IONISING RADIATION INCIDENTS IN DIAGNOSTIC IMAGING

Notification of the exposure of patients
“We also need to investigate impartially, learn what happened and – most of all – we need to share the information to try to stop it happening again.”

Patrick Snedden
Chair of the Ministry of Health's Quality Improvement Committee
Introduction

The exposure of patients to ionising radiation for diagnostic purposes is an indispensable part of health care. Most of these exposures proceed as planned. However, each year a small number are notified to the National Radiation Laboratory (NRL). The main reasons for these incident notifications are that the wrong person was exposed, or that a patient received a radiation dose much greater than intended. These exposures can cause distress to the patient involved and, in extreme cases, can cause harm.

The majority of incidents involving the exposure of patients to ionising radiation in medical imaging are of low radiation dose and consequently of minimal risk. However, approximately one quarter of the incidents notified to NRL have involved computerised tomography scans where patient doses are more significant. Incidents have also included procedures involving the injection of patients with a contrast agent or the wrong radiopharmaceutical. Causes of incidents include equipment faults, clerical errors, failure of staff to follow the three-point check (ie, name, date of birth and address), and referral errors such as the mislabelling of a request form.

This leaflet has been produced as part of a Ministry of Health initiative, through NRL and with the endorsement of professional bodies, to encourage and facilitate the reporting of incidents involving the exposure of patients and to describe how the supplied information will be utilised. The Ministry’s initiative aims to improve:

• the level of incident reporting;
• overall patient care by reducing the number of incidents; and
• the standard of radiation safety for patients through the further development of a safety culture.

Reporting requirements for incidents involving the exposure of patients

The use of irradiating apparatus (eg, x-ray equipment), or radioactive materials for any purpose, is restricted to persons who hold a licence under radiation protection legislation or who are acting under the supervision or instructions of appropriately licensed persons. Licences are generally subject to a condition requiring compliance with a code of safe practice. Codes give the minimum safety requirements that must be satisfied for different planned exposure situations (eg, the use of radionuclides in nuclear medicine). The codes applicable to diagnostic imaging require that as soon as practicable the following patient exposures are investigated and reported to NRL:

• A radiation incident involving the exposure of a patient or patients to a radiation dose much greater than intended.
• A radiation exposure of a patient where none was intended, as in the case of mistaken identity.
• A radiation exposure of the embryo/foetus where the exposure had not been included in the justification process.
• In diagnostic radiology, an unexpected skin injury to a patient resulting from a prolonged radiation exposure in an interventional procedure.

Incidents are notified using a simple standardised report form. The form does not require the name of the patient or of the staff involved. The form can be completed online through NRL's website or downloaded from http://www.nrl.moh.govt.nz/regulatory/incidentform-patientexposures.pdf
**What we expect of diagnostic imaging staff**

A licensee must notify NRL if an incident involving patient exposures meets the reporting requirements in the applicable code of safe practice.

The reporting of incidents is a positive contribution to patient care and a driver for continual improvement. It is often an uncomfortable situation for staff when something has gone wrong. However, staff can have confidence that they will be reporting into a system based on trust, consistency and support.

All incidents must be reported following the facility’s prescribed reporting procedures.

**What you can expect of NRL**

NRL promotes the reporting of all incidents by fostering trust through the demonstrable treatment of all reports in a fair and consistent manner.

All notified incidents involving patient exposures will be acknowledged and added to an NRL-maintained database. Incidents involving a patient exposure that are classified by the hospital’s or facility’s internal reporting system as a *serious or sentinel adverse event* will be subjected to an on-site investigation by NRL. Incident reports are analysed to identify common causes and effective corrective and preventive actions taken.

When all information pertaining to an incident has been obtained an *incident summary* will be drafted and provided to the person notifying the incident for verification.

*An incident summary will exclude any information that might identify the patient, staff or the hospital or the facility involved.*

Incident summaries will be provided routinely on an annual basis to clinical directors of all diagnostic imaging departments using ionising radiation and other nominated persons.
Glossary

**Safety culture**
A safety culture is defined as follows by the International Atomic Energy Agency (IAEA) in relation to the protection of persons against ionising radiation in its Basic Safety Standards, 1996 (IAEA, 1996):

“A safety culture shall be fostered and maintained to encourage a questioning and learning attitude to protection and safety and to discourage complacency, which shall ensure that:

(a) policies and procedures be established that identify protection and safety as being the highest priority;
(b) problems affecting protection and safety be promptly identified and corrected in a manner commensurate with their importance;
(c) the responsibilities of each individual, including those at senior management levels, for protection and safety be clearly identified and each individual be suitably trained and qualified;
(d) clear lines of authority for decisions on protection and safety be defined; and
(e) organisational arrangements and lines of communications be effected that result in an appropriate flow of information on protection and safety at and between the various levels in the organisation of the registrant or licensee.”

**Radiation protection legislation**

**Code of safe practice**
These are documents for different planned exposure situations such as diagnostic radiology or nuclear medicine that give requirements that must be complied with by a licensee. The codes applicable to diagnostic radiology and nuclear medicine are respectively:

- Code of Safe Practice for the Use of X-Rays in Medical Diagnosis. NRL C5.
- Code of Safe Practice for the Use of Unsealed Radioactive Materials in Medical Diagnosis, Therapy and Research. NRL C3.


**Radiation incident**
Any unintended or ill-advised event when using irradiating apparatus, or radioactive material for diagnostic purposes which results in, or has the potential to result in, an exposure of a patient outside the range of that normally expected for a particular planned exposure, including events resulting from equipment failure, the failure of procedures, and the failure to follow procedures, or poor judgement or human error.

**Incident Summary**
These do not include any information that might identify the patient, staff or the hospital or the facility involved. The following is an example of how a possible incident will be summarised:

<table>
<thead>
<tr>
<th>ID</th>
<th>Classification</th>
<th>Date</th>
<th>Summary</th>
<th>Actions taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>Clerical error</td>
<td>31 January 2009</td>
<td>A patient underwent a needless CT scan. The effective dose was approximately 3 mSv. Human error was identified as the main cause. The patient had previously been booked for a CT scan. However, later the scan was cancelled. Relevant staff did not receive the relevant documentation and the CT scan was carried out.</td>
<td>Review of processes. A soon-to-be commissioned electronic patient referral system should ensure little chance of a recurrence.</td>
</tr>
</tbody>
</table>
The following guidance on the interpretation of much greater than intended is based on that issued by the UK’s Health and Safety Executive (HSE, 2006). The multiplying factor indicates how much the radiation dose (effective dose or mean glandular dose) received by a patient as a result of a diagnostic radiology or nuclear medicine radiation incident should exceed the intended dose for consideration to be given for the need to report the incident to NRL.

The interpretation of intended dose is subjective, not least in relation to interventional radiology and when variations between patients are considered. However, diagnostic reference levels derived locally and expressed in terms of quantities such as post mAs reading, screening time, dose-area product, dose-length product and reference activity should provide a reasonable guide.

### Diagnostic Radiology

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Guideline multiplying factor to be applied to intended dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventional radiology, radiographic and fluoroscopic procedures</td>
<td>2</td>
</tr>
<tr>
<td>involving contrast agents and computer tomography examinations</td>
<td></td>
</tr>
<tr>
<td>Mammography and all other radiographic examinations not referred to elsewhere in this table</td>
<td>10</td>
</tr>
<tr>
<td>Radiography of extremities, skull, dentition, shoulder, chest, elbow and knee</td>
<td>20</td>
</tr>
</tbody>
</table>

### Nuclear Medicine

<table>
<thead>
<tr>
<th>Effective Dose</th>
<th>Guideline multiplying factor to be applied to intended dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greater than 5 mSv</td>
<td>1.5</td>
</tr>
<tr>
<td>Less than or equal to 5 mSv, but greater than 0.5 mSv</td>
<td>2</td>
</tr>
<tr>
<td>Less than or equal to 0.5 mSv</td>
<td>20</td>
</tr>
</tbody>
</table>

### Serious or sentinel adverse event

“A health care event is an event or circumstance that could have led or did lead to unintended and/or unnecessary harm to a patient, and/or a complaint, loss or damage.

An adverse event is a health care event causing patient harm that is not related to the natural course of the patient’s illness or underlying condition.

A serious adverse event has required significant additional treatment but is not life threatening and has not resulted in major loss of function.

A sentinel adverse event is life threatening or has led to an unanticipated death or major loss of function.”

(The Quality Improvement Committee, 2009)

### References


USEFUL WEB ADDRESSES:

NRL Home page:
http://www.nrl.moh.govt.nz

Incident reporting form:

Copy of this leaflet:

Codes of safe practice:

Copies of the
Radiation Protection Act 1965 and
Radiation Protection Regulations 1982:

In an emergency contact the National Radiation Laboratory:
03 366 5059 during office hours
or 021 393 632 any other time.
This leaflet has been endorsed by:

New Zealand Institute of Medical Radiation Technology

The Royal Australian and New Zealand College of Radiologists

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