBCT) to the planning CT. Training for treatment staff members was carried out in appropriate matching.
Palliative tongue	A patient was administered a palliative radiation treatment of 14 Gray (Gy) in four fractions incorrectly prescribed to the right side of the tongue. This patient in fact had a histologically-proven diagnosis of a locally advanced squamous cell carcinoma arising in the sublingual region of the left oral cavity invading the floor of the mouth and lateral tongue.	The booking form did not include site and laterality of tumour. It was stressed to the radiotherapy staff at the hospital that booking form(s) must include site and laterality of tumour.

Treatment type	Description	Actions taken
Electron	The patient had 2 lesions on the left forearm adjacent to each other. One was being 'actively' treated a 7cm circle and 9MeV electrons to a prescribed dose of 20Gy/5#. The adjacent lesions was due to be treated the following week also using a 7 cm circle and 9 MeV with an 8Gy/1# dose. When setting up field to be treated the patient had 2 dressings on forearm which were removed. The 'actively' treated lesion had no skin marking. The yet to be treated lesion had a 7cm circle drawn around it from the clinical mark-up performed on the 2/2/18. A template used by the treatment staff to cross check the skin marks and it was noted that it was difficult to align/match to the marked up field but this was thought to be due to the unstable landmarks in this site. Additionally, the documented set-up instructions requested to pack the lesion with bolus material to profile. The 'actively' treated lesion was flat, the lesion yet to commence was raised, and because of the clinical marks and features of the lesion this led the treatment to think the correct lesion had been identified for treatment. The treatment team did not consider the flat lesion to have been the one receiving active treatment. The patient was treated. Upon returning to the room to release the patient from the Linac couch, it was noticed that the 'actively' treated lesion had a faint number '3' left behind in texta on the patient skin but the team had treated the other lesion. Through further analysis using the template it was determined that the incorrect lesion had been treated. The Radiation Oncologist has advised that the clinical consequences resulting from this incident are insignificant to the outcome of the patient treatment - i.e. the lesion accidentally treated will receive the prescribed dose over 2 treatments instead of 1. The lesion supposed to have been treated will receive the same prescribed dose over 5 fractions but over 9 elapsed days.	<ol> <li>An independent audit of the complete treatment/planning record has been conducted - this highlighted numerous things that needed addressing including improvements in clinical photography and landmarking, clinical handover and increased utilisation of electronic patient alerts in the EMR.</li> <li>A debrief session was held with all staff involved with the case to go through the audit outcome and to discuss how this issue could be avoided in the future</li> <li>The case was discussed at the senior RT meeting to communicate and address the issues highlighted with the expectation of immediate implementation of improvements.</li> </ol>