

Australian Government Australian Radiation Protection and Nuclear Safety Agency



Australian Radiation Incident Register

Annual Report

1 January 2016 to 31 December 2016



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Contents

Summary1
Introduction2
Purpose and scope 2
Source of the incident reports 2
New developments
Overall statistics4
Number of incidents reported 4
Estimated doses received as a result of incidents 4
Types of incidents reported5
Feature topic: nuclear medicine6
Causes of incidents
Primary cause
Contributing factors
Summary of controls and preventative measures implemented15
Summary of recommendations made in reports15
Summary of common incidents by cause16
Human error
Equipment error/malfunction16
Summary of incidents by category17
Diagnostic radiology: 279 incidents
Nuclear medicine: 73 incidents
Radiotherapy: 16 incidents
Other: 22 incidents

Summary

Radiation is routinely used across Australia by more than 40,000 licensed users, performing 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 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 2016 increased by about 12% from the previous year. ARPANSA has actively promoted the benefits of reporting all incidents including low consequence and near-miss events and in 2016 introduced a new web portal for reporting. Recent increases in reporting levels are considered to be due to an improvement in reporting practices rather than an increase in incidents. It is likely that further increases in report numbers are possible as reporting practice continues to improve.

An incident will typically have one primary cause, such as human error, which is the proximal cause of the event. However, the incident will typically have a number of contributing factors, for example, time pressures and not following procedures. Often if one of these contributing factors had not existed the incident would not have occurred.

Human error was the primary cause identified in the majority of reported incidents in 2016, which is consistent with previous years. Reinforcement of correct processes or practices and training and education were the most common mitigating and preventative measures identified.

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 other organisational or technological controls (e.g. processes, procedures, physical or engineering controls). These controls may not be effective in the long term as they often rely on the awareness of individuals rather than addressing underlying contributing factors such as procedures and workflows or technological solutions. While reliance on administrative controls is to be expected for many of the uses of radiation, the information in incident reports suggests that many of the contributing factors could be identified prior to the incident. In the majority of cases, similar incidents have been reported previously to the ARIR.

Improvements to the ARIR have made it easier to identify and share recommendations and learnings. The most common recommendations made on the incident reports related to procedures which should have been followed, such as performing patient/procedure identification. A number of recommendations related to technology such as use of alerts on electronic referral systems and flagging when two patients with a similar name are booked on the same day. Other recommendations related to procedural improvements such as clear labelling, and communication processes. Learnings from individual incidents are highlighted through the report along with a summary of the incident.

Introduction

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 <u>Radiation Protection Series No.6</u> (RPS6), *National Directory for Radiation Protection (NDRP)* specifies the types of incidents that must be reported to ARPANSA for compilation in the ARIR. These reporting arrangements are agreed by the ARPANSA Radiation Health Committee (RHC) which includes representatives from radiation regulators of each Australian jurisdiction. For more information on the RHC and ARIR can be found on the <u>ARPANSA</u> website.

This report was approved for publication in December 2017, 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 2016.

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 effort 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 state and territory 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, jurisdictions which do not regulate some types of non-ionising radiation and so do not receive incidents 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 which led to the incident, as well as recommendations or preventative actions implemented or 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 2016. Learnings highlighted are taken from the incident report, typically these are identified by the reporter or in some instances by the submitting regulator. Similarly doses were estimated by the reporter based on calculated individual dose, or in some cases on typical doses for a procedure.

New developments

ARPANSA has implemented a new web enabled system to aid the collection of incident reports from state and territory regulators. This has resulted in a number of improvements including:

- A newly refined set of questions, which help to share learnings as well as identify causes and contributing factors.
- A web portal submission system, which is easier to complete than the previous form.
- Workflows to assist ARPANSA in the collection and review of incidents. This includes the ability to flag an incident as having potentially significant learnings and a priority for review.
- Enhanced analytics and grouping, which aids analysis.

Improvements have already resulted in an improved ability to categorise incidents and identify learnings. This enhances ARPANSA's ability to share these learnings including through this report.

The new system was rolled out with participation of state and territory regulators. It is recognised that it will take time to adjust to the changes. For example, some state regulators have updated their incident reporting forms such as the ACT and SA who have developed their own online forms.

We expect the system to grow and improve based on user feedback and in response to analysis of data recorded in the system.

Australian Governme	nt	Test Incident 3	
Australian Radiation Pr	rotection and Nuclear Safety Agency	Who is Submitting the Report?	
A Regulator incidents ARPANSA Website		Jurisdiction Reference for Incident* Date Submitted	Test Incident 3
Incident Details		Submitting on Behalf of " Jurisdiction " When and Where did the Incident happen?	Igg Test Contact Commonwealth
Location 🖌 Incident 🖌 Cause Individu	ats Resolution and Recommendations Submit	Date of Incident * Location of Incident *	09/12/2016 Test Location
Why did it happen? What were the ca	uses of the incident?	Was the source or activity under regulatory - *	No
Direct Cause *		What happened?	
Human Error	•	Incident Category (Primary) *	Medical - Diagnostic Radiology (CT)
		Incident Category (Secondary)	Higher dose due to incorrect settings/procedures
Contributing Cause(s) *		Incident Category - Other	
Procedure not Followed Properly Quality Control Checking Failure Fror in Order or Order Interpreted Wrongly	Inadequate Supervision/ Leadership Procedural Deficiency Limitation of IT or Other Equipment	Occupation of Workers * Occupation of Other Workers	Electrician
Duplicate Order	Workload Pressure	Incident Description *	Test Description
Similar Patient Profile	E Fatigue		

The ARIR Web Portal for Regulators

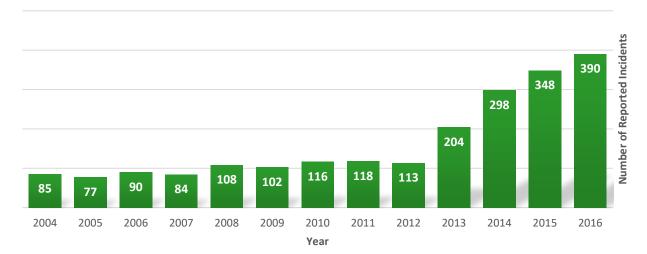
This web based form guides regulators through the options with dropdown menus and filters based on incident type etc.

Overall statistics

Number of incidents reported

The number of incidents reported continues to increase. In 2016 there were 390 incidents submitted which represents an increase of 12% compared to 2014. ARPANSA has been raising awareness and promoting the profile of the ARIR since 2012. This includes the upgraded database and web portal in 2016, and the reporting criteria outlined in the NDRP which were updated in 2012.



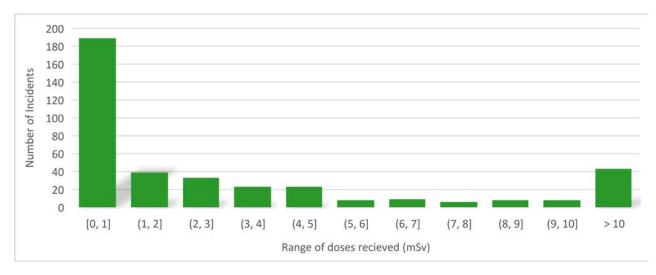


Estimated doses received as a result of incidents

Table 1 Dose statistics for incidents, not including beam therapy. Note percentages rounded.

Effective Dose	Number of Incidents	%
<1 mSv	183	47%
1 mSv-10 mSv	159	41%
10 mSv-100 mSv	47	12%
>100 mSv	1	<1%





Types of incidents reported

Table 2 provides 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 14 million diagnostic procedures including approximately three million CT scans were carried out in 2016 according to Medicare Benefits Schedule (MBS)¹ information.

	20	16	20	15	20	14	20	13	20	12
Incident Category	No.	%	No.	%	No.	%	No.	%	No.	%
Medical - Diagnostic Radiology (All)	279	72%	236	70%	178	64%	114	62%	66	62%
+ Diagnostic Radiology (CT)	(143)	(37%)	(135)	(40%)	-		-		-	
+ Diagnostic Radiology (Plain Film/RX)	(110)	(28%)	(91)	(27%)	-		-		-	
+ Diagnostic Radiology (Interventional)	(22)	(6%)	(9)	(3%)	-		-		-	
+ Diagnostic Radiology (Dental)	(4)	(1%)	(1)	(0%)	(3)	(1%)	(2)	(1%)	(1)	(1%)
Medical - Nuclear Medicine	73	19%	84	25%	74	26%	52	28%	28	26%
Medical - Radiotherapy	16	4%	8	2%	14	5%	9	5%	6	6%
Medical - Non-Ionising Radiation (including medical laser)	1	<1%	3	1%	1	<1%	1	1%	0	
Non-medical/Industrial - Sources Found/Lost/Stolen	15	4%	1	<1%	2	1%	2	1%	2	2%
Non-medical/Industrial - Imaging (inc Industrial Radiography, XRF, XRD, and security)	3	1%	1	<1%	6	2%	1	1%	1	1%
Non-medical/Industrial - Contamination	1	<1%	1	<1%	4	1%	3	2%	2	2%
Non-medical/Industrial - Irradiator/Accelerator	1	<1%	1	<1%	0		0		0	
Non-medical/Industrial - Transport of radiation material	1	<1%	1	<1%	1	<1%	3	2%	1	1%
Other	0		12	4%	18	6%	19	10%	7	7%
TOTALS	39	90	33	36	28	30	18	85	10	06

Table 2:	Overall ARIR statistics for 2016 com	pared with previous four	vears. Note percentages rounded.

¹ For more information on Medicare Benefits Schedule statistics visit <u>http://medicarestatistics.humanservices.gov.au/</u>



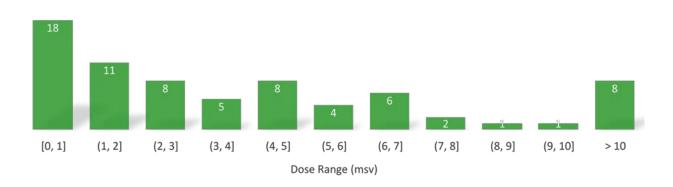
Nuclear medicine imaging uses small amounts of radioactive material in the form of radiopharmaceuticals. These are administered to patients, in most cases via an intravenous injection to diagnose a range of diseases, including many types of cancers, heart disease and renal function. The most common radioactive material used is technetium 99m, which is typically generated from molybdenum produced at the ANSTO OPAL reactor in Sydney. Common diagnostic imaging techniques include planar and Single Photon Emission Computed Tomography (SPECT). Positron Emission Tomography (PET) radiopharmaceuticals such as fluorine-18 in fluorodeoxyglucose(FDG) are generally produced in a cyclotron and have a much higher energy. Therapeutic uses of radiopharmaceuticals are used for the treatment of certain cancers. An example of this is iodine-131 for the management of thyroid conditions.

Nuclear medicine is used widely across Australia with more than 600,000 diagnostic nuclear medicine procedures and 3,000 therapeutic procedures carried out in 2016 according to the MBS. Findings from the analysis of 73 nuclear medicine incidents reported to the ARIR in 2016 are presented in Table 3 and Figure 3 below.

Category	Number of reports	Average dose per incident	Range of doses per incident
Spills, leaks, extravasation	15	3 mSv	0-9 mSv
Incorrect radiopharmaceutical	16	4 mSv	1-12 mSv
Incorrect dose	8	4 mSv	1-6 mSv
Scanning equipment malfunction	9	8 mSv	1-35 mSv
Radiotherapy (radionuclide)	1	-	-
Other	24	5 mSv	0-15 mSv
Total	73	4 mSv	0-35 mSv

Table 3: Nuclear medicine incident statistics

Figure 3 – Distribution of diagnostic nuclear medicine incident doses



Spills, leaks, extravasation (15)

Leakages and spills (7)

Where leaks and spills are detected they are typically cleaned up without significant exposure to staff (average 0.3 mSv). However, these incidents have the potential for higher doses if the contamination is not quickly detected and actioned.

A number of incidents involved leakages during administration. These incidents highlight the need to ensure that connections are secure and flushed with saline as appropriate.

Example Cases		
A patient was being administered with ¹⁸ F-FDG via a cannula when the extension tubing and the three-way tap became disconnected. A volume of product containing an activity of 90 MBq was spilled on the bed, floor, and the technologist's shoes. The report identified that training of the nurse who cannulated the patient was a factor in this incident.	During a stress test using ^{99m} Tc-MIBI, the syringe attached to a three-way tap leaked approximately half of the radiopharmaceutical (400 MBq) onto the treadmill and floor. The report noted that the three-way tap was found to be incompletely tightened to the extension tubing.	During the injection for an angiographic procedure a small amount of ¹³¹ I-Lipiodol contaminated the floor. The fact that Lipiodol can dissolve some plastics, such as polystyrene, was noted in the report as a potential contributing factor. In future, absorbent material to catch any leaking radioactive material will be implemented for these procedures at this practice. This will aid in cleanup and prevent the spread of contamination. The use of Luerlock systems is recommended by manufacturers due to the higher backpressure experienced during the injection in these procedures.

Learnings: One institution implemented an additional check by the technologist to physically inspect all components prepared by the nurse immediately prior to administration.

Spills or leakages can also occur from the syringe prior to injection such as during transport.

Example Case

¹³¹I-Lipiodol leaked from a syringe prior to use. The syringe had a capped needle which is thought to have leaked when the lid of the shield pushed on the plunger. In this instance 280 MBq leaked, of which 50-60 MBq spilt onto the floor. The room was not in use and clean-up was performed resulting in minimal exposure.

Learnings: As a result of the incident this type of syringe will no longer be transported with a needle cap; instead a plug infusion combination screw cap will be used.

Spills can also occur during the preparation and Quality Control (QC) phase. This is particularly important for higher activity nuclear medicine which can require substantial shielding. This shielding can restrict movement and lead to ergonomically unfavourable setups. It is important to consider the human factors in the setup of these workstations.

Example Case

A product vial containing ¹⁸F-FDG was dropped during dispensing. When discharging a product vial containing ¹⁸F-FDG from the dispensing hot cell into a tungsten transport pot the dose rate indicator on the operator's Electronic Personal Dosimeter (EPD) suggested that the vial had not fully dropped into the tungsten pot and was only partially shielded. After attempting to rectify the problem, the operator assumed the vial was within the tungsten pot and opened the drawer. The vial dislodged from the top of the pot and fell onto the floor under the dispensing hot cell. This resulted in a small crack in the bottom rim on the vial. Most of the product was retained in the vial however a small amount of contamination was found on the floor underneath the dispensing hot cell.

Learnings: As a result of this incident bubble wrap drapes lined with absorbent material have been fitted so that in the unlikely event of a vial being dropped the risk of damage to the vial is low. To improve visibility, the battery operated light was replaced with an LED light which is automatically turned on when using the dispensing hot cell.

Extravasation (8)

In eight incidents extravasation of the radiopharmaceutical occurred. This is the leakage of intravenously (IV) infused liquid into the extravascular tissue around the infusion site. Calculated effective dose for these incidents ranged from 1.4 - 7.7 mSv (average 5 mSv). In addition to the procedure not being of diagnostic value, extravasation can result in higher skin doses as the radiopharmaceutical concentrates near the skin. In some instances there were signs that the cannula had not been correctly sited, junior staff with insufficient training had performed the cannulations, or the saline flush procedure was not correctly followed. In some cases a cause was not determined and the reports note that cannulation was performed by senior staff with no visible indication that the dose was extravasating during administration.

Example Case

Extravasation occurred during the second part of a patient's Myocardial Perfusion Study. When the IV catheter in the patient's arm was checked the patient said it stung. The Nuclear Medicine Technologist (NMT) adjusted the catheter and it seemed to be working; the patient said they felt some pressure but when asked about pain said "not really". After the ^{99m}Tc-Sestamibi (1040 MBq) was injected followed by 5 ml of saline flush the NMT noticed swelling under the skin. The patient was scanned under the gamma camera and all the activity was localised in the patient's arm.

Learnings: It was determined that a new model of cannula made it more difficult to determine if it had dislodged, as such the decision was made to revert to the previous model of IV Catheter which has lower pressure.

Wrong radiopharmaceutical injected (16)

In some instances the required radiopharmaceutical was not clear on the request form. If the wrong radiopharmaceutical is used the radioactive material may be delivered to the wrong region of the body and the procedure may not be of clinical value. If there is any doubt, the NMT should always confirm the required procedure. However where one procedure is significantly more common than another complacency can occur.

Example Cases	
An incorrect request form was used by the referring physician; the form had been altered to include a handwritten change which was not picked up by staff. ¹⁸ F-FDG was administered instead of ⁶⁸ Ga-Ocreotate. The scan was of no clinical benefit. The estimated additional dose to the patient was 10 mSv.	Changes in the referral form did not require the same information as the previous version. While the registrar added a sticker indicating the appropriate scan onto the printed referral form, this was not picked up. ¹⁸ F-FDG was administered instead of ⁶⁸ Ga-Ocreotate. The scan was of no clinical benefit. The estimated additional dose to the patient was 12 mSv.

Learning: The referral form should include sufficient identifiers to indicate the type of request and not require annotation or additional modification.

Labelling is an important control measure in nuclear medicine and was a contributing factor in a number of nuclear medicine incidents. Labelling can be complicated by the fact that shielding used to protect the operator can often hide labels which would otherwise identify the product, while labelling on the outside of the shielding can be mismatched to the contents.

Example Case

In one instance two different renal scans were scheduled for the same time. The doses were dispensed by the lab and placed in shielded syringes on trays with the printed dose slip and an absorbent tray liner. The tray liners have the scheduled time of injection, the patient name and the procedure written on them. The needle cap also had a printed sticker with the isotope and activity. In this instance the tray was (incorrectly) labelled with the patient's name and radiopharmaceutical DSMA (dimercaptosuccinic acid). The dose slip was labelled 'renal' which matched the type of procedure to be performed. However, when commencing the procedure the NMT read the label on the needle, which correctly identified the pharmaceutical as MAG3 (mercaptoacetyltriglycine), and halted the injection. This partial injection resulted in an additional 1.4 mSv. On closer examination the dose slip was also labelled with a different patient's name. This highlights the importance of clear labelling and QC.

Learning: The label 'renal' could describe a number of radiopharmaceuticals and a more specific label such as DSMA should be used.

Radiopharmaceuticals may be prepared onsite using a kit or supplied from a radiopharmacy which is offsite. While there are a number of checks in place to ensure the correct dosage and pharmaceutical type is supplied, it can be difficult to detect supplier errors prior to injection.

Example Case

^{99m}Tc-Disofenin was incorrectly supplied labelled as ^{99m}Tc-MAG3. This was only noticed after uptake was observed. The hospital contacted the supplier who confirmed this was the likely issue. The patient received an additional 0.7 mSv and the scan had to be repeated.

Radiopharmaceutical dose larger than prescribed (8)

Quality Control (QC) checks are an important part of patient safety. There are typically a number of steps in place to ensure that a single error does not result in additional dose to patients. However, incidents highlight situations where the information in documentation was not reviewed which may have prevented an incident.

Example Cases	
A patient received a higher radiopharmaceutical dose than required due to incorrect time (set at 1 hour post injection) entered into computer system for dose draw up and calibration. The additional activity increased the patient's effective dose from 7.3 mSv to 11.5 mSv, an increase of 4.2 mSv or 56%. This error was not picked up during the checking procedures and the error was only noted after the injection had started.	A patient who was part of a research study was to receive 185 MBq of ¹⁸ F-FDG A junior medical radiation scientist administered 500 MBq as they made an error with the body mass index calculator in the scheduling database and did not read the trial information. This was not picked up in subsequent checks and resulted in an additional 6 mSv patient dose.
One dose of nuclear medicine was calibrated on the wrong isotope setting. The accompanying dose slip indicated the setting used however this was not picked up in subsequent checks. This resulted in the patient receiving an effective dose 4.2 mSv higher than required.	A junior NMT mistakenly calculated the required dose based on 2 MBq/kg instead of 1.5 MBq/kg. This resulted in an additional 5 mSv of dose to the patient.
Learning: This highlights a potential tendency for complacency in QC checking particularly where errors are comparatively rare.	Learning: Adequate training and supervision is especially important for junior staff.

A large fraction of QC tasks are frequently performed with a low rate of error. This includes reconstitution and binding errors or chemical impurities. The difficulty of dealing with low likelihood high consequence risks is far reaching, from everyday situations like wearing seatbelts to large scale complex operations like offshore oilrigs. When a task is repeated frequently without an issue, complacency can easily set in. When we expect a favourable outcome we can lose awareness of the true risk associated with a task or the importance of controls that are rarely challenged.

Example Case

Reconstitution of ^{99m}Tc-MAG3 was not picked up in the QC. The cause was thought to be that when the counting tubes were sealed the two elutes were the mixed-up, thorough the incorrect lids labelled '1' and '2'. The sample of 1% purity was incorrectly interpreted as 99% purity. This incident resulted in an additional dose of approximately 1.6 mSv to the patient. Improvements in labelling and workflow were implemented.

Learning: The report noted that a contributing factor may be that failure of MAG3 reconstitution is quite rare. NMTs performing the procedure are therefore generally expecting a pass result and may be less alert to the possibility of failure.

Scanning Equipment Failure (9)

Four incidents involved failure of the CT scanner partway through acquisition. One incident involved CT tube failure. In two incidents the image could not be retrieved after scanning. In one incident a gamma camera failure resulted in the administered activity being of no clinical benefit.

The average additional dose to patients was 8 mSv. While in some cases there was a repeated failure of the same equipment, there were no trends in model or failure type which might indicate systemic failures.

Radiotherapy involving nuclear medicine (1)

Radiotherapy using nuclear medicine involves targeting an organ or site which will be subjected to a large amount of radiation. While this is typically hundreds of times that of a diagnostic procedure, it is targeted at tissue to be destroyed. As such it is generally not appropriate to compare the doses received by healthy tissue during diagnostic procedures with that received by unhealthy tissue during therapy. Due to the high doses used it is very important to ensure that the correct dose is delivered to the correct patient. In one instance this did not occur.

Example Case

A labelling issue resulted in a mix-up of treatments for two patients aged 55 and 69 with mid-gut metastatic NeuroEndocrine Tumour (NET) and Small Cell Lung Cancer (SCLC). Both patients were admitted to receive Peptide Receptor Radionuclide Therapy (PRRT) as a day procedure using a combination of ¹⁷⁷Lu-Octreotate and ⁹⁰Y-Octreotate.

Due to a production delay doses were delivered to the ward in a non-routine fashion. On opening the transportation box the technologist found that a removable label on one syringe case had become unstuck (during transportation) and attached itself to the adjacent syringe case. Rather than returning to the lab to re-measure the sample the technologist made a judgement on which label had become unstuck.

The result was that the labels were swapped and as a consequence Patient A received a dose intended for Patient B and visa-versa. Routine post-therapy imaging revealed Patient A had received a dose of ⁹⁰Y-Octreotate only rather than the combination treatment.

Learning: An immediate action taken was to use a smaller patient label attached onto the syringe. This label needs to be small enough to fit inside the dose shield and permit viewing of the volume scale on the bore of the syringe. Additionally the practice will introduce the use of labels that cannot be accidentally removed.

Other (23)

Injected with radiopharmaceutical without benefit (12):

Two patients self-discharged and one was inadvertently discharged after being injected but before the scan was performed. Four patients were not scanned due to medical complications unrelated to the nuclear medicine. Three procedures were carried out incorrectly due to errors in the referral, order or transcription. In two cases the procedure was not of clinical benefit due to an injection error.

The average dose for these incidents was 5 mSv. For more information on diagnostic procedures involving Unnecessary scans see page 17.

Incorrect patient or scanning procedure (5)

Three incidents involved the incorrect scanning procedure being selected or a positioning error on the CT. Two incidents involved incorrect patients.

The average dose for these incidents was 4 mSv. For more information on diagnostic procedures patient miss-match errors see 'Wrong patient/region' on page 18.

Not otherwise classified (5)

A Co-57 marker was lost. One incidents involved a staff member accidently entering a SPECT/CT room during warmup, and one patient was scanned who was later found to be pregnant.

One patient had a gates blood pool study, and the injected radiopharmaceutical did not sufficiently bind to the red blood cells. The patient was re-scanned with a different radiopharmaceutical.

In one incident contrast in the cannula tubing bonded with the radiopharmaceutical and so did not enter the patient. As a result the CT scan had to be repeated.

In a glomerular filtration rate (GFR) test the administration of the radiotracer was performed through the same line as the blood sample was taken. As a result some of the tracer remained in the line and the procedure was non diagnostic.

Causes of incidents

Primary cause

For all incidents reported in 2016, human error was identified as the primary cause in 274 (71%). This is consistent with previous years.

Figure 4 –Incidents by primary cause

	12%		6%	,
Human Error (71%)	5%	4%	,)	2%
 Human Error (71%) Equipment Malfunction Unclear/ Unknown (6%) Patient Factors Outside Medical Procedure Complicated\Complications (4%) Equipment Deficiency (4%) 	e of Operator Contr	ol (5%)		

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 elements which lead to human error see the <u>ARPANSA Holistic Safety Guide</u>.

Equipment malfunction

Malfunctions include software and hardware failures. This can range from 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.

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, procedure takes longer than expected. This is reportable as an incident.

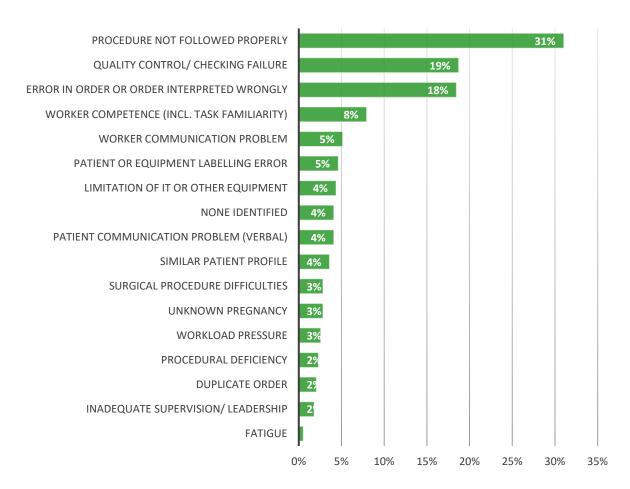
Contributing factors

An incident will often have a number of contributing factors. However, these factors are not always identified in the report. In some instances such as medical complications during a procedure, or equipment failure, these factors may not be readily apparent. In 4% of incidents no information on contributing factors was provided; in other instances the information provided did not allow for contributing factors to be analysed. For example, the report stated the actions which should have been taken (e.g. limiting field size) rather then why actions were not taken.

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 31% of incidents. The next biggest factors were errors in quality control and issues related to orders or referrals.

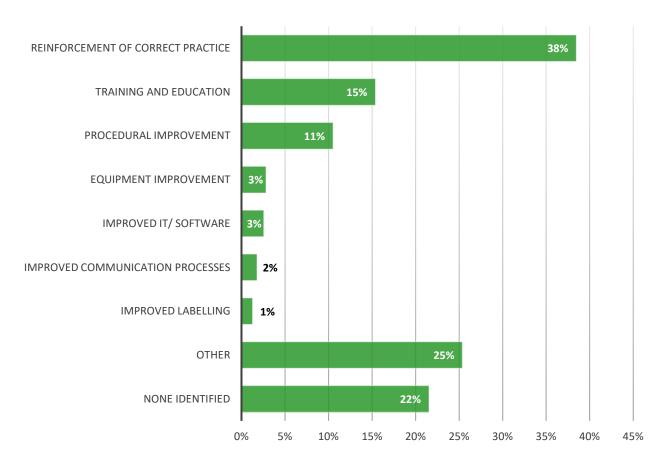
Figure 5 – Contributing factors identified in 2016 incidents



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 almost 78% of reports. No actions were identified in cases where equipment faults could not be reproduced, 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 2016 such actions were taken in 38% of the incidents, which is consistent with previous years (42%, 33%, 41%).





Summary of recommendations made in reports

The most common recommendations made in incident reports were:

- Clear and effective procedures should be followed by staff.
- Quality checks such as 3C (Correct Patient, Correct Site, Correct Procedure/Protocol) and 'time out' should be followed and their importance emphasised.
- Use alerts on electronic systems such as flagging when two patients with a similar name have booking on the same day or where special requirements exist (e.g. stress test only).
- Labelling and communication processes should be clear.

Summary of common incidents by cause

Human error

More than 70% of all incidents reported human error as the primary cause.

The most common contributing factors were individuals not following procedures (43%), errors in orders or in the interpretation of order instructions (26%) and QC failures (25%). A detailed assessment of the underlying contributing factors was rarely reported.

Where human error was the primary cause, preventative measures included reinforcement or reminder of correct procedure/good practice (51%), further training or education (20%), procedural changes (12%) and equipment changes (4%). No preventative measures were identified from 8% of the reports submitted. Additionally, a number of reports identified preventative measures which indicated that no changes had occurred, such as "more thorough attention to detail by requesting doctor".

Human factors improvements were implemented after some incidents. Many of these were relatively simple to implement. Examples include improved labelling and storage of sources and improvements in communications protocols and procedures.

Equipment error/malfunction

Equipment failure includes situations such as software failure, for example on a CT scanner, where the procedure had to be repeated thus increasing the dose to the patient.

In 47 incidents equipment failure was identified as the primary cause. While a number of repeat failures and software issues were identified and reported to manufacturers, 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.

Summary of incidents by category

Diagnostic radiology: 279 incidents

Diagnostic radiology incidents reported in 2016 included:

- Unnecessary scans (26%) including repeat scans and duplicate orders
- Imaging the wrong region (45%), for example imaging the left leg instead of the right leg, or the wrong settings/procedure being selected (6%)
- Imaging the wrong patient (20%)
- Equipment failure (13%)
- Imaging where the patient was later found to be pregnant (6%)

Туре	Number of incidents reported	Effective dose per incident (mSv) Note: does not include skin or critical organ doses. Average Range	
Computed Tomography (CT)	144	7.5	0 - 45
General X-ray	109	0.4	0 - 3
Fluoroscopic/Interventional	22	0.8	0 - 9
Dental	4	0.02	0 - 0.02

Table 4: Overall statistics for diagnostic radiology incidents

Unnecessary scans

Order errors including duplicate orders were responsible for 35% of unnecessary scans. Other incidents included selecting the wrong procedure, patient positioning errors, deleted images, and processing a follow up examination too early.

Example case:

An unnecessary duplicate cervical spine X-ray was carried out on patient. Initially an e-order was received and the radiographer arranged time for the patient to arrive at the imaging department. A second eorder was placed by a different clinician for the same exam on the same patient. The second request was actioned before the first request. When the patient returned to the imaging department the second time identification checks failed to identify the error and the patient did not advise that they had already been x-rayed earlier in the day. With the (relatively new) electronic ordering system it had been expected that the doctor authorising the exam would receive a warning that it may be a duplicate. It appears now that such warnings are only given for inpatients whereas this patient was an outpatient at the time of the second request.

Learning: Digital order systems should flag duplicate requests for outpatients as well as inpatients.

Wrong patient/region

Imaging the wrong patient or region occurred in 38% of diagnostic radiology incidents. Of these 31% were due to errors made in the order or interpretation of the order. Not all of the remaining incidents could be categorised by cause but many of them involved individuals not following correct patient identification procedures.

The remedial actions and preventative measures implemented focused on individual performance or reinforcing the importance of procedures among staff/team members. These controls are typically not effective in the long term as they rely on the awareness of individuals rather than addressing the underlying contributing factors on an organisational level.

Example case:

Patient mistakenly given elbow X-ray when they were meant to have head CT. The radiographer requested staff to bring Patient A for right elbow X-ray as per request form. Patient B (who coincidentally had the same surname, similar age and clinical history) was brought instead. The radiographer talked to the patient and then x-rayed the patient without doing the identification check. The radiographer later requested Patient B be brought in for a head CT. The radiographer was informed that Patient B had already been x-rayed earlier that day. Patient B received an unnecessary elbow X-ray. The practice reviewed the patient identification procedures training for all staff and the referral checklist to ensure checks are recorded.

Learning: The report recommended six monthly audits of compliance against the patient checking procedure, annual review of training outcomes/effectiveness, and two yearly review of the training program.

Nuclear medicine: 73 incidents

See the nuclear medicine feature topic starting on pages 5.

Radiotherapy: 16 incidents

Four incidents related to planning or optimisation including a transcription error and existing medical conditions not being taken into account in the treatment plan. For example, in one instance optical nerve contouring was not optimised.

Misalignment or targeting the wrong tissue occurred in another four incidents.

Example case:

A 16cm offset was not applied because sufficient quality pre-treatment imaging was not done as the patient was in pain.

Learning: This report recommended that a minimum of two anatomic landmarks should be used for position verification prior to treatment delivery.

Example case:

Post imaging review identified a better imaging match than what was used.

Pre-treatment verification images are routinely undertaken to ensure patient alignment matches the intended treatment position prior to the delivery of each planned fraction of radiation. In one case the standard protocols for treatment planning, positioning, and imaging were applied. Orthogonal images were acquired and analysed online. These images used a primary anatomical match point (vertebrae) in conjunction with a secondary match point (ribs) to validate treatment position. It was noted at the time that there was some difficulty obtaining an absolute match in each of the image views. This was attributed to rib movement due to the patient's deep inspiration/expiration. The treatment fraction of 4 Gy was delivered to the calculated position.

During routine retrospective review of the orthogonal images by an independent radiation therapist, it was observed that a shift of 3 cm superiorly would have resulted in a better overall match of ribs and vertebrae. This observation was made using a different image filter not available in the online image matching software.

Learning: Alternative pre-treatment imaging should be considered where it is hard to definitively obtain a geographical match.

Consideration of previous treatment and communication was highlighted in two incidents. In one instance a patient had begun to receive treatment at one institution which was later repeated when the patient was transferred. In another case the effect of multiple fields of treatment were not considered in the treatment plan. The report concluded that a sum plan should have been generated to calculate the combined dose of the previous treatment and current/intended treatment taking into account beam divergence.

Another incident involved a change of treatment options which was not well communicated. This highlighted the need for the development and implementation of verbal and electronic protocols for the suspension or cessation of treatment.

During a brachytherapy treatment the source became detached from the planned position during treatment of a tumour located in the eye.

Incorrect patient matching occurred in two cases. One involved cone beam CT equipment malfunction during a planning and the other involved inadvertent staff exposure (<10 μ Sv).

Other: 22 incidents

Incidents involving lost, stolen or found radiation sources (4)

One X-ray fluorescent (XRF) device was stolen and two portable density/moisture gauges (PDMGs) were stolen and later recovered. One PDMG was recovered after being stolen in 2013 and a hydroprobe was found and disposed of overseas.

Example case:

A vehicle was stolen from the premises of a geotechnical service company. The vehicle contained two PDMGs. While the vehicle had a tracking device installed and was recovered promptly, the two PDMGs had been removed. These were subsequently discovered in the town from where they were stolen. Enhancements to the security of these sources were subsequently implemented.

Learnings: This incident highlights the importance of security measures to protect sources when not in use. The use of vehicle tracking was shown to assist in the recovery.

Detection of radioactive material (11)

Ten incidents involved trucks passing through portal monitors at a waste recycling and recovery centre. In all instances the material was identified as short lived medical radioisotopes. The originating hospital was identified during investigations by the regulator. As the material is short lived it can be disposed of with appropriate measures. However the hospital should have stored the material until it had decayed prior to transport and disposal. These incidents highlight the effectiveness of portal monitors in detecting radioactive material.

A member of the public reported finding material labelled as radioactive. The radiation regulator attended and determined that the container did not contain radioactive material. The container had previously contained a medical isotope (technetium) which has a short half-life (6 hours). The container now appeared to contain bird seed.

Non-Ionising Radiation (1)

A medical laser near-miss incident occurred where a staff member was not wearing appropriate safety glasses when the specialist was about to commence the procedure.

Transport (1)

A transport incident where, as a result of a motor vehicle accident, a portable density/moisture gauge became dislodged from the vehicle. The source was still in its transport case and testing confirmed it had not sustained damage.

Non-medical imaging (3)

Two industrial radiography and one XRF incident resulted in higher than normal dose to workers. All doses were below statutory limits.

Example case:

A staff member placed his left thumb and forefinger into the x-ray beam for 10 to 15 seconds while replacing a phosphor target inside an x-ray diffraction device. This was due to the beam not being correctly aligned with the goniometer. While initially calculated maximum dose rates were significant and above limits for extremities, no deterministic effects were observed after two weeks of monitoring. As such, it was assessed that the actual doses were significantly lower than calculated and below limits.

Non-medical Laboratories and Accelerators (2)

Two laboratory incidents, one involved emission above the monthly requirements, and one involved the spill of material.

Example case:

A shielded container is used to transport a glass vial containing 7 GBq of ¹⁸F for PET from a hatch in the production area of a cyclotron laboratory across the main corridor and into a despatch room. The lids of the shielded containers are designed such that a 270° turn will firmly secure the lid. However the lids were known to screw down so firmly that it could be difficult to remove the lids when the vial was to be retrieved from the container. It was common practice therefore, to leave the lids loosely screwed down by turning only 180° or less.

In this instance as the worker lifted the container onto the bench the container clipped the edge of the bench. As a result the worker had to push the container, weighing approximately 10kg, to ensure it did not fall. During this action, the lid of the container decoupled from the base of the container. The base fell a short distance (~10cm) onto the bench and tipped onto its side. The vial inside the container fell out and rolled across the bench away from the worker. The worker reached out, grabbed the vial and quickly inspected it to determine the its integrity and then placed it back into the shielded container. The lid was then screwed down onto the container.

No spill of ¹⁸F occurred. The total time that the vial was outside the shielded container was 10 - 20 seconds. The effective skin dose was estimated to be 0.9 mSv. If the vial had broken, the dose could have been considerably higher.

Learning: Lids can jam on to the body of shielded containers particularly when the lid has been sprayed with a liquid as is routinely done in this instance. However, it was found that if a larger O-ring was installed onto the lid it prevented the lid from jamming onto the body. This shows the importance of considering human factors, such as a worker's reluctance to seal a container in a manner that makes it hard to open, when designing processes and performing risk assessments.