Introduction

The Australian Radiation Incidents Register (ARIR) is a repository of information from Commonwealth, State and Territory radiation regulators. It is intended to raise awareness of radiation incidents across Australia and their causes.

This report is a summary and analysis of data from the 109 incident reports submitted to the Register for incidents which occurred in 2012.

Further information on the ARIR can be found on the ARPANSA website.

Purpose and Scope

The purpose of this report is to assist in the identification of topical areas in which safety effort may be focussed and the practices which may be either adopted or avoided to improve radiation protection. To achieve this purpose focus is directed at the causes of incidents.

Schedule 13 of Radiation Protection Series No.6 (RPS6), National Directory for Radiation Protection (NDRP) specifies the types of incidents that must be reported to ARPANSA for compilation in the Australian Radiation Incident Register (ARIR). Reporting arrangements are agreed by the ARPANSA Radiation Health Committee which includes representatives from radiation regulators of each Australian jurisdiction. ARPANSA has no control over the depth of information included in incident reports outside of the Commonwealth jurisdiction.

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

The total number of reports the Register received in 2012 was 109. These reports were distributed amongst 11 of the 31 domains used to categorise incidents and are listed in the table below together with numbers from previous four years for comparison:

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Uncertainty over reporting practices makes it problematic to draw conclusions on trends without further analysis of information that is not available to the Register (e.g. levels of actual reporting, number of medical procedures undertaken).

Medical uses of radiation account for 90% of incidents reported to the Register in 2012. From 2006 to 2012 there has been an upwards trend in the reporting of incidents involving diagnostic radiography. The reporting levels of nuclear medicine and radiotherapy, the two other main domains reported, remained similar throughout this period.
Causes of Incidents

The largest primary cause of reported incidents is human error accounting for 76 (70%) incidents. It was not possible to determine the primary cause of a further 16 incidents but there is a high likelihood that these would also be related to human error. The full spread of primary causes is:

- Human Error – 76 incidents
- Unclear – 16 incidents
- Equipment malfunction – 9 incidents
- Patient factors beyond control – 7 incidents
- Equipment deficiency – 1 incident

Human Error

Incident reports stated human error as the primary cause in 70% of the 2012 incidents. The cause of a further 15% of incidents was not specified in the incident report but it is possible that the majority of these were also caused by human error.

Analysis of the reports does not always permit the determination of contributing factors that led to the human error. However, where this is apparent the largest contributing causes are a failure in quality checks and quality control (25 incidents), errors in orders or in the interpretation of order instructions (22 incidents), problems in worker communication (9 incidents) and production pressures (7 incidents). In a small number of incidents there were problems with communication systems which did not provide the level of control needed by the users. These problems were unknown by the particular user and included IT systems not permitting an order to be changed once lodged or a failure to identify duplicate orders.

In roughly one third of the incidents that provide some insight on contributing causes, it is apparent that there were multiple failures associated with the incident. In these cases it is quite possible that the incident would not have occurred if one of the contributing causes had been prevented.

A review of incidents where human error was the primary cause indicates that the focus of preventative measures is directed at punitive actions, training and education. Reports suggest that in 22% of incidents, the actions taken by management were limited to reminding staff involved to follow operating protocols and procedures. In a few cases formal warnings were issued. In a further 8% of incidents training and education were included alongside these reminders. Overall training and education was used following 23% of incidents of human error. Procedural changes were implemented after 20% of incidents.

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

In 30% of incident reports there are no preventative measures indicated to prevent repeated incidents.
Unclear

There was insufficient data contained 16 incident reports to determine a root cause. Information provided to the Register is processed beforehand Commonwealth, State and Territory regulators to remove any identifying information. An inability to determine the cause from ARIR data does not imply that an incident has not been properly investigated within its own State or Territory jurisdiction.

ARPANSA, in conjunction with the RHC is currently reviewing reporting requirements with the aim of capturing more information to aid cross jurisdictional learning. This will include improvements on root cause analysis of incidents.

Equipment Malfunction

The reported incidence of equipment malfunction leading to a radiation incident was low. No common failure of equipment was identified in the data submitted to the Register.

The most common consequence of a malfunction or breakdown was a repeated medical procedure after medical equipment failed mid-way through a procedure or by the time taken to repair equipment delaying the procedure and leading to re-administration of a short half-life radiopharmaceutical. One report noted that a CT scanner had failed to store the scan data due to the selected image resolution being set too high. This was one of two incidents reported where scan data was not recorded. In another reported instance an intermittent fault with a CT scanner was tolerated for a period on the basis that the fault was evident before scans commenced (thereby having no patient impact). Later the same fault was found mid-scan. A small number of patients were required to undergo repeat procedures as a consequence.

Outside of the medical industry there were two incidents worthy to note. The first regarding a borehole source which was temporally lost and later recovered. The cause of this incident was associated with a corroded winch cable. The corrosion was promoted and hidden by the practice of covering the steel cable with electrical tape. This practice has now been stopped in the organisation concerned. The second is a currently unexplained increase in the intensity of a non-medical laser during set-up. Improved task familiarity and procedural improvements are now being used as added safeguards for prevention.

Equipment Deficiency

A single incident was primarily caused by an equipment deficiency and concerned an electronic request for a CT scan. The physician sent a cancellation request electronically but once registered the system did not allow it to be cancelled electronically or let the cancelling physician know that the scan had failed to be cancelled.

In this instance both training and procedural changes were used to prevent repeated incidents. There was no indication in the incident report that suggested the ordering system would be modified.

It was noted that a number of human error incidents indicated that equipment deficiency contributed to their cause (see above).
Patient Factors beyond Control

There were six instances reported of medical procedures to patients who were unknowingly pregnant at the time. From information provided in the reports there was no clinical error made in performing the procedures. In one an opportunity to detect the pregnancy in a scout scan was missed.

One incident involved a nuclear medicine patient that became distressed in isolation following administration of a radiopharmaceutical. The patient self-discharged against medical advice. Residual activity was calculated at 1.4 GBq and the patient was advised of precautionary measures to be observed.

Whilst counted under human error, it was also apparent that patient behaviour contributed to some incidents listed where human error was listed as the primary cause.

Incidents by Category

This section reviews industry or domain specific data for incidents reported in 2012. Most incidents reported were medical incidents with causes associated with a range of medical practice and not specific to radiation incidents. An analysis of general incident causation is provided in the previous section of this report; Causes of Incidents.

Diagnostic Radiography: 64 Incidents

Of the 64 reported incidents in diagnostic radiography, 57 involved CT scans, five X-ray and three surgical procedures with x-ray. The average effective doses of CT and X-rays not associated with surgery were 6.4 mSv and 1.7 mSv respectively. The highest individual absorbed dose was a 10.9 Gy skin dose received due to complications during an aortic coarctation stent procedure. The effective dose was not reported for this incident.

Sub-categorisation of diagnostic radiography incidents shows that:

- 28 unplanned examinations were conducted.
- 14 examination were conducted on the wrong body part
- 13 examinations were unnecessarily repeated
- 6 examinations were conducted on unknowingly pregnant patients
- 2 incidents involved issues relating to equipment

In regard to the first four sub-categories the causes of each incident are typical of general clinical environments, i.e. they are causes which can be seen across all medical practice and are not restricted to medical procedures involving radiation.

The first of two incidents relating to radiation apparatus were for CT scans which appeared normal but for which the images were blank. No error logs were recorded and the scan was repeated successfully without incident. No information was provided in the report to the Register regarding the fault.
The second incident involved an unauthorised change to an x-ray machine by a student. The radiographer noticed that an audible signal was of longer duration and terminated the exposure. The requirement to closely supervise students was reinforced as a result.

Nuclear Medicine: 27 Incidents

The average effective dose received by patients in reported incidents involving nuclear medicine was approximately 9mSv. The reported primary cause in the majority of incidents was human error (17 incidents). Where identified the largest contributing causes was a failure of quality control (8 incidents)

Sub-categorisation of nuclear medicine shows the following:

- administration of an incorrect scanning agent (9 incidents);
- administration of a radiopharmaceutical without a binding agent (3 incidents);
- the improper supply of the radiopharmaceutical by supplier (3 incidents);
- administration of a diagnostic agent but the scan was not performed (4 incidents);
- the wrong dose (2 incidents);
- administration of an unnecessary radiopharmaceutical (1 incident);
- the wrong procedure (1 incident);
- ineffective scan due to inadequate reconstitution (1 incident);
- patient contamination (1 incident);
- exposure of service engineer (1 incident), and;
- patient self-discharged early (1 incident).

The reports of administration of an incorrect scanning agent by the clinic did not provide a clear picture of contributing causes. In three cases failure of quality control is highlighted and in one production pressures. The range of preventative measures focused on improvements to labelling and storage of the radiopharmaceuticals and the strengthening of procedures for quality control.

Two of the three incidents associated with supplier errors involved the supply of a radiopharmaceutical with the incorrect biological binder. In each case, this became apparent after administration to the patient. The third was the supply of a radiopharmaceutical with a lower dose than requested. This error was identified via a calibration check at the clinic and not administered to a patient. Each of these issues was a failure in quality control by the supplier.

Of four incidents where the scan was not performed following the administration of the scanning agent, three were associated with equipment failure. In two incidents the gamma cameras malfunctioned and in a third the apparatus failed due to the tripping of circuit breakers during the test of a hospital emergency power supply. In each case the scanning agent had decayed before the scan could be performed and needed to be re-administered. The fourth incident was caused by clinical difficulties with the agent being delivered only subcutaneously.

Two patients received the wrong doses. The first was given one tenth of the prescribed dose which was insufficient to obtain a scan image. This was caused by misreading the label. In the second two prescribed doses were given in wrong order. The error was identified after the first dose was given.

Before being accepted to be part of a trial, one patient was administered a radiopharmaceutical and was later found to be not eligible. The requirement to obtain trial acceptance was reinforced to staff.
Radiotherapy: 6 Incidents

There were six incidents reported for radiotherapy. The primary cause of four of these was human error, the other two were equipment malfunctions.

Sub-categorisation of radiotherapy shows the following:

- misalignment of treatment area (2 incidents);
- incorrect dose (1 incident);
- wrong region (1 incident);
- repeat CT (1 incident);
- unnecessary CT (1 incident).

One instance of misalignment of treatment area occurred when a previous set of alignment tattoos were incorrectly used. This was due to human error and was identified after two days of treatment. The absorbed dose delivered as a result of the error was 5.6 Gy. A recommendation arising from this was to place the tattoos nearer to the treatment area. The second incident was due to a human error leading to the incorrect isocentre placement. 1.8 Gy was delivered to healthy tissue as a result.

An incorrect dose was delivered to one patient due to an error in calculations that were then entered into the treatment apparatus. The error was identified after eight of ten fractions. The delivered dose from eight fractions was considered to be the equivalent of the full ten fraction procedure.

One incident of human error resulted in the wrong region being exposed. Two regions, each requiring its own set up points, were due to be treated. Treatment was correctly delivered for the first region (thoracic spine) and automatic field sequencing in computer verification system made the field for second region (lumbar vertebrae). The operator assumed the set points were the same for both regions and overrode the treatment couch position reading so that the treatment for the lumbar region was also delivered to the thoracic region.

One incident involved a CT scanner used for radiotherapy planning. The machine had an intermittent fault that was causing the scanner to stop. The fault had been attended to on a number of occasions by an in-house service engineer without any reassurance that the fault was fixed. Initially the fault was experienced before scans commenced however later, on 5 occasions, it happened mid scan requiring each scan to be repeated.

One incident concerned a CT scanner that failed to load the reference image data set which is required to perform a "3D-3D" match. The system did not prevent the acquisition of a Cone Beam CT (CBCT) on a patient when the reference data set did not load. This resulted in an unusable CBCT image acquisition and thus an unnecessary irradiation of the patient. The manufacturer has advised that the issue was related to the image resolution being set too high and causing the system to crash. The CBCT functionality of the linear accelerators installed at the clinic was withdrawn from service pending a remedy by the manufacturer and the image resolution permanently set to an acceptable size.
**Non-Medical External Exposure: 2 Incidents**

These incidents were very similar but completely unrelated. In each instance, contractor maintenance workmen failed to heed warning signs and worked on the roof above either a linear accelerator or neutron generator. In each case it was estimated that maximum effective doses in the order of 10 µSv would have been received.

**Contamination: 2 Incidents**

One incident occurred at a nuclear medicine isolation ward. A blocked toilet over flowed and was attended by a plumber who was unaware of a radiological hazard. The dose was not specified in the report.

The second incident involved the spillage of contaminated water in an industrial setting during a maintenance process. Two maintenance workers received low doses of 6 µSv and 21 µSv (effective). The incident report indicated human error as the primary cause and poor quality control, lack of task familiarity, production pressure and procedural deficiency as contributing causes. Improved training and procedural changes were implemented to prevent the incident recurring.

**Laser: 1 Incident**

This incident involved the activation of a Class 4 laser in rural Australia in place of a Class 3 laser. No people were exposed. All activities using lasers (Class 3 and Class 4) being undertaken outside of specific designated areas were suspended as a result.

**Unauthorised disposal**

One incident involved the destruction of night vision equipment containing tritium. A number of items were placed in a hessian sack and broken with a hammer before disposal through normal waste. It was estimated that the effective dose to the worker would be less than 1 mSv.

A second incident regarded the disposal of I-125 seeds from a clinical environment. The seeds were sterilised and then disposed as normal clinical waste. The staff involved were not familiar with the correct procedures.

**Borehole Logging: 1 Incident**

A source was temporarily lost when a wire winch cable snapped due to corrosion. The corrosion had been promoted by the use of an adhesive tape covering which trapped moisture around the steel cable and masked visibility of the resulting corrosion. The organisation concerned has instructed workers not to wrap adhesive tape around cables.

**Dental: 1 Incident**

This incident involved the accidental activation of a dental x-ray unit in the presence of a pregnant staff member. The cause was human error. The effective dose delivered was estimated at 2 µSv.
**Laboratory: 1 Incident**

This incident concerned an unsealed source and was caused by the accidental spilling during manual handling coupled with a malfunction of a temperature regulator on a hotplate. The source was cleaned without a dose to workers.

**Transport**

The single transport incident concerned the shipment of five sealed sources in a single package using a commercial flight from Australia to Germany. On arrival in Germany the package was found to have been incorrectly fitted and the contents partially dislodged and outside of its shielded position. Conservative estimates suggest that the effective dose to a person handling the package based on 10 minutes exposure to be 6.6 mSv. The conservative estimate of effective dose to a passenger seated directly above the cargo bay storage location during both legs of the flight is 4.6 mSv. The cause of this incident was human error. Training will be provided to workers to prevent recurrence.

Note: This incident was reported to the International Atomic Energy Agency as a level 2 incident on the International Nuclear Event Scale (INES).

**Comments and Conclusions**

The number and range of reported incidents in 2012 is comparable with previous years.

Analysis of incident causes indicates that many had multiple contributing causes and it is quite possible that the incident would not have occurred if one of the contributing causes had been prevented. This is the basis for the James Reason ‘Swiss Cheese’ model of safety where an incident or accident only occurs where there is an alignment of vulnerabilities. Shoring up vulnerabilities can block a pathway leading to the incident and often small changes to operating environments can bring about a meaningful reduction in the number of incidents and accidents that occur.

The majority of reported incidents cite human error as the primary cause. Analysis of contributing causes and preventative measures suggests that there is high reliance on actions taken by individuals. Whilst this is to be expected in many applications of radiation, the information in incident reports suggests that many of the risk factors could be identified beforehand. Examples include failures in quality control processes, particularly cross checking of information, problems with labelling and ordering systems and more general communication issues. Many of these risks are associated with skill and rule based human performance. Compared to the emphasis on reinforcement of correct processes and training, which are the most common preventative measures in incident reports, task analysis can assist in matching processes and instructions to the strengths and weaknesses in skill and rule based human performance and may lead to long lasting improvements.