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Australian Radiation Incident Register

Annual Report

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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.

Reporting of all radiation incidents is encouraged, including minor events, near misses and other opportunities which could lead to valuable learnings. 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 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. More information on the RHC and ARIR can be found on the ARPANSA website.

This report was approved for publication in December 2018, 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 which occurred in 2017.

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 preventative 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.

All example cases provided in this report are summarised from submitted incidents which occurred in 2017. Learnings highlighted are taken from the incident report. Typically these are 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 on typical doses for that procedure.

Contents

Summary of incidents occurring in 2017

Radiation is routinely used across Australia by more than 50 000 licensed users who perform millions of individual tasks each year. The incidents which 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 Australian Radiation Incident Register (ARIR). Incidents submitted to the ARIR are analysed and the results published to raise awareness of common hazards and to identify and promote practices which could prevent future incidents.

The number of incidents reported in 2017 increased by 47% from the previous year. ARPANSA has actively promoted the benefits of reporting all incidents including low consequence and near-miss events. Recent increases in reporting levels are considered to be due to an improvement in reporting practices rather than an increase in incidents, and it is likely that the number of reports will continue to increase.

This year's report includes a focus on computed tomography (CT) scanning incidents. In 2017, one incident reported to the ARIR was also reported to the International Atomic Energy Agency (IAEA) on the International Nuclear and Radiological Event Scale (INES) at a level three ('serious incident'). There were none at level 2 ('incident'); other incidents were rated at level one ('anomaly') or level zero ('deviation').

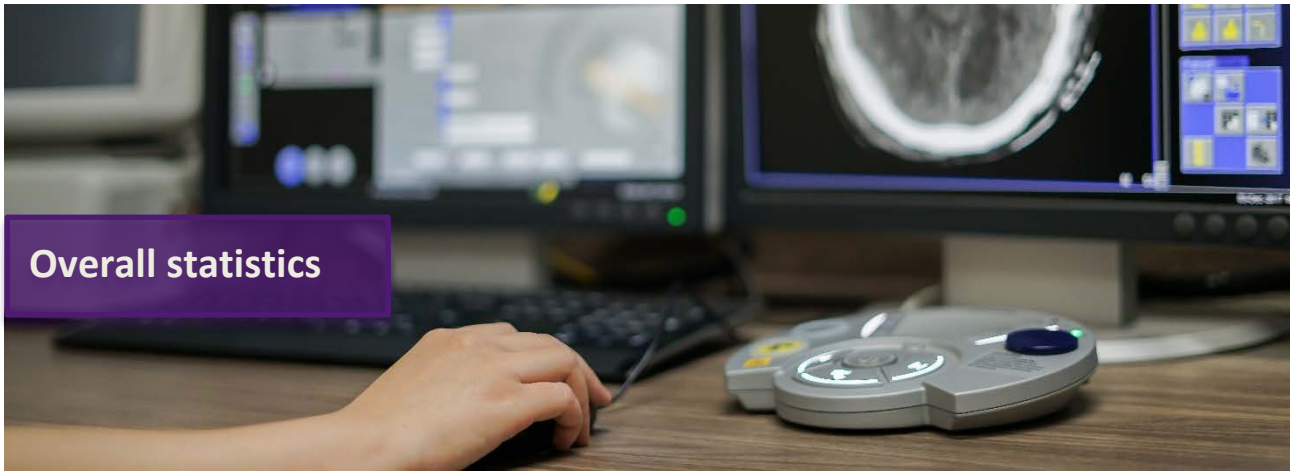
Human error was the primary cause identified in the majority of reported incidents in 2017 which is consistent with previous years. While an incident will typically have one primary (proximal) cause, incidents generally have a number of contributing factors, for example, time pressures, labelling issues, 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.

Analysis of contributing factors and preventative measures suggests that where these incidents occur there is often a high level of reliance on actions taken by individuals, rather than on other organisational or technological controls (e.g. processes, procedures, physical or engineering controls). Reinforcement of correct processes or practices and training and education were the most common mitigating and preventative measures identified.

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.

The most common recommendations made on the incident reports related to:

- following procedures, for example, performing current patient/procedure matching processes
- designing workflows with the worker in mind, for example, deleting unused or inappropriate CT protocols from selection lists while ensuring protocols are still available for common procedures. This removes the need to modify parameters while still ensuring obscure procedures are not accidentally selected
- clear communication, for example, use of full text in place of acronyms that may be easily be confused such as 'CTCAP', 'CTAP' and 'CTPA'
- training and supervision, for example, ensuring that staff (including nuclear medicine technologists using CT) have sufficient training to operate a CT in various situations and settings
- effective monitoring of controls, for example, ensuring that controls (including quality assurance activities) are adequately monitored with awareness by the workers of the risks and potential outcomes. Operational experience gained in monitoring of controls should be used to drive changes and review risks.

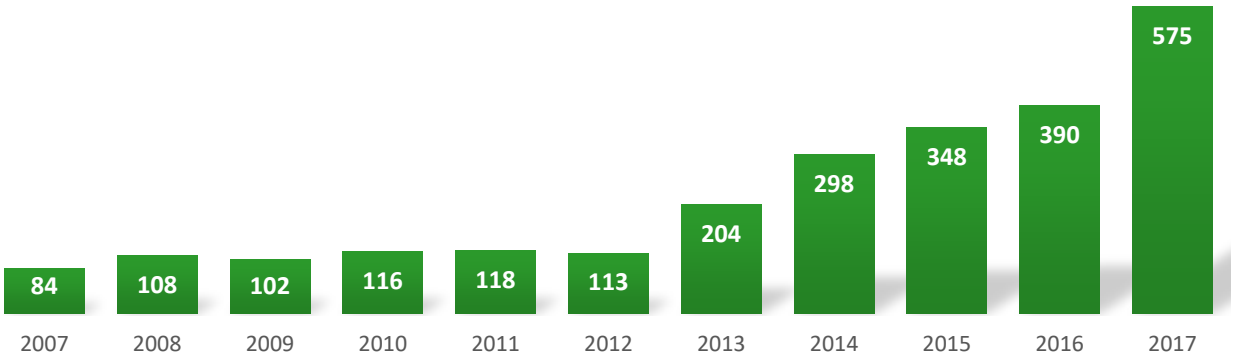


Overall statistics

Number of incidents reported

The number of incidents reported continues to increase. In 2017 there were 575 incidents submitted which represents an increase of 47% compared to 2016. These increases are considered to be due to an improvement in reporting practices. ARPANSA has been raising awareness and promoting the profile of the ARIR since 2012, including the upgraded database and web portal for regulators introduced in 2016.

Number of incidents reported to the register over time



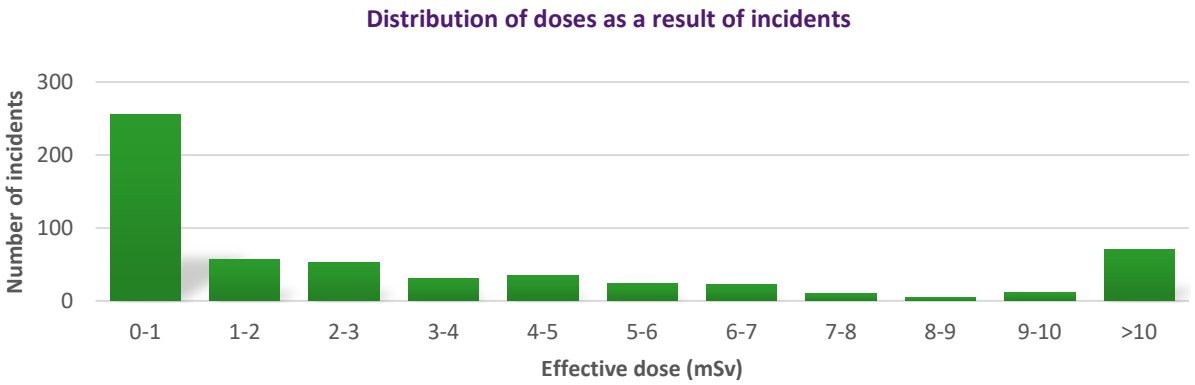
Estimated doses received as a result of incidents

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 milligray – mGy) 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	250	43%
1 mSv–10 mSv	248	43%
10 mSv–100 mSv	73	13%
>100 mSv	4	<1%

Note: percentages rounded



Types of incidents reported

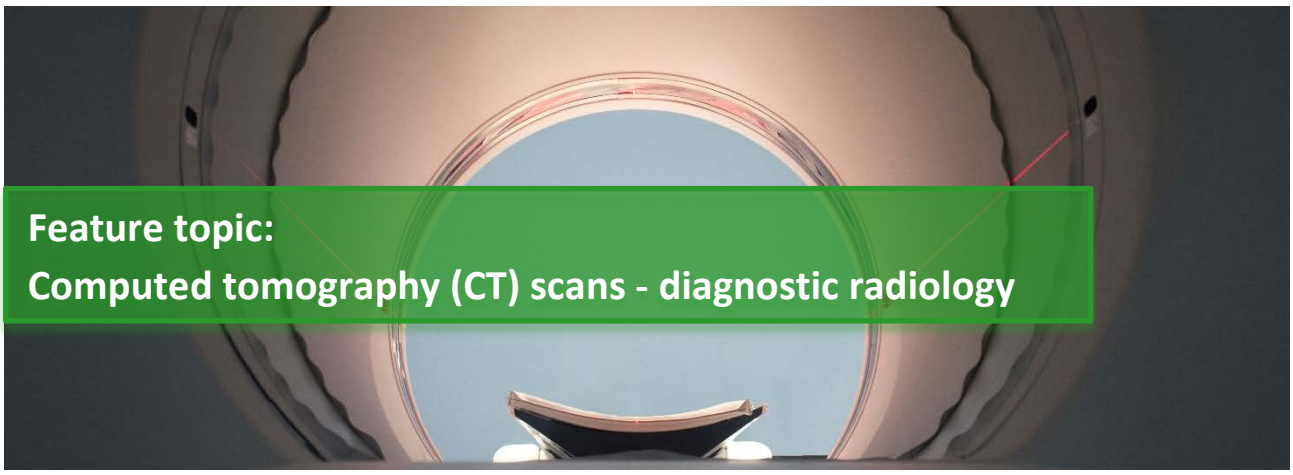
The table below shows the number of incidents by category over the last five years. The largest category, which includes more than half of all incidents, continues to be diagnostic radiology. This is expected as diagnostic radiology, which includes medical imaging procedures such as general X-rays and 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 2017 according to Medicare Benefits Schedule (MBS)[1] information.

[1] For more information on Medicare Benefits Schedule statistics visit http://medicarestatistics.humanservices.gov.au/
Note: this does not include examinations which are billed under arrangements other than Medicare, as such the actual numbers of procedures performed may be higher.

Overall ARIR statistics for 2017 compared with previous four years

	2017		2016		2015		2014		2013	
Incident category	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Medical - Diagnostic Radiology (All)	418	73%	279	72%	236	70%	178	64%	114	62%
+ Diagnostic Radiology (CT)	*212*	*(37%)*	*(143)*	*(37%)*	*(135)*	*(40%)*	-		-	
+ Diagnostic Radiology (Plain Film/RX)	*164*	*(29%)*	*(110)*	*(28%)*	*(91)*	*(27%)*	-		-	
+ Diagnostic Radiology (Interventional)	*34*	*(6%)*	*(22)*	*(6%)*	*(9)*	*(3%)*	-		-	
+ Diagnostic Radiology (Dental)	*8*	*(1%)*	*(4)*	*(1%)*	*(1)*	*(0%)*	*(3)*	*(1%)*	*(2)*	*(1%)*
Medical - Nuclear Medicine	114	20%	73	19%	84	25%	74	26%	52	28%
Medical - Radiotherapy	21	4%	16	4%	8	2%	14	5%	9	5%
Medical - Non-Ionising Radiation (including medical laser)	1	<1%	1	<1%	3	1%	1	<1%	1	1%
Non-medical/Industrial - sources found/lost/stolen	4	<1%	15	4%	1	<1%	2	1%	2	1%
Non-medical/Industrial - imaging (inc Industrial Radiography, XRF, XRD, and security)	1	<1%	3	1%	1	<1%	6	2%	1	1%
Non-medical/Industrial - contamination	5	<1%	1	<1%	1	<1%	4	1%	3	2%
Non-medical/Industrial - irradiator/accelerator	1	<1%	1	<1%	1	<1%	0		0	
Non-medical/Industrial - Transport of radiation material	0	<1%	1	<1%	1	<1%	1	<1%	3	2%
Other	10	2%	0	0%	12	4%	18	6%	19	10%
Total	**575**		**390**		**336**		**280**		**185**	

Note: percentages rounded



Feature topic:
Computed tomography (CT) scans - diagnostic radiology

More than 3.25 million diagnostic CT scans and more than 250 000 nuclear medicine/CT scans were carried out in 2017 according to MBS information. The vast majority of these scans are carried out without incident. However, incidents indicate areas where performance could be enhanced.

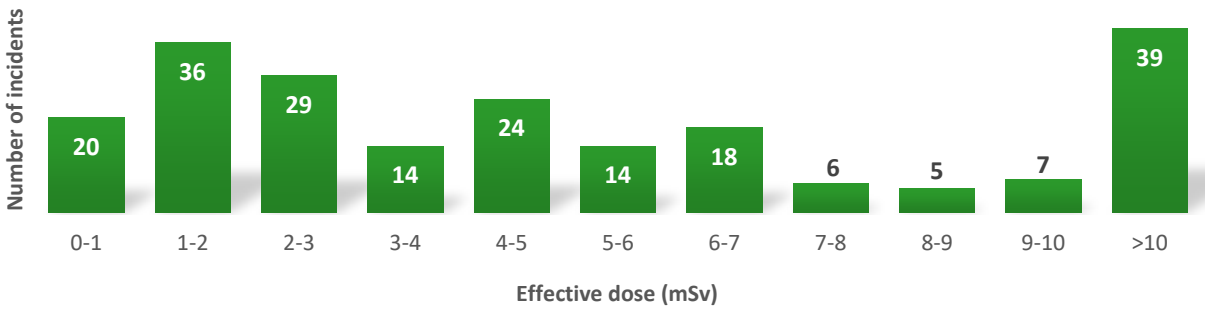
Nuclear medicine procedures and radiotherapy procedures that involve CT are also included in the analysis of this section and are included in the statistics in other areas of this report.

Computed tomography (CT) scan incident statistics

Category	Number of reports	Average dose per incident	Range of doses per incident
Unplanned procedures (incorrect site/procedure/patient)	172 (80%)	7.8 mSv	0–106* mSv
Equipment failure	27 (13%)	5.4 mSv	0–22 mSv
Unknown pregnancy	12 (6%)	Dose to foetus ranged from 5 to 55 mSv. Average 12 mSv	
Other	2 (1%)	13.5 mSv	4.7–22 mSv
Total	**214**	**7.4 mSv**	**0–106* mSv**

* This maximum dose was due to an incident that included 19 patients, individual effective doses ranged from 2-11mSv.

Distribution of computed tomography (CT) scan incident doses



Unplanned procedures

The principles of justification and optimisation ensure that a patient receives only justified procedures and that protection is optimised without jeopardising the diagnostic outcome. Under this process procedures are planned to be delivered to a patient for a specific benefit such as for the diagnosis of disease. Procedures that differ from what was planned (where the referral was not followed as intended) form the largest fraction of incidents in CT.

Computed tomography (CT) scan incident statistics for unplanned procedures

Category	Number of reports	Average dose per incident	Range of doses per incident
Incorrect site/procedure	91 (53%)	8.4 mSv	0–106 mSv
Incorrect patient	52 (30%)	6.1 mSv	0–51 mSv
Unnecessary procedure (e.g. duplicate)	29 (17%)	8.9 mSv	1–51 mSv

These incidents have the potential to significantly affect patient outcomes if not picked up and wrong clinical decisions may be made based on this imaging. Where incidents are detected and patients re-scanned, 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.

Patient identification and procedure matching is a critical control for these types of incidents. This includes:

1. verification of the patient presenting for imaging
2. matching information provided on the patient e.g. to the referral
3. a time-out prior to the procedure to confirm key details
4. post-procedure image recording

While patient identification requirements apply to all practices, local requirements differ across jurisdictions and implementation will vary between hospitals or practices.

This section outlines typical processes and provides examples of incidents from 2017 where these controls have not been effectively implemented.

1. Verification

Verification should always be carried out with at least three identifiers e.g. full name, date of birth and address/medical record number. These should be framed as open questions (What is your name? What is your date of birth? What are you here for? Please point to the area you're having imaged today) rather than closed questions (Are you John Smith?). Where the patient is a child or unable to confirm these details, the details should be confirmed with the patient's designated representative. If no representative is available, then the patient's identification band or a staff member accompanying the patient is used to verify the patient's identity.

Example case: open questions

A radiographer attempted to identify the patient with closed questions. The patient confirmed the details (of a different patient) and was scanned using the procedure for that patient at the incorrect site.

(Effective dose: 3.7 mSv)

2. Matching information

Depending on the hospital and jurisdiction patient matching procedures, typically referred to as 3C procedures (correct patient, correct site/side, correct procedure), are employed and should confirm the referral information and clinical need.

Example case: incorrect site/procedure

Failure to observe 3Cs protocol resulted in the misinterpretation of a request for CT examination of abdomen and pelvis (i.e. common acronym of 'CTAP') which was confused with 'CTCAP' (CT Chest/Abdo/Pelvis). The scanning of the chest region was not required and did not have clinical benefit.

(Effective dose: 4.7 mSv)

3. Time-out

Immediately before the procedure, after all preparation steps have been completed, a 'time-out' is to be called. Team members will then verbally confirm the correct patient identity, the correct procedure to be performed, and the correct site/side is identified (and marked if applicable).

Example case: patient matching

The radiographer requested Patient A, but the porter collected patient B by mistake (they have the same initials). A 3Cs check was not fully performed and patient B was incorrectly scanned with CT KUB protocol.

(Effective dose: 2 mSv)

4. Post procedure

Following image acquisition, the images and information is often required to be used by another health professional, such as a specialist or the referrer. Post-procedure confirmation of the image is required to confirm (at a minimum) that patient details and the side (laterality) marker attached to the post-processed image are correct. In addition, it is important to ensure that any electronic file is verified and linked to a record correctly. Post-procedure image reviews affords an opportunity to compare the images to the request. These checks also provide effective detection of where the above processes have failed to prevent unnecessary imaging.

Example case: post-procedure checks

A CT chest scan for an inpatient was requested with the notes 'no contrast - Post pleural tap'. Staff completed the CT scan and when reviewing images noted there was fluid remaining in the chest. Staff then checked clinical history where they realised the pleural tap had not been completed. It was noted that discussion with patient would have concluded that no recent pleural tap has been performed.

(Effective dose: 1.7 mSv)

Further resources

There is a wide range of resources available for further information on this topic

- Australian Commission on Safety and Quality in Health Care - Ensuring Correct Patient, Correct Site, Correct Procedure Protocol (including CT specific protocols, imaging factsheets, and standard)
- Patient identification and procedure matching guideline, Queensland Health
- Is it possible to eliminate patient identification errors in medical imaging?, Danaher et al.
- When should your radiologists take a 'time out'?, Stephanie Krentz

Examples of incidents from 2017

For each sub-category within unplanned procedures, further examples are provided together with a summary of learnings. Learnings are taken from the recommendations identified by the incident reporter or corrective actions taken. For each incident, there is a brief description of the incident and the excess effective dose received by patients.

Note that discussions in other sections of this report such as for high hazard, low probability procedures on page 24 may also apply to these types of incidents.

<table>
<tr><th colspan="2">Example cases: unnecessary procedure</th></tr>
<tr><td>A patient presented to the radiology department of a hospital for a high resolution CT scan of the chest. The patient was booked at an earlier date due to a clerical error by staff in the radiology department. The radiographer did not check the referral properly and conducted the scan. A radiologist reviewed the images and decided that the patient still required a scan on the date initially intended.
(Effective dose: 3.8 mSv)</td><td>A patient at a hospital underwent an unnecessarily repeated CT scan of the cervical spine about two months after the required scan. Both CT scans were performed using the same referral card. The cause of the incident was radiology administrative staff making two bookings for the scan based on a printed copy of the referral form from digital system.
(Effective dose: 2.2 mSv)</td></tr>
<tr><td rowspan="2">A patient at a hospital unnecessarily received a second CT scan of the kidney, ureters and bladder (CT KUB) under the same request as the first scan on the previous day. This was caused by multiple copies of the same request being faxed down to the medical imaging department. The electronic request system did not automatically alert staff of possible duplication of procedure because the same procedure was entered as two different procedures, i.e. CT scan of the abdomen non contrast and CT KUB non contrast.
(Effective dose: 11 mSv)</td><td>A patient at a hospital underwent an unnecessary repeat of a CT scan of the chest, abdomen and pelvis because the same scan had been carried out from another campus of the hospital.
(Effective dose: 35 mSv)</td></tr>
<tr><td>A patient at a hospital received an unnecessary CT scan of the chest. The patient was referred for a follow-up CT chest scan on a particular day in 2018 but the scan was performed one year too early due to staff not reading the request carefully.
(Effective dose: 2.4 mSv)</td></tr>
<tr><td colspan="2">Learnings:
It is important for radiology staff to check the scan histories at the time of booking and the time of the procedure. This should be regularly reinforced though training and education.
The following additional measures were identified to improve the request system:
display alert if a study is booked within a certain timeframe (e.g. 48 hours) of a previous identical episode. The user must acknowledge this alert in order to continue
all inpatient request forms to have a coloured sticker placed on the request, detailing if the patient has had a previous CT scan within the last 5 days. If ‘yes’, then this is checked for the same body area. If ‘yes’ again, then this will require verification by a radiologist as documented by the radiographer
scheduling software to include a display of the requested date of the procedure on screen.</td></tr>
</table>

Example case: wrong patient

A patient in the emergency department (ED) at hospital attended radiology with a referral for a wide field-of-view CT imaging scan covering the body from the head to the abdomen. During the scan it was discovered that the request was meant for another patient but had the first patient's details on the referral (wrong patient label). The CT scan of the brain, cervical spine and chest had already been performed but the CT scan of the abdomen to complete the scan was aborted.

(Effective dose: 11 mSv)

A patient at a medical imaging practice had an unintended CT thoracic and abdominal aortogram. The referring physician printed out the incorrect patient details and consequently wrote a referral for the wrong patient.

(Effective dose: 13 mSv)

A patient had an unintended CT scan (CTPA-Spiral Angio). The technologist incorrectly identified the patient and consequently accidently scanned the incorrect patient.

(Effective dose: 6 mSv)

***Learnings**:*

- *correctly following 'time-out' / patient identification procedures*
- *digital referral systems can provide controls to help prevent selecting the wrong patient. These controls should be reviewed where failures are identified*
- *the use of patient labels on the request form can lead to the wrong sticker on the wrong form.*

Example case: incorrect protocol for research trial

Between 2012 and 2017 a total of 19 participants in a research trial had CT scans performed that were inconsistent with that specified in the trial protocol and consented to by the participants.

The trial protocol requires a 10 cm scan length at specified mA and kV. Two scans were to occur one at baseline and a follow-up at 24 months.

The most common error involved scanning a greater length than the specified 10 cm.

While the CT radiographers (and radiologists) should know that a research trial scan might require a special scan protocol, and consult a folder stored in the CT scan area with details of these protocols, the request did not easily identify this requirement. Further contributing factors identified were that:

a) radiographers were feeling overwhelmed by scan requests

b) research trial scans are normally routine

c) the folder might not have been easily found at short notice

The trial research coordinators have been collecting data from the Radiology Department with a stated intention of notifying participants of dose in excess of the planned dose, and potentially excluding those with excess dose from further scanning.

Actions implemented so far include making research imaging protocols available through a web link for radiographers. The report noted that further discussion and actions are required.

(Excess effective dose to research participants ranged from approximately 2 to 11 mSv)

***Learnings**:*

Procedures should clearly provide for situations where imaging requires a special protocol.

Example case: incorrect settings/procedures	
A patient underwent a radiation therapy planning CT of the lumbar spine. In the same session, the patient received an unnecessary whole brain radiation therapy planning CT scan. This was due to misinterpretation of the responsible doctor's referral (via email) and failure by the radiation therapists to confirm the correct imaging site. A diagnostic CT of the brain with contrast had actually been intended. (Effective dose: 1.4 mSv)	*A patient at a medical imaging practice presented with a referral for a cervical spine CT and was incorrectly entered for a lumbar spine CT by the bookings clerk. The radiographer checked the procedure against the patient stickers created for the documentation rather than from the written referral and clinical information provided. The patient also confirmed that he had back pain when asked by the radiographer.(Effective dose: 11 mSv)*
A patient at a hospital underwent a CT pulmonary angiogram (CTPA) instead of a CT carotid angiogram (CTCA) due to radiographer error. The error was not specified in the report. (Effective dose: 4 mSv)	*Patient received a cervical CT scan instead of a cervical x-ray. The handwritten referral was not interpreted correctly due to poor handwriting and similarities in the required CT and X-ray. (Effective dose: 2.4 mSv)*
A patient at a hospital underwent the CT component of a PET/CT scan with arms positioned up instead of with arms down as is protocol. The CT scan was repeated with the correct protocol. (Effective dose: 3.7 mSv)	*An incorrect scanning protocol was selected by a technologist, which used significantly higher mAs than required. The selected protocol was not commonly used and could have been removed from the system. (Effective dose: 3 mSv)*
CT request form, completed by an ED doctor, was mislabelled with another patient's label. Patient was correctly identified by their wrist band and on the request form. The Patient also gave verbal consent for CT scan. The unnecessary CT scan could have been avoided if the patient was asked what they were to have scanned. (Effective dose: 2.3 mSv)	*A patient at a medical imaging practice underwent an incorrect CT scan. The radiographer in question misread the referral. The referral was for a CT coronary angiogram (CTCA) but the radiographer performed a CT pulmonary angiogram (CTPA) instead. (Effective dose: 8.1 mSv)*
A nuclear medicine PET/CT scan was commenced with CT component being completed first. Patient had to urgently use the toilet. A 'low dose' CT was attempted by modifying the settings but the scan was not of diagnostic quality. The entire scan had to be restarted when the patient returned including the CT component. (Effective dose: 14 mSv)	*A patient received a PET scan and a CT (portal venous abdominal pelvis) scan. The technologist received a phone call, interrupting the set-up of the CT machine. The PET/CT scanner in question uses an older operating platform that is very complex, requiring multiple steps. Following the phone call, the technologist initiated the scan thinking that it had been set-up correctly. However, the incorrect level had been set. (Effective dose: 5 mSv)*
Learnings: • *Medical Imaging Technologists and clerical staff need to be trained regularly in correct patient and procedure ID procedures and the entering of patient and imaging details* • *common acronyms which are similar should be avoided (e.g. 'CTCAP', 'CTAP', 'CTPA'), instead the procedure should be written out (e.g. 'CT Chest/Abdo/Pelvis', 'CT coronary angiogram')* • *where a referral is ambiguous (including due to poor handwriting) the referral should be followed up with the referring practitioner* • *a separate procedure for common settings (e.g. 'low dose scanning protocol') can be developed which removes the need to modify parameters* • *unused or inappropriate protocols can be deleted from selection list* • *ensure that staff (including nuclear medicine technologists using CT) have sufficient training to operate a CT in various situations.*	

Staff training and supervision

A number of reports highlighted where ineffective training and supervision were a factor in the incident. The medical field frequently has students, new staff, and changing practices, which impose specific training requirements on operators. The regular training of staff to maintain competencies, and when gaining experience in new modalities or procedures, needs to be effectively managed.

Example case: supervision

A student did not realise they had not completed pre-injection scans (for placement of bolus tracking region of interest) and told a nurse they were ready for contrast injection. Pressing the scan button triggers the injection of contrast, and there is a delay prior to bolus tracking for the nurse to supervise the injection and exit the room prior to the scan starting. With the nurse still in the room, the student pressed the scan button and the pre-injection ROI scan (single image) was completed. Supervision of the student was inadequate due to distraction of the supervising radiographer by a phone call regarding another patient.

(Effective dose: 0.0004 mSv)

***Learnings**:*

Recommend a second radiographer be present to complete other tasks such as answering phone calls, organising patients etc. to enable full supervision of the trainee/student.

Patient factors

Factors outside of operator control

Workflows, including where patients wait and the areas they can access, are important not only to providing a good patient experience but can have a significant impact on safety. This is particularly important in nuclear medicine settings, where patients have been injected with radioactive material.

Example case: emergency shutdown

Patient A was directed to the toilet by staff but instead entered the scan room, where patient B was being scanned, by activating the open door button outside the scan room. Once in the room the doors shut and he hit the emergency stop to get out.

On pressing the emergency shutdown the UPS (uninterruptible power supply) tripped circuit breakers and reconstruction towers. Staff spent 60 minutes bringing the machine back to a workable mode.

Patient B's scan was 90 seconds away from completion but due to total shut down of system scan data was lost, and the scan had to be repeated. Additional radiation to patient A was negligible since they entered during a PET scan (not during CT).

CCTV is used to allow observation of uptake rooms and the scan room as direct observation is not always possible. However, patient A was not sighted on the CCTV nor did they call out and were not picked up by the microphones in the scanner room.

(Effective dose patient B: 4.7mSv)

***Learnings**:*

- *Advice is being sought regarding the prospect of electronic door locking of PET/CT entry doors. The safety of patients needs to be considered to ensure that locks do not adversely affect access or egress in emergencies*
- *Clear signage is important in assisting patient flow and reducing inadvertent activation of safety systems.*

Pregnancy

Twelve incidents were reported where pregnant patents have undergone CT scans. In all cases the patient indicated she was not pregnant and standard procedures were followed. These cases highlight that these checks are important, but that the testimony of the individual is not always reliable. Under the *Code Of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation* (RPS 14) biochemical tests are only required prior to therapeutic nuclear medicine administration. However, in at least one instance, a test was carried out and returned a negative despite the patient being pregnant at the time of the scan. Dose to the foetus was typically less than 10 mGy, however the maximum was 23 mGy.

Example case: unknown pregnancy
Patient presented for a CT examination. All patient checks were performed appropriately and the patient was questioned about her pregnancy status. The patient believed she was not pregnant at the time of the examination. However, from the CT images it was evident that the patient was pregnant. *(The radiation dose to the foetus as a result of the incident was approximately 6 mGy)*
A patient at a medical imaging practice underwent a CT scan of the abdomen and pelvis. All patient checks were performed properly and the patient indicated that she was not pregnant. She later discovered that she was pregnant at the time of the procedure. *(The radiation dose to the foetus as a result of the incident was approximately 23 mGy)*

Equipment failure

Repeat exposure/higher dose due to equipment failure

While equipment failure is difficult to predict, it is important to perform regular maintenance.

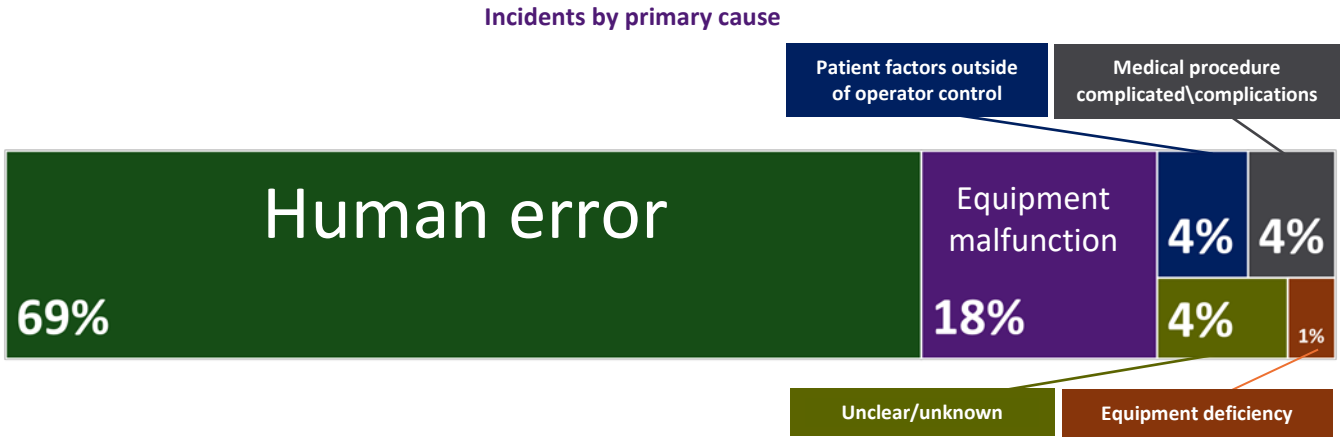
Example case: CT equipment failure
In two incidents the equipment artefact head had an issue which lead to two patients requiring repeat scans. After the first incident, engineers investigated and believed the problem was solved. After the second incident the engineers investigated further and found a large accumulation of dust in the equipment. Once the dust was cleared, the artefact issue was solved. *(Effective dose: 2 mSv per patient)*
***Learnings**: Engineers now clean the dust from internal system approximately every 6 weeks.*

For nuclear medicine CT scans, including positron emission tomography/computed tomography (PET/CT) scans, radiation doses can be significantly higher. If the patient has already been injected with radioactive material, and needs to be administered with radioactive material a second time, they will receive twice the associated dose in addition to any CT component. These are typically reported as nuclear medicine incidents rather than CT incidents. Eleven PET/CT equipment failure cases were reported with an average additional effective dose of 16 mSv and a maximum of 41 mSv. The critical path should be assessed for PET/CT imaging with consideration of uptake time and scan time. For example, in some incidents an alternate scanner could be used without the need to administer additional radiopharmaceuticals.

Example case: PET/CT equipment failure
Two patients at a hospital received an unnecessary radiation dose from the injection of 325 MBq of Flourine-18 fludeoxyglucose (F-18 FDG) due to malfunction of the power supply for a reconstruction and processing computer of a PET/CT scanner. A faulty power supply was replaced and the scanner returned to clinical service but the replacement power supply then malfunctioned. Two patients had been injected with FDG for scanning; one patient also underwent the CT component of the scan. *(Effective dose: patient A (CT scan & FDG) 15 mSv, patient B (FDG only) was approximately 5 mSv.)*

Primary cause

Across all incidents reported in 2017, human error was identified as the primary cause in 69% (369) of cases. This is consistent with previous years.



Human error

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 rather that the outcome of human actions was undesirable. For more information on this and on elements which lead to human error see the ARPANSA Website and Holistic Safety Guide.

Equipment malfunction/deficiency

Malfunctions include 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

Examples of this are where the patient suffers from claustrophobia or self-discharges.

Medical procedure complications

In some cases medical complications can result in a higher than normal dose. For example, during a complex surgery a significant fluoroscopic dose may be delivered when the procedure takes longer than expected. This is reportable as an incident.

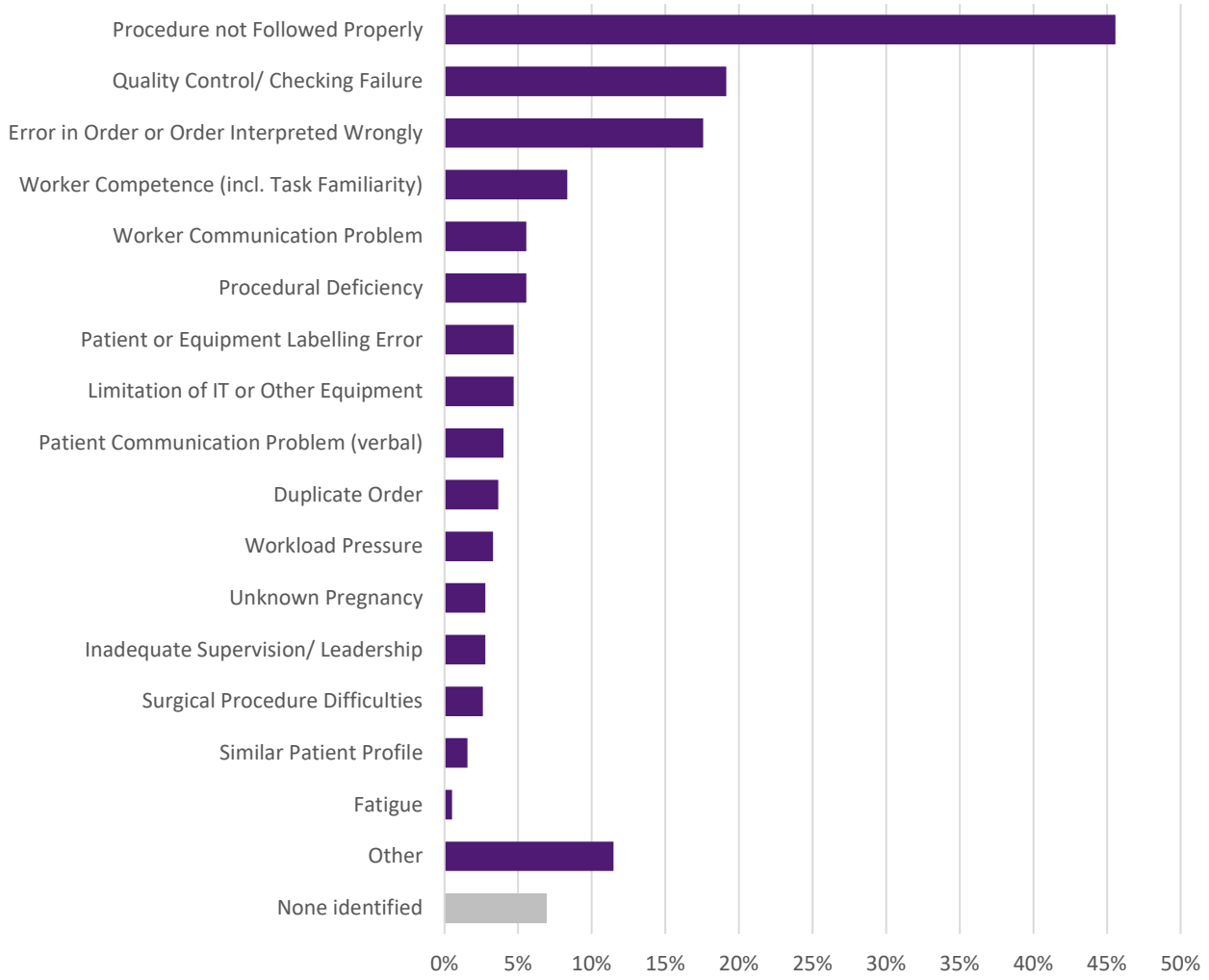
Contributing factors

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 7% 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. Often small changes can significantly reduce the likelihood of an incident 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.

Contributing factors identified in 2017 incidents

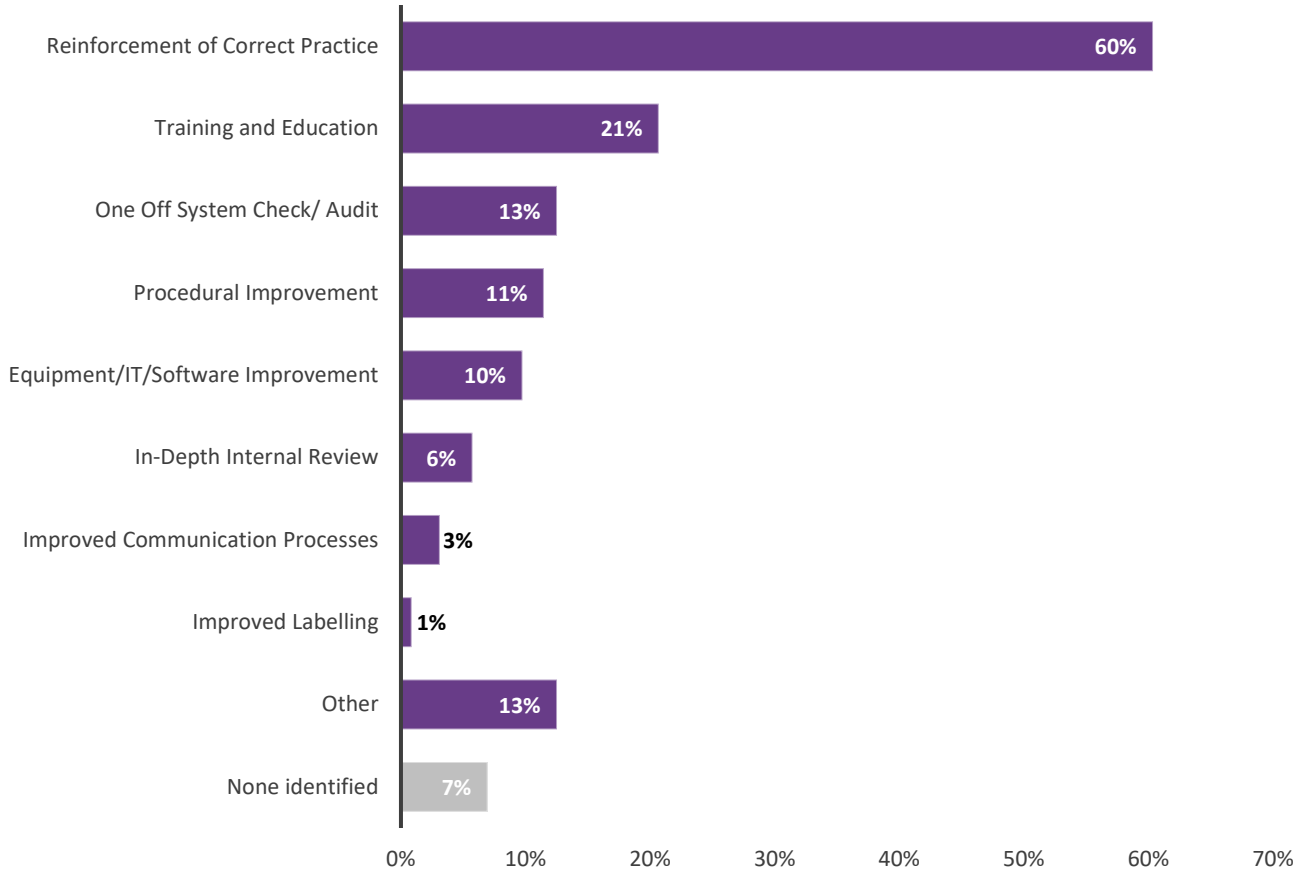


Summary of controls and preventative measures implemented

Preventative measures are the actions taken as a result of an incident to prevent recurrence. One or more remedial actions were identified in 93% of reports, which is an increase from 78% in previous years. 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 2017 such actions were taken in 60% of incidents. While this is an increase from previous years (30–40%) this is believed to be due to changes in the reporting system rather than changes in remedial actions taken. This remedial action may not be effective in the long term if used in isolation.

Remedial actions taken to prevent recurrence in 2017



Summary of recommendations made in reports

The most common recommendations made in incident reports were:

- Staff following clear and effective procedures. This includes quality checks, 3C procedure (correct patient, correct site, correct procedure/protocol) and 'time-out'. The importance of these should be emphasised to all staff including supervisors and management staff
- consideration of human factors in workflow and system design. This includes the use of computer systems with alerts and workstation set-up
- effective monitoring of critical controls and ensuring awareness of low probability, high consequence events.

Summary of incidents by category

Diagnostic radiology

This category covers medical imaging which is performed using an X-ray apparatus. The feature topic covers computed tomography (CT) scans while other types of uses are considered in this section.

Overall statistics for diagnostic radiology incidents

Type	Number of incidents reported	Effective dose per incident Note: does not include skin or critical organ doses.	
		Average	Range
Computed tomography (CT)	214	7.4 mSv	0–106 mSv*
General X-ray	164	0.5 mSv	0–10 mSv
Fluoroscopic/interventional	34	0.7 mSv	0–10 mSv skin doses up to 14Gy
Dental	8	0.02 mSv	0–0.13 mSv

* This maximum dose was due to an incident that included 19 patients. Individual effective doses ranged from 2–11 mSv.

Non-CT diagnostic radiology incidents reported in 2017 included:

- unnecessary scans (52%) including imaging the wrong region/procedure (27%), or imaging the wrong patient (13%), duplicate orders (12%). These incidents are consistent with those discussed in the CT section of this report
- equipment failure (29%)
- medical complications (7%)
- imaging where the patient was later found to be pregnant (4%)

Equipment failure

Fifty-seven incidents occurred where equipment failure resulted in a higher dose or a repeat examination.

Example case: orthopantomogram (OPG) equipment failure
Halfway through an OPG scan, the system unexpectedly stopped. Patient was rescanned on a different OPG unit. Vendor service department was called. The service engineer reattached a cable that had come loose due to the circular motion of the head of the OPG unit. Engineer certified the system to be able to be used. Three days later the cable again became loose and the same failure occurred. When called back in, the engineer tied down the cable to prevent it coming loose again. *(Effective dose: 0.016 mSv)*
Learnings: *Ensure that equipment is serviced regularly and to secure cabling on moving equipment*

Example case: wireless detector failure
A low battery error message for a detector interrupted a long leg stitch examination, causing the unit to abort any further stitching images. The full exam had to be repeated. This is being investigated by the manufacturer. *(Effective dose: 4.4 mSv)*
Learnings: *All wireless detectors should be routinely checked to ensure that they are fully charged prior to an examination, or turned off if unneeded, pending further advice from the manufacturer.*

Accidental footswitch activation

For interventional radiology, which provides minimally invasive image-guided diagnosis and treatment, a surgeon or radiographer typically uses the X-ray apparatus via a foot pedal. This ensures the operator, who is wearing protective gowns, is free to use their hands during the procedure.

The following five incidents involved accidental exposures though inadvertent use of footswitches:

- foot pedal was caught under the patient table which depressed the footswitch (6 mSv). (See example case below)
- a radiography/fluoroscopy unit continued to operate when the radiographer took their foot off the exposure switch. Other steps such as the emergency stop button did not cut power. The unit had to be turned off at the mains power outlet (0.6 mSv)
- a staff member accidently stepped on the X-ray footswitch (<0.01 mSv)
- inadvertent activation of X-ray beam by rolling bed onto the footswitch during patient transfer (<0.01 mSv)
- the patient trolley was accidentally parked on the radiation exposure footswitch which caused the X-ray system to screen for about one minute. However, the unit was not directed toward staff or patients (<0.01 mSv)

Presently some jurisdictions require that for this type of equipment the exposure switch must be designed so that it cannot be accidentally operated. This may be achieved by shrouding the footswitch or by the provision of an isolation switch at the operator's console.

Footswitch protection, such as a raised side barrier or an enclosure over the switch (shrouding), can reduce the possibility of accidental activation by beds, trolleys and staff. However, these barriers are not always readily available from the manufacturer or supplier and sometimes need to be developed in-house. Additionally in some situations, the use of a shrouded footswitch may be undesirable due to ergonomic or other site-specific requirements.

Example case: footswitch

A patient at a hospital was positioned on the catheterisation lab table while sedated in preparation for a procedure.

When the radiographer turned the 'disable X-ray' button off, X-ray acquisitions immediately started unintentionally because the foot pedal was depressed under the patient table. The radiographer pressed the emergency stop button on the control panel, but this only ceases movement of the X-ray unit. The exposure could not easily be terminated as the 'disable X-ray' button is not able to be depressed during acquisitions, and the table could not be raised to release the foot pedal since actuation of the emergency stop ceased table motion.

After 46 seconds of acquisitions, the radiographer held in the power off button, which powered down the unit and terminated X-ray radiation.

(Effective dose: to the patient was approximately 6 mSv)

Learnings:

Hospital units need to carry out a risk assessment in relation to imaging and ancillary equipment in order to determine weak points and potential failure scenarios and implement appropriate controls.

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: shielding

A patient received a shoulder X-ray while standing against a wall on the ward using a mobile X-ray source. The patient queried with the radiographer, and subsequently with the regulator, whether there was protection for the people on the other side of the wall. The radiographer was under the impression that the walls between rooms on the ward were lead-lined, but when queried with the hospital it became evident that they are not.

The hospital has now changed their work practices to ensure that X-rays are taken in a manner to ensure that exposure to any other potential persons behind walls is minimised.

Learnings:

X-ray exposure should be performed against appropriate shielding barriers, and appropriate procedures should be followed to deal with a radiation source.

Example case: lead gowns (personal protective equipment (PPE)		
A staff member unintentionally did not wear lead protection during a fluoroscopy procedure. *The staff member had scrubbed in for the procedure to catheterise the patient and had forgotten to put on lead protection. The staff member had intended to wear the lead protection once the catheter was in place, and prior to any radiation exposure. However, they forgot and remained unprotected for the remainder of the exam, which included fluoroscopic screening. The radiographer did not notice this.*	*A staff member unintentionally did not wear lead protection during a fluoroscopy procedure.* *A staff member was assisting in a complicated catheterisation procedure and intended to put on the top section of the lead protection once the catheter was in place, prior to any radiation exposure. The staff member was wearing the bottom half of the lead protection with the thermoluminescent dosimeter (TLD) badge on top of the PPE. The staff member was present for six seconds of the fluoroscopic screening before this was noticed.*	*A student on clinical placement returned a higher than expected dose. The student was involved in a number of screening procedures but wore a protective gown at all times.* *After further investigation they were asked to demonstrate how they wore the gown and badge and it was identified that the badge was fully exposed and not underneath the gown as it should have been.*
Learnings: *All medical imaging staff working in fluoroscopy, especially radiographers, should check that all staff within the procedure room are wearing the appropriate personal protection prior to any screening.*		

Nuclear medicine

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.

Nuclear medicine incident statistics

Category	Number of incidents	Average dose per incident	Range of doses per incident
Incorrect radiopharmaceutical /dose	47	8 mSv	0–25 mSv
Scanning equipment malfunction	13	13 mSv	0–41 mSv
Extravasation	13	Skin and effective doses vary based on degree of extravasation and are difficult to estimate accurately	
Incorrect patient	7	6 mSv	0–24 mSv
Dose administered (not scanned)	7	9 mSv	5–19 mSv
Spills, leaks	4	1 mSv	0–4 mSv
Other	23	4.3 mSv	0–29 mSv
Total	**114**	**5.7 mSv**	**0–41 mSv**

Incorrect patient

Patient identification is discussed in the feature topic starting on page 5. Similar factors were identified in nuclear medicine incidents.

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.

Example case: administration of incorrect radiopharmaceutical

A patient at a hospital presented for a cardiac rest/stress study as an outpatient. The rest scan involved the first injection of a radiopharmaceutical 767 MBq technetium-99m (Tc-99m) sestamibi, which was performed with no difficulties. The injection for the stress scan was prepared by an intern who had been drawing doses up for the entire morning. The intern had returned from a tea break just prior to preparing the stress dose. In the interim, the hot lab had been in use by another person. Inadvertently, the intern used a similar appearing but incorrect vial to draw up the dose without checking the vial labels before or after drawing up the injection. Consequently, the patient was injected with the correct amount but incorrect radiopharmaceutical for the desired scan (Tc-99m pertechnetate instead of Tc-99m sestamibi).

(The effective dose as a result of this maladministration was approximately 10 mSv)

Learnings:

Nuclear medicine technologists need to be trained regularly in correct patient and procedure ID procedures, with particular stress on the thorough checking of the radiopharmaceutical and activity.

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. In a number of incidents the use of technology (e.g. software), and human factors (e.g. colour of radiopharmaceutical containers) were identified as contributing causes.

The following recommendations were identified in reported incidents that occurred in 2017:

- review hot lab procedures and workflow to assess if work practice can be improved. For example, through technology changes or human factor considerations
- limit the number of different radiopharmaceuticals in the drawing up area of the hot lab at any one time. Reconstituted radiopharmaceuticals should not be stored in the drawing up area to ensure appropriate selection of radiopharmaceuticals for each dose being prepared
- new hot lab software with barcode scanning capability will be installed in the near future. Until this time, there will be two technologists rostered in the hot lab to double-check every dose
- improve labelling in the hot lab including use of colour to differentiate between radiopharmaceuticals. The chief technologist now checks all doses
- consider the use of colour coding to distinguish different pharmaceuticals and radioisotopes. Australia should develop a uniform coding scheme for different pharmaceuticals and radioisotopes.

Example case: labelling issues

A patient was due for a brain scan requiring 900 MBq Tc-99m Neurolite to be administered. During dispensing of the requested dose, another dose for a different patient (850 MBq Tc-99m hydroxymethylene diphosphonate (HDP) bone scan) was being recalibrated, and the incorrect label exchanged for the correct dose. This exchange led to the misadministration of a bone scan instead of the requested brain scan. The technologist who administered the incorrect source returned to the hot lab and immediately identified the error. The technologist informed the supervisor, physician and radiation safety officer immediately. The patient was informed what had happened by the physician. It was explained to the patient that there was no significant risk from having the administration. It was explained that they would have to return another day for the original test. The patient was compliant with this information and was rebooked for another day.

(Effective dose: 3.7 mSv)

Learnings:

The dispensing work instruction will be updated to state that only the vial containing the radiopharmaceutical being dispensed will be in the dispensing workstation when drawing up patient doses.

Change control

When identifying new processes or controls to be implemented it is important to assess any potential risks that might be affected by the new process. This is important for all changes, including improvements, as the potential negative effects of the improvement need to be considered. This includes considering the consequence if the planned change is not implemented as intended, unintended consequences, and how the change could affect potential incidents.

Example case: change control

In the nuclear medicine department of a hospital, a vial containing approximately 10 GBq of Tc-99m broke in a microwave oven during preparation of Tc-99m sestamibi causing contamination of the oven. The microwave oven was decontaminated before being used again. No significant exposures to staff.

Learnings:

Trials of new equipment using radioactive material should be carried out first with non-radioactive samples.

Radiotherapy involving nuclear medicine

Example case: patient self-discharge

A patient was permitted to self-discharge from hospital following administration of 3.5 GBq Iodine-131 (I-131). The patient did not follow the instructions provided and contaminated a residence, which resulted in exposure to the patient's family. The contamination was primarily of the rear yard where the patient urinated outside. Communication issues with the patient were identified as a factor in this incident.

The patient was convinced to return to isolation in hospital by regulatory staff and a hospital radiation safety officer. The rear yard of the residence was cleared of contamination by removing turf and soil contaminated by I-131 and storing until remaining activity has decayed. Ninety-five per cent of contamination was able to be removed from the yard of the residence.

Following the incident the hospital reviewed procedures for management of non-compliant patients, and self-discharge of radioisotope therapy patients.

(Dose to staff and carers was not estimated as there are a significant number of factors which were unknown. However, staff, including those involved in the clean-up of residence, were wearing personal dosimetry badges and did not have results which were significant.)

Learnings:

Contact the regulatory authority before patients are allowed to self-discharge in these situations. The regulatory authority has powers to direct individuals to take specified actions in certain situations. Incident may have been avoided if authority was contacted prior to patient self-discharge

Radiopharmaceutical production and quality control

During the production of nuclear medicine high-activity, 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 procedures and that doses to patients are minimised.

High-hazard, low-probability procedures

In simple terms, hazard refers to the danger of something, which is graded by the severity of potential outcomes. The risk is the product of hazard and its likelihood. For example, sharks might be a high hazard when considering the risk of ocean swimming but the risk is actually very low as seen by the rarity of actual shark attacks. Where a significant hazard exists there are often a number of controls in place that primarily affect the likelihood of the event occurring, or the ability to mitigate the consequence of adverse event.

From the production of the isotope (either using an accelerator or a reactor) to the preparation, distribution and application of the final medicine, many processes deal with material of significant radioactivity. These processes often involve a large number of human actions that need to be followed precisely, and are subject to a large number of controls, to ensure both the quality of the final product and the safety of the workers. As such, while there is often a high hazard, there is a low probability of an incident occurring.

In these highly controlled workplaces many of the controls can become habitual. Where effective controls are used there is no negative outcome. People tend to feel safe and confident of successful outcomes. Over time, this can lead to workers becoming complacent of the risk, by perceiving the hazard (consequence) and the risk to be lower than they actually are. For example, a worker may carry out a quality control (QC) process to confirm the quality of a radiopharmaceutical daily without ever encountering an error. Eventually the worker may perceive the test as of little value despite the impact on the patient, and the likelihood of finding an error, being the same. For example, in the molybdenum breakthrough test described in this section, a failed sample is rare because of the reliability of the equipment and previous controls that are implemented before the final check for molybdenum. However, the molybdenum check, due to the potentially significant impact to the patient, is a critical control. The potential for complacency, which is a normal and predicable human behaviour, should be factored into the workplace risk assessments and controls. Not only does the check itself need to be done effectively, but there should also be a process to regularly validate that it is being done effectively. Similar incidents were discussed in the 2016 ARIR annual report, which included a focus on nuclear medicine incidents. A number of incidents reported to ARIR note contributing factors such as ‘inattention’ or ‘complacency’.

If a process control is simple and rote, forming habits around these skill-based behaviours can be effective. Like wearing a car seatbelt, the worker will implement these controls without effort or even conscious thought. However, these controls can also be inadvertently forgotten, especially if the worker is momentarily distracted, and as such should be actively monitored to ensure they are always applied. In the case of seatbelts, modern cars provide extra protection (an audible alert if we forget to wear the seatbelt), for this predictable human error. Designing an error, or deviation, to be clearly evident—such as a red vial amongst blue vials—can be highly effective.

Where a control is complex and highly cognitive, then a different type of process is often required that relies on the worker’s knowledge and skill. A routine task that does not go as planned may suddenly change from a situation with routine, simple, skill-based controls to a complex situation requiring cognitive effort to avoid or minimise harm.

Rule-based procedures alone may not be effective in preventing these occurrences. For example, a worker will often try to pick up an accidentally dropped vial, even where this is not in line with procedures. This was also identified in incidents covered by previous ARIR annual reports.

It is important to ensure that workers continue to be aware of the hazards and risks of their work as well as the critical controls in place. That knowledge should extend to the management of any potential consequences if the hazard is realised. To remain effective these controls need to be monitored, and operational experience used to drive improvements where required.

Molybdenum (Mo-99) breakthrough

Technetium-99m (Tc-99m) is a very common nuclear medicine for diagnostic procedures. The short half-life of Tc-99m helps to minimise dose to patients, as it does not remain in the body for a long time after injection. However, this makes shipping Tc-99m long distances difficult. When shipping to Australia, a generator that contains a source of longer-lived molybdenum-99 (Mo-99) is shipped, from which the technetium is then extracted. Generators may be shipped to individual hospitals or to a radiopharmacy which prepares the products for local hospitals.

The Mo-99 should remain contained within the generator, while the Tc-99m is extracted a number of times (elutions). The Mo-99 can 'break through' after these successive elutions where the solution has been sitting in the generator, or can be caused by manufacturer defects. A test is required to be performed to detect this potential contamination. The final radiopharmaceutical, at the time of administration to the patient, must not contain more than 1 MBq of Mo-99 for every GBq of Tc-99m under the Australian national Safety Guide for Radiation Protection in Nuclear Medicine.

If the test is not performed prior to injection, patients may receive improper medical diagnoses and a significant radiation dose to the liver, bladder, or kidney from the unwanted Mo-99. As this testing is required to be performed by the users of the generator, it may not be performed by a hospital if it receives pre-prepared 'unit doses' from a radiopharmacy supplier.

Example case: molybdenum breakthrough

Two hospitals reported excess Mo-99 in a vial of Tc-99m pertechnetate. The vial had been supplied by a Melbourne radiopharmacy that uses Australian manufactured generators.

The contents of the vial were analysed by ARPANSA via high-purity germanium (HPGe) analysis. The results of the analysis, which agreed with the initial hospital evaluation, found the Mo-99 concentration at the time of administration was 5.45 MBq Mo-99 per GBq of Tc-99m. This is significantly above the limit, and should not have been dispatched to a hospital.

Learnings:
The manufacturer issued an alert highlighting the concerns that some customers may not be using the generator as per the 'directions for use'. Specifically, the completion of step 10 to ensure that the generator column is eluted of all the normal saline solution, which is required to ensure that the Mo-99 bound to the generator column does not come off the column. The alert also reminded users of the requirement that the eluate be measured for its Mo-99 content (breakthrough test) using gamma spectroscopy test or an equivalent validated method.

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, and a higher likelihood for contamination as a very small amount of liquid can potentially contaminate a large area.

If contamination is not detected, it could lead to exposure of workers including from ingestion or inhalation of radioactive material.

Example case: contamination event 1 (Mo-99)

A QC worker contaminated their gloves and hands with a high specific activity (7.5 MBq/µL) Molybdenum (Mo-99) QC sample.

The worker was performing routine operations of removing the cap from the sealed vial using a de-capping tool within a shielded fume cupboard. The vial became dislodged and was immediately recovered by the operator. However, in the process this led to contamination of the workers gloves. After removing the gloves, the operator found the skin under their gloves was also contaminated. The operator then washed their hands in accordance with the decontamination procedure.

The spill was cleaned soon after the event, which is standard practice for spills to reduce the risk of spreading contamination. However, this destroyed evidence that would have provided useful information in re-constructing the accident, such as the quantity of material spilled on the gloves.

A review of the procedures and work practices found a number of contributing factors including:

- *The radioactive content of the QC sample was greater than the minimum required to achieve the test result. There is a balance in ensuring the QC sample accurately reflects the batch and minimising the hazard to the operators. Following the incident a solution with reduced activity was shown not to degrade the quality of the test.*
- *The de-capper tool used was degraded and had not been regularly maintained.*
- *The analyst de-capping technique and glove changing process were less than optimal.*
- *Ergonomic design. The lead pot had a well deeper than the vial making it difficult to grasp the vial with the forceps. The use of steel forceps on a glass vial make it difficult to grip the vial unless it is held by the neck of the vial.*
- *The long-cuff gloves that were to be used as the base gloves, with standard gloves worn over them, were not used because of a lack of supply. Use of these gloves, rather than two pairs of standard gloves, may have reduced the risk of skin contamination during glove removal.*
- *The hazard of the solution had been underestimated by the organisation, and the associated risks, were not well known to operators or the organisation.*

The contamination led to a significant dose to the skin on the hands. The resultant skin dose was initially calculated to be greater than 850 mSv, which is above the statutory annual dose limit 500 mSv. Medical treatment and monitoring of the person continued for months after the event. Based on the appearance of tissue reactions on the analyst's hands the absorbed skin dose to the hands is estimated to have been in the range of 20 Gy. This was reported on the IAEA International Nuclear Event Scale (INES) as a level 3, serious incident.

Learnings: *At the time of this report a number of measures have been and are being put into place to reduce the risk of the same thing happening again. However, reviews are still in progress and further actions are anticipated to be taken. Initial actions include:*

- *using the minimum source activity for quality control purposes*
- *re-designing the apparatus and work space used*
- *creating visual guides (posters) on correct technique as part of improved training*
- *updating requirements on preserving the scene of the incident/accident*
- *conducting a review of risk assessment to consider the hazard of the source without the controls in place (inherent risk), and to ensure that workers are aware of the 'worst case' scenario*
- *promoting organisational learning, including past incidents and monitoring and recording deviation from approved processes. These should be fed into risk assessments and work place controls.*

Example case: contamination event 2 (Lu-177)

In preparation for Lutetium (Lu-177) therapies, a supplied dose of approximately 20 GBq of high specificactivity (40 MBq/µl) was split into three smaller doses.

The splitting of the supplied dose was carried out in a shielded fume hood. It was found later that the area in and around the fume hood was contaminated by Lu-177, and contamination was also found on the floor and other surfaces in the laboratory.

Later investigations concluded that the dose vials and gloves worn during the splitting of the dose became contaminated, which was spread to the equipment beside the fume hood and nearby surfaces. The contamination was able to be spread widely as the specific activities of the solutions involved were very high, which meant a small volume of material could contaminate a large area. Monitoring and the workflow for the movement of material and staff did not minimise the contamination.

Learnings:
As a result of this incident a number of controls were highlighted and strengthened where they were not found to be sufficiently effective. These included:

- *Workflow enhancements:*
  - *All work with Lu-177 compounds will take place inside the laboratory (removing the need to enter and exit the lab).*
  - *Measurements of activity are now carried out inside the lab close to the production hot cell to minimise movement of Lu-177 within the department. Once calibrated, a dose calibrator inside the hotcell will be used.*
  - *A new thin layer chromatography unit is to be used in QC room for quality control. This will help to avoid movement of Lu-177 samples outside the QC room.*
- *Improved waste handling:*
  - *Greater use of disposable surfaces will help ensure that any potential contamination of equipment or working surfaces is contained and easily removed.*
  - *A waste bin inside the production hot cell, beside the sharps container, is to be used for all waste including gloves, plastics tubes, vials and tips of pipettes.*
  - *Additional lead bin placed outside the hot cell, beside an existing bin. Both used for kits with residual activity and hot waste, to allow decay to less than 25 µSv/hr (unshielded) before it moves to the radiation store.*
- *PPE and monitoring improvements:*
  - *Wipe testing to be carried out after each run and the results reviewed by a Medical Physicist. The production person will check the outside of Lu-177 hot cell, benches and the floor inside the production room. A Medical Physicist will check the production & QC room at the end of each synthesis.*
  - *Gowning and de-gowning in the pass through space between QC room and production room. All staff must gown up before entering the production room. During each exit from the production room, feet and hands MUST be checked by handheld probe located in the pass through area.*
  - *Hand-foot monitor installed outside of Lu laboratory.*

Example case: contamination event 3 (F-18)

During a production run of a fluorine (F-18) labelled compound a worker was contaminated on gloved hands. The production was being conducted under supervision and was being performed in a hot cell.

It was noted by the workers that the first of two reactions that day did not behave according to other previously observed reactions. The first reaction was discarded into the in-cell disposal bin, and the reaction was performed a second time. During this second reaction a supervisor found the first discarded vial was still visible and had not dropped into the waste bin completely. To reduce shine, using tweezers, the supervisor reached into the cell and pushed the vial deeper into the waste bin. It was found after the event that the plastic bag inside in the shielded container was not correctly fitted preventing items from dropping freely into the bottom of the container. The contamination may have occurred when the supervisor reached into the hot cell.

Upon removing their arms from the hot cell the outer gloves were removed and placed into a waste bin. Routine checks indicated that the supervisor's gloves, lab coat and oversleeves were contaminated. The background radiation levels in the laboratories also appeared to be higher than normal, so two other occupants were advised to leave. No further contamination of clothes or personal effects was found. However, the laboratory and the adjacent laboratory revealed contamination and both were closed until the following day as a precaution.

It was considered that if the reaction vessel had been capped, or had the waste container allowed the spent reactor vessel to fall into the waste container correctly, then this event would not have happened. Capping each vessel is not standard practice, as this would lead to additional radiation dose to hands and risk possible contamination due to the recapping procedure.

Learnings:

Training procedures and records that relate to the use of volatile radioisotopes need to be reviewed. Specifically more granular training modules for in-cell handling of hazards and training records that reflect specific pitfalls with handling volatile unsealed radioisotope sources.

The work practices and hazard assessments for volatile compounds needs to be reviewed and considered separate from other compounds.

Radiotherapy

Radiotherapy doses are difficult to compare with diagnostic doses. A very large dose is delivered to a specific area for clinical benefit, while other areas receive smaller doses. In some instances this area might be misaligned or a dose delivered to the wrong site. 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).

Five incidents related to CT acquisition for therapy planning are included in the feature topic on page 5.

Radiotherapy incident statistics

Category	Number of reports	Doses
Planning CT	5	Ranging from 1–14 mSv. Average dose 6 mSv effective dose
Treatment site	5	Up to 10 Gy additional dose to the incorrect site
Treatment dose	4	Additional doses ranged from 2 to 12 Gy to the treatment volume.
Unknown pregnancy	1	37 mGy to the foetus
Total	**15**	

Incorrect treatment site

Misalignment or targeting the wrong tissue occurred in five incidents.

Example case: treatment site	
A patient underwent radiation therapy treatment which included 45 Gy in 25 fractions to the pelvis (Phase 1) and 10 Gy in 5 fractions to positive right external iliac node (Phase 2 – boost volume). The boost volume was incorrectly contoured for the left external node. *The radiation oncologist approved the treatment plan. The radiation therapist commenced treatment to boost the volume and incorrectly covered the left nodal volume in accordance with the planning data.* *The radiation therapist did not query why the electronic request for treatment identified the right side for the Phase 2 boost where the treatment plan boosts a left sided volume, or that the prescription site naming does not specify laterality.* *(excess dose to left side 10 Gy)*	*A patient received superficial radiation treatment to the wrong scar on their forehead.* *The description of the area to be treated was too vague and the radiation oncologist marked the wrong scar to be treated.* *Changes are being made to simulation documentation which includes partner/carer identification of treatment site if applicable.* *(5 Gy to incorrect area, additional 10% to area overlapping with treatment area)*
Learnings: • *Provide concise notes on the area of excision, which may include a diagram/drawing of the area to be treated.* • *Partner/carer identification of treatment site if applicable, including the provision of a mirror for the patient to identify the site if appropriate.*	

Incorrect dose

Targeting the wrong tissue and errors in quality control occurred in another four incidents.

Example case: incorrect dose

A patient was given a prescription for palliative therapy for lung cancer of 30 Gy in 10 fractions. However, 30 Gy in 5 fractions was incorrectly entered into the treatment planning system, effectivity doubling the dose per fraction.

Standard quality assurance procedures were followed in the subsequent planning process. Despite independent checks, the incorrect fractionation was not detected. During treatment the Radiation Therapists were not aware that that the patient was receiving double the prescribed dose per fraction and the patient was booked for the intended 10 fractions.

A quality assurance program of new linear accelerators was being undertaken which included the use of thermo luminescent dosimeters (TLD) placed on the patient to verify the radiation output from the linear accelerator. This TLD monitoring for palliative patients is not a routine procedure. The results from the TLD were reviewed after the patient had attended 7 fractions.

When the patient attended hospital for what would have been his 8th fraction, the patient's oncologist explained the dosimetry error and subsequent risks to the patient from the radiation he had received, and monitored for any side effects from his treatment.

(The patient had received an excess of 12 Gy for a total of 42 Gy to the target volume)

Learnings:

Care was stressed to radiation therapists entering planning information. This incident highlights how a small error can propagate and may not be picked up in quality checks.

Pregnancy

Under the *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation* (RPS 14) biochemical tests are required within 24 hours of administration of therapeutic nuclear medicine administration. Other procedures require reasonable steps to be undertaken for any procedure which is likely to result in a radiation dose of more than 1 mSv to an embryo or foetus.

The pregnancy status of therapeutic patients is typically established prior to commencing the procedure. However, a course of treatments can be delivered over an extended time frame.

Example case: pregnancy (therapy)

Patient discovered she was pregnant during course of radiotherapy. Prescription was for 50 Gy in 25 fractions, of which 23 fractions were delivered. Treatment was discontinued once the doctor was aware of pregnancy and had discussion with patient.

(The patient had received 46 Gy to right breast as part of treatment, foetal dose 37 mGy in total)

Learnings:

Develop a protocol or checklist for checking the pregnancy status of women of child-bearing age over the course of the treatment.

Other incidents

Lost, stolen or unauthorised disposal of sources

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

Example case: lost source

A mobile fluoroscopic unit suffered failure of the camera component, and due to age and parts being unavailable, was deemed beyond repair. The unit (still being able to produce x-rays) was removed from the department and placed in storage awaiting appropriate destruction and disposal. It is believed the unit was moved there around June 2016. Numerous attempts have since been made (~May–June 2017) to locate the unit for destruction once an engineer was available, but staff are no longer able to locate it.

***Learnings**:*

This incident highlights the importance of maintaining effective control of inventory and unused sources.

Example case: stolen source

A portable X-ray fluorescence unit was stolen during early hours of the morning. An alarm code and key were used to gain entry to the building and secured storage area. No exposure, harm or damage has been recorded.

All previously used alarm codes have been cancelled and new codes issued to all current employees. Existing keys and locks to the building/radiation storage area are also being replaced. Four new CCTV cameras are being installed overlooking storage areas and external entrances.

***Learnings**:*

This incident highlights the possibility of 'insider threat' and the value of security measures such as CCTV surveillance.

Example case: unplanned discharge

It was discovered that the pump to an empty waste tank at a hospital had been left on but the manual valve was closed. Investigations suggest that a staff member entered the waste tank room and accidentally left the pump on. Approximately 6.2 GBq of Iodine-131 (I-131) was released into the sewerage at a concentration of 0.0075 MBq/L. Waste from four other patients was essentially pumped straight into the sewerage as this pump was left on resulting in an additional 11 GBq of I-131 at a concentration of at most 0.014 MBq/L being released into the sewerage. No significant doses to any persons were estimated to have been received as a result of this incident.

***Learnings**:*

Physicists have been instructed to double-check all the switches before leaving the waste tank room. Relevant staff who have access to the waste tank room should be reminded to contact a physicist before operating any of the switches. In future whenever physicists are informed of maintenance that needs to be carried out in the waste tank room, they shall check the switches are in their correct positions once the maintenance has been completed.

Non-ionising radiation

Only incidents which 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 case: laser
A laser operator was concerned that her health has been affected by exposure to laser-generated plumes. Inadequate ventilation was reported and the owner/employer did not provide respiratory protection of an appropriate filtration level. Operators were unaware of the need to wear masks, and so were choosing not wear any. The operator claims to have suffered a range of health effects and submitted a WorkCover claim for eczema.
***Learnings**:* *This incident highlights the need for employers to provide appropriate respiratory protection, and install adequate ventilation.*

Borehole logging

Two borehole sources became stuck prior to being recovered.

Example case: borehole logging
A borehole logging source was dropped down a drill hole during the logging of a gas drainage hole. The Ceasium-137 source was dropped down the hole after the cable was severed approximated 48 meters above the source. There was a rig available nearby and recovery operations where conducted successfully.
A logging tool had become stuck down a well at an offshore rig, prior to being recovered. The logging tool contained a dual source assembly Caesium-137 and Americium-241/Beryllium logging source at an estimated depth of 4248 meters. Recovery attempts were successful.

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 which are installed at an industrial site. As these sources often contain radioactive material, there is no way to turn them off if something goes wrong, such as the source becoming stuck.

Example case: stuck source
A source became stuck inside the delivery tube fitted to a Delta 990 camera. At the time, there was a 3300 GBq (89 Curies) of iridium (Ir-192) source located in the device. *(Effective dose: 1.96 mSv during the recovery process)*
***Learnings**:* *Management planned new ways to place pipework in the exposure bay to reduce chance of recurrence.*

Non-medical laboratories, irradiators and accelerators

Irradiators, accelerators and similar industrial equipment that uses very high dose rates is designed to prevent operators being present while the source is in operation. This is achieved through diverse layers of protection, such as the use of shielding, interlocks, keys and time-delay switches. For nuclear facilities this is commonly referred to as defence in depth. It is important that where engineering controls are used to protect workers, that these controls must be understood and maintained appropriately. This includes an effective monitoring and testing of the controls to ensure that they operate as planned. This can help to prevent a common mode failure, which can remove several layers of the defence.

Example case: irradiator shutter failure

When undergoing a routine irradiation experiment at an irradiator a worker entered the room with the shutter in the open position. The source shutter failure was detected through higher radiation levels on a wall-mounted radiation monitor and a handheld survey meter.

The failure of the shutter to close, or the higher radiation levels detected, should have prevented access to the area. However due to multiple failures including the physical failure of the shutter mechanism, in a manner which made the sensors for the interlock ineffective, the operator was not prevented from accessing the room. The indicators lights also showed normal operations.

The incident was investigated and a number of contributing causes were found including:

- *the interlock was incorrectly configured to only prevent access at a level of radiation significantly above the maximum level that could be present in the room, and was therefore effectively disabled*
- *an alarm was sounding which should have turned off prior to the operator entering the room. However, this alarm sounds whenever the source is in operation, which led the operator not to notice the alarm when entering the room*
- *maintenance requirements of the aged equipment were not well understood and warning signs of mechanical failure were not identified as serious and not actioned*
- *changes to the routine checks on the interlock systems did not undergo a risk assessment, such as considering potential incidents, which contributed to the conditions leading up to the event not being recognised*

Doses to the staff were low during the incident and recovery operations. However, doses at the point of exposure for irradiators can be very high. As a result of this incident the facility was shutdown ahead of planned decommissioning.

(Effective dose during incident and recovery: <0.1 mSv)

Learnings:

- *alarms should not sound under routine conditions as this can desensitise operators to alarms*
- *the configuration, maintenance and testing of safety systems (e.g. interlocks) must be well understood to ensure they are effective*
- *all changes to the functional tests of the safety system should undergo risk assessment and evaluation prior to being implemented.*