THE ANNUAL REPORT OF

THE RADIATION ADVISORY COMMITTEE

FOR THE FINANCIAL YEAR ENDING JUNE 2009

RADIATION ADVISORY COMMITTEE

Melbourne, Australia

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Daniel Andrews MLA
Minister for Health

Dear Minister

Pursuant to Section 110 of the *Radiation Act 2005*, the Radiation Advisory Committee submits the 2009 annual report of the Committee for presentation to Parliament.

Yours faithfully

Dr John Heggie
Chair
RADIATION ADVISORY COMMITTEE

CONTENTS

RADIATION ADVISORY COMMITTEE

The Radiation Advisory Committee is established under Section 110 of the *Radiation Act 2005*. The term of appointment for the Committee was the period 17 August 2005 to 16 August 2008.

(i) Composition

The Radiation Advisory Committee met on 11 occasions from July 2008 to June 2009.

The members of the Radiation Advisory Committee during the period 1 July 2008 to 16 August 2008 were:

<table>
<tr>
<td> 
Dr. John Heggie (Chair)
Consultant medical physicist

Meetings attended:2</td>
<td> 
Dr. David Bernshaw
Consultant Radiation Oncologist
Peter MacCallum Cancer Centre

Meetings attended: 2</td>
</tr>
<tr>
<td> 
Mr. Philip Brough
Chief Medical Imaging Technologist
Department of Medical Imaging
Geelong Hospital

Meetings attended: 2</td>
<td> 
Mr. Peter Burns
Acting CEO
Australian Radiation Protection & Nuclear Safety Agency

Meetings attended:1</td>
</tr>
</table>

Dr. Roslyn Drummond
Radiation Oncologist
Peter MacCallum Cancer Centre

Meetings attended: 1

Professor Robert Gibson
Deputy Head, Department of Radiology
University of Melbourne

Meetings attended: 2

Dr. Ken Joyner
Director
Global EME Strategy & Regulatory Affairs
Motorola Australia Pty Limited

Meetings attended: 2

Dr. Geza Benke
Research Fellow
Dept of Epidemiology & Preventive Medicine
Monash Medical School

Meetings attended: 2

The term of the Committee expired on 16 August 2008. A new Radiation Advisory Committee was appointed for the term 17 August 2008 to 16 August 2011. The members of the Committee for the period 16 August 2008 to 30 June 2009 were:

Dr. John Heggie (Chair)
Consultant medical physicist

Meetings attended:8

Dr. David Bernshaw
Consultant Radiation Oncologist
Peter MacCallum Cancer Centre

Meetings attended: 6

Mr. Peter Burns
Acting CEO
Australian Radiation Protection & Nuclear Safety Agency

Meetings attended: 5

Professor Robert Gibson
Deputy Head, Department of Radiology
University of Melbourne

Meetings attended:4

Dr. Roslyn Drummond
Radiation Oncologist
Peter MacCallum Cancer Centre

Meetings attended: 9

Dr. Ken Joyner
Director
Joyner and Associates
Telecommunications Consultancy

Meetings attended: 4

Dr Graeme O'Keefe
Principal Scientist
Austin Health

Meetings attended: 7

Dr Russell Horney
Physicist
Department of Medical Imaging and Radiation Sciences
Monash University

Meetings attended: 8

Mr Russell Booth
Chief Nuclear Medicine Technologist
Medical Imaging Department
St Vincent's Hospital

Meetings attended: 9

Mr Stephen White
Chief Nuclear Medicine Technologist
Cabrini Health

Meetings attended: 7

Associate Professor Rob Davidson
Head of Discipline, Medical Radiations
RMIT University

Meetings attended: 5

(ii) Responsibilities

The Radiation Advisory Committee is to advise the Minister for Health or the Secretary of the Department of Human Services, on any matters relating to the administration of the *Radiation Act 2005*, referred to it by the Minister or the Secretary including the following:

(a) The promotion of radiation safety procedures and practices.

(b) Recommendation of the criteria for the licensing of persons and the qualifications, training or experience required for licensing.

(c) Recommendation of which radiation sources should be prescribed as prescribed radiation sources.

(d) Recommendation of the nature, extent and frequency of tests to be conducted on radiation apparatus and sealed radioactive sources.

(e) Codes of practice, standards or guidelines with respect to particular radiation sources, radiation practices or uses.

Section 110 of the Radiation Act requires that the Committee must give the Minister a report on its activities during a financial year no later than 1 November following that year.

1. INTRODUCTION

Throughout the year a number of issues were considered by the Committee including:

- the licensing and training requirements for various radiation practices;
- radiation incidents;
- non-ionising radiation matters; and
- a variety of research projects involving the irradiation of human volunteers.

The Committee would like to thank the Radiation Safety Team of the Department of Human Services for their continuing assistance and support.

2. IONISING RADIATION

2.1 Research involving irradiation of human volunteers

The Committee evaluated proposed research projects where doses to volunteers exceeded dose constraints specified in the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes 2005* (RPS No. 8) and where there was no benefit to volunteers who are patients. Approval of other research projects involving radiation exposures of human volunteers was the responsibility of institutional human research ethics committees.

A list of the research projects considered by the Committee is provided in Appendix 1.

2.2 Radiation incidents

The Committee continued to review reports of radiation incidents, accidental radiation exposures and maladministrations reported to the Radiation Safety Team.

Of the reports of unplanned exposures:

- 10 involved an unintended computed tomography (CT) scan being performed on a patient.
- Four involved misalignment of a radiotherapy treatment field.
- Six involved medical imaging of patients who were subsequently found to be pregnant.
- Seventeen involved the maladministration of a radiopharmaceutical to a patient.
- Three involved the development of tissue reactions following interventional fluoroscopy procedures.

Follow-up actions by practices designed to prevent recurrences were monitored. Information was circulated to radiological practices generally explaining common errors that can lead to radiation incidents.

The Committee believes that, in the interests of open reporting, the identification of staff members involved in these medical incidents should not be mandatory.

In addition to the medical incidents, four industrial incidents were reported:

- A Melbourne company lost two 3.7 GBq Am-241 sources.
- A vehicle transporting a nuclear density moisture gauge was involved in a transport accident but the gauge was undamaged.
- A nuclear density moisture gauge was stolen from another company and subsequently returned.
- A 37 GBq Am-241 source from a radiation gauge on a hot steel mill was found to be leaking. The source and gauge housing were stored on site pending disposal.

A list of incidents, accidental exposures and maladministrations is provided in Appendix 2.

2.3 Regulation of the consignment and transport of radioactive material

The Committee was advised of a review by the Department of the licensing arrangements for management licences that permitted the transport of radioactive material. A discussion paper had been prepared in 2008, detailing recommendations for improvements to the licensing of the transport of radioactive material. The differing requirements between jurisdictions posed major problems for consigners and transport companies and the Radiation Safety Team was exploring possible regulatory changes to help rectify this problem and to create a more robust licensing structure for transport of radioactive material.

2.4 Submission for approval of a course in rural and remote radiography

The Committee considered a submission from a company for approval of a course in rural and remote radiography for general practitioners.

The Committee determined that the course would be acceptable subject to the course content being amended to reflect Victorian legislative requirements. The Committee also recommended that the course provider give consideration to employing a medical physicist experienced in radiation protection and radiology to present the radiation physics and radiation protection sections of the course.

2.5 Introduction of 320 Slice CT scanner at a Melbourne Hospital

The Committee was informed that the Minister for Health had received correspondence from a radiologist at a Melbourne Hospital alleging improper practices regarding the use of the new 320 slice Toshiba CT scanner at the hospital. The radiologist alleged that the scanner was being used to screen asymptomatic persons. This issue was subsequently reported as an incident.

2.6 Application for use licence for the use of CT scanners by a cardiologist

The Committee was informed that the Radiation Safety Team had received an application for a licence to use CT scanners by a cardiologist.

The Committee was reminded that the only medical practitioners currently permitted to hold a licence to use CT scanners were radiologists. This had been the first application for use of a CT scanner that had been received by a medical practitioner who was not a radiologist.

The Committee was advised that the proponent had completed the American College of Cardiology/American Heart Association level three training in cardiac CT. The Committee was unsure whether this level of training would allow for sufficient competency to use CT equipment safely. The Committee requested that further information be sought regarding this training program.

After reviewing the information provided by the Radiation Safety Team on the level three training program, the Committee was of the opinion that the focus of the training program was on interpretation of CT images used in cardiology. The program did not appear to provide training in the operation of CT scanners. It was agreed that, whilst the program would provide an equivalent level of training in cardiac image interpretation to that possessed by a qualified radiologist, it would not adequately train a medical practitioner to use CT scanners. Therefore, it was deemed that the completion of the level three training program was not relevant in considering the suitability of the application for a use licence.

2.7 Implementation of the ARPANSA Code of Practice for the Security of Radioactive Sources

The Committee was updated on the progress of the implementation of the Code of Practice for the Security of Radioactive Sources.

The Committee noted that there were numerous issues that were raised by the code. These included the preparation of source security plans, transport security plans, and background checking of persons dealing with security enhanced sources. It was noted that it would be difficult to implement background checking of staff in practices where there was high staff turnover or where many staff have access to source storage areas such in brachytherapy rooms.

The Committee was advised that the Radiation Safety Team had facilitated training sessions for stakeholders in conjunction with the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

In accordance with an agreement between jurisdictions, compliance with the code of practice was to be made mandatory from July 1 2009 for persons who possessed security enhanced sealed radioactive sources. This would be brought about by making compliance with the code of practice a condition of licence for those persons who possessed a management licence that authorised the possession of such sources.

2.8 Licensing of medical radiation practitioners

The Committee was advised that the Radiation Safety Team was in the process of contacting persons registered with the Medical Radiation Practitioners Board of Victoria (MRPB) encouraging them to apply for a use licence.

The exemption from the requirement to hold a use licence for persons holding registration with the MRPB was due to expire on 31 August 2009. After this date, radiographers, nuclear medicine technologists, and radiation therapists needed to hold a use licence before they could use radiation sources.

The implementation of a licensing regime for medical radiation practitioners was seen as a positive step to align the practitioners with other professional groups using ionising radiation.

3. NON-IONISING RADIATION

3.1 Regulation of Solaria in Victoria

The Committee was informed of the progress in the regulation of solaria in Victoria.

Interim regulations for the solaria industry were in force for a period of 12 months from February 2008. These interim regulations were replaced with permanent regulations on 1 February 2009.

These new regulations introduced new responsibilities for both the operators of solaria and their staff to:

- ensure that those under 18 are prevented from using tanning units;
- improve the assessment of skin types prior to exposing a new client to UV by requiring an assessment of skin type against a six grade skin-type scale; and
- improve the determination of the maximum exposure time.

In addition, the regulations require all exposures to be supervised, staff be appropriately trained, warning notices be displayed and informed consent be obtained from all clients.

These new regulations underwent a detailed regulatory impact assessment which found that the regulations can be expected to prevent between nine and 12 deaths from melanoma over the next 10 years.

The Radiation Safety Team worked closely with all jurisdictions to put in place a national uniform agreement to regulate tanning units across Australia. This was adopted by the National Radiation Health Committee in March and is to be endorsed by the Australian Health Ministers Council.

A web-based national training program is being developed by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) to assist businesses train their staff and increase their awareness of the risks and how to perform skin type assessments.

3.2 WHO World Cancer Report 2008

This report was tabled for the information of the Committee. In relation to electromagnetic fields, the report reached the following conclusions.

- *Extremely low frequency (ELF) electromagnetic fields generated by electrical power transmission have been associated with an increased risk of childhood leukaemia, but the findings are not conclusive. Even if this association is real, the number of excess cases is likely to be very small.*
- *Radiofrequency radiation emitted by mobile telephones has been investigated in a number of studies. There is some evidence that long-term and heavy use of mobile/cellular phones may be associated with moderate increased risks of gliomas, parotid gland tumours, and acoustic neuromas; however, evidence is conflicting and a role of bias in these studies cannot be ruled out.*
- *With reference to radio frequency, available data do not show any excess risk of brain cancer and other neoplasms associated with the use of mobile phones.*

- *With reference to ELF fields, available data allow us to exclude any excess risk of (childhood) leukaemia and other cancers at the levels of exposure likely to be encountered by most (>99%) of the population).*
- *To date there is no convincing biological or biophysical support for a possible association between exposure to ELF fields and the risk of leukaemia or any other cancer*

3.3 Review papers on mobile phones and brain tumours

Khurana et al (article in press, Surgical Neurology 2009) conclude that there is adequate epidemiologic evidence to suggest a link between prolonged mobile phone usage and the development of ipsilateral brain tumour.

Croft et al (Australasian Physical & Engineering Sciences in Medicine, Volume 31, Number 4, 2008, 255-267), however, state that the epidemiologic research designed to determine whether the use of mobile phones has any effect on health, in particular head and neck tumours, is particularly heterogeneous, making it difficult to pool in a meta-analysis. Although there have been individual reports of associations between mobile phone use and tumours, this research is not consistent and, on balance, does not provide evidence of an association. There are reports of small associations between mobile phone use ipsilateral to the tumour for greater than 10 years, for both acoustic neuroma and glioma, but the authors argue that these are especially prone to confounding by recall bias. The reported associations are in need of replication with methods designed to minimise such bias before they can be treated as more than suggestive.

3.4 The Committee's view on possible health effects of power frequency electromagnetic fields.

The Committee's position is that, based on the total database of scientific research, there is insufficient evidence to conclude that exposure to normally encountered environmental levels of power frequency electromagnetic fields causes adverse health effects in humans.

3.5 The Committee's view on possible health effects of radiofrequency radiation

The additional evidence reviewed by the Committee during the year has not altered its position that there is no substantive evidence to suggest that exposure to radiofrequency radiation can increase the risk of chronic health effects such as cancer. However, the Committee acknowledges the current controversy over mobile phones and their base stations and will continue to review the relevant research literature.

APPENDIX 1 RESEARCH PROJECTS CONSIDERED BY THE COMMITTEE

TITLE OF RESEARCH PROJECT
A Randomised, Multicenter, Multinational Phase II study on trastuzumab plus docetaxel versus trastuzumab plus docetaxel plus pertuzumab versus trastuzumab plus pertuzumab versus pertuzumab and docetaxel in patients with locally advanced, inflammatory or early stage HER2 positive breast cancer. Proposed research study to be carried out at Barwon Health and St John of God Hospital (Protocol Number: HREC 08:44). The Committee approved the project subject to the following requirements: • Approval from the Barwon Health Research and Ethics Committee. • The radiation risk statement to be modified by removing references to risk of cancer and replacing these with an indication of the radiation dose to be received as a result of participating in the project.
A Prospective, Randomised, Double-blind, Placebo-controlled, Parallel-group, International Multicentre Phase III Trial of PI-88 in the Adjuvant Treatment of Post-resection Hepatocellular Carcinoma. The Committee approved this research project.
RAAFT First Line Radiofrequency Ablation versus Antiarrythmic Drugs for Atrial Fibrillation Treatment: A Mutli-center Randomized Trial. The Committee approved the study pending verification of the dose assessment by an independent health physicist.
IMS III Interventional management of stroke trial clinical protocol. The study was approved subject to verification of the dose assessment by an independent health physicist.
Utilisation of coronary CT angiography (CCTA) in cardiac risk stratification. The Committee approved the research project.
A Phase III, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Prochymal™ (Ex-vivo Cultured Adult Human Mesenchymal Stem Cells) Infusion in Combination with Corticosteroids for the Treatment of newly diagnosed Acute GVHD. The total effective dose to participants would be approximately 48 mSv, which exceeded the dose constraints set out in the ARPANSA Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes. As a result, the Committee recommended that the Radiation Safety Team advise the researchers to demonstrate that the radiation exposures proposed are likely to result in a substantial benefit, and to amend the radiation risk statement for participants.
Adjuvant immunotherapy with anti-CTLA-4 monoclonal antibody (ipilimumab) versus placebo after complete resection of high-risk Stage III melanoma: A randomized, double-blind Phase 3 trial of the EORTC Melanoma Group. The Committee approved the research project subject to the inclusion of a radiation risk statement in the participant information and consent form.

A double-blind, randomized, placebo-controlled phase III study to assess the safety and efficacy of recMAGE-A3+AS15 Antigen Specific Cancer Immunotherapeutic as adjuvant therapy in patients with resectable MAGE-A3-positive Non-Small Cell Lung Cancer. The study was approved subject to amendment of the radiation risk statement for participants.
A randomized, double-blind, placebo-controlled, multicenter phase III study of RAD001 adjuvant therapy in poor risk patients with Diffuse Large B-Cell Lymphoma (DLBCL) of RAD001 versus matching placebo after patients have achieved complete response with first-line rituximab chemotherapy. The Committee approved this study subject to clarification of the age range of participant group, and median life-expectance of the 'poor-risk' subgroup or patients with diffuse large B-cell lymphoma.
An Investigation of Non-Invasive Coronary CT Angiography Using Aquilion ONE 320-slice Multi-Detector CT Imaging in Comparison to Invasive Angiography and Intravascular Ultrasound Imaging for Assessment of Stable Coronary Artery Disease. The Committee requested that the full study protocol be provided by the proponents, as well as further justification of the proposed radiation exposures, and the rationale for the number of proposed participants.

APPENDIX 2 INCIDENTS, ACCIDENTAL EXPOSURES AND MALADMINISTRATIONS REPORTED TO THE COMMITTEE

DESCRIPTION OF INCIDENT	ACTION TAKEN
A radiotherapy patient undergoing treatment for lung cancer on a linear accelerator received multiple treatment fractions that were misaligned. The patient concerned was scheduled to receive 30 treatment fractions in total. An incorrect treatment reference point was tattooed on the patient. During the assessment of the pre-treatment portal image, staff failed to detect that there had been field misplacement. After the 6th treatment fraction the first routine weekly portal image was assessed and at this time the field misplacement was detected. As a result of the field misalignment, 44% of the tumour volume was under-dosed, and an equivalent area of healthy tissue received an unintended dose of approximately 14 gray (Gy).	Following the incident, the patient's clinical needs were reviewed, and a modified treatment plan implemented following re-imaging to confirm treatment position. The patient concerned had been informed of the incident. The incident had also been reported to the sentinel event program of the Department of Human Services, as well as the Clinical Risk Committee of the radiotherapy centre. A root cause analysis investigation was performed, and a schedule of corrective measures to be undertaken with a timetable for completion of these corrective measures was provided. The Committee expressed concern about the elapsed time between the date of the incident and the date at which the incident was reported.
A patient from the emergency department at a Victorian hospital inadvertently underwent a CT scan of the abdomen with contrast on 12 May 2008. The total effective dose to the patient as a result of the CT scan was approximately 10 millisievert (mSv). On the date in question, CT staff at the hospital had received a medical imaging request for a patient to have a CT scan of the abdomen. The patient was called and another patient that had a very similar name was transferred into the CT room. The intern radiographer used the hospital's "timeout questionnaire" incorrectly, asking the patient "Are you Mr …?". The patient responded 'Yes'. The intern radiographer claims that he/she asked for the patient's date of birth, however, did not check this against the correct request form. To complicate matters, the emergency department had forwarded a request form to CT staff for the second patient to have a chest x-ray when he was finished in CT. It was only after the CT was completed that it was discovered that there were different names and UR numbers on the two imaging requests.	Staff involved were reminded of the importance of correctly identifying patients. A reminder was given to all radiographers (and students) to identify patients correctly using the CT timeout procedure. In particular, they were reminded that patients were required to provide their names themselves. Nurse unit managers were reminded regarding the correct identification of patients by nurses prior to injection of a drug (in this case IV contrast media). The Committee expressed concern that the incident occurred despite a timeout procedure being in place. The Chief Radiographer at the hospital advised that he would write to the Medical Radiation Practitioners Board and request that it provide information regarding proper patient identification in one of its newsletters.

DESCRIPTION OF INCIDENT	ACTION TAKEN
A 34 year-old female patient received a CT guided facet joint injection at a Melbourne hospital on 2 June 2008. A private medical imaging practice had an arrangement to provide medical imaging services at the hospital The procedure had been intended and the patient was correctly identified by radiography staff. The procedure included two scout views and five helical scans. On 10 June 2008, the patient notified the hospital that she had just become aware that she was approximately 10 weeks pregnant. The equivalent dose to the patient's uterus was approximately 7.6 mSv as a result of the scan.	Radiation Safety Team wrote to the imaging practice and confirmed that staff at the practice ask whether female patients of child bearing age who present for medical imaging procedures are pregnant.
A 74 year-old female patient received an unintentional CT scan of the abdomen. At the time of the unintended scan, there had been two patients scheduled for a CT scan. The first patient had been scheduled at 4.30pm for an abdominal scan, and the second patient had been scheduled for a CT scan of the head. The radiology staff member involved requested the second patient; however the nurse in attendance thought the radiographer had meant the first patient. The identity of the patient was not checked or clarified in the emergency department or in the CT room. Subsequently, the incorrect patient underwent an unnecessary abdominal CT scan. The estimated radiation dose received as a result of this incident was stated to be 427 "mGy". The Committee questioned the correctness of this dose and asked to see the methodology regarding its derivation.	In response to this incident, the hospital conducted a root cause analysis involving the emergency department, the radiology department, and the Quality/Risk Manager. This analysis included the review of processes used at other hospitals used to request, receive, and identify patients prior to procedures. It did seem, however, that staff did not follow a positive identification protocol prior to performing the scan. The Radiation Safety Team provided a timeout procedure form to the medical imaging department practice and determined that the value of 427 referred to in the incident report was in fact a dose-length product and that the effective dose estimated from this was about 7 mSv.
A 41 year-old female patient was scheduled for a thyroid scan that involved the administration of 282 MBq technetium-99m (^{99m}Tc) pertechnetate. The patient was asked prior to the scan whether or not she was pregnant and she responded that she was not pregnant. Her response to this question was recorded on the referral form. It was subsequently discovered she was pregnant. The equivalent dose to the patient's uterus was approximately 2.3 mSv as a result of the scan.	The appropriate steps were taken by staff to determine her pregnancy status prior to the scan. The Committee noted that the uterus is not a good surrogate for the foetus when estimating foetal radiation exposure from radiopharmaceuticals. The Committee suggested using a different technique for the radiation dose estimate and recommended recalculating the dose estimate.

DESCRIPTION OF INCIDENT	ACTION TAKEN
A 76 year-old male patient was the subject of an unintentional CT (IVP) scan during the investigation of haematuria. Although the CT scan had been scheduled for the patient, it had been unintentionally repeated several days after the original scan because the request slip was first faxed to the imaging department, and then physically delivered, resulting in a duplicated booking. The duplication had only been noticed several days after the unnecessary scan. The patient received a total effective dose of approximately 42 mSv as a result of the unnecessary scan.	The Committee was advised that there had been a pre-existing policy of not accepting internally faxed request slips to ensure duplicate bookings were not made. In this instance, however, the requesting department had not been made aware of this policy. The Chief Radiographer at the hospital advised that this had now been rectified. It was noted that incidents involving duplication of requests may be avoided by clerical staff checking patient booking histories in the radiology information system prior to scheduling a scan.
A patient undergoing palliative radiotherapy received a treatment field that was rotated 90° to the intended orientation. Due to a need to provide fast pain relief for the patient, the planning was performed using a clinical mark-up technique rather than the usual method of virtual planning. The planning technique used involved the manual entry of treatment parameters into the database used to deliver treatment, bypassing checks that would normally be conducted with virtual planning. In this case the rotation of the collimator head had been incorrectly entered into the database, and the error was not picked up until the treatment was underway. The Committee was advised that the radiation therapists concerned had noticed that the field was incorrectly rotated during the treatment, but decided not to stop treatment as the patient's carer was in the control area at the time. The radiation therapists had been concerned that stopping the treatment prematurely would upset the carer. The Committee was advised that the radiation oncologist overseeing the patient's case was satisfied that the intended clinical outcome had been achieved by the treatment despite the incorrect field rotation, and that it did not cause the patient significant detriment.	The centre was uncertain as to the reporting requirements for radiotherapy incidents. The centre was aware that the Department of Human Service's publication "Radiation Incident Reporting Requirements: specified that a variation of 10% or more in dose delivered from the prescribed dose must be reported to the Department. However there had been uncertainty as to whether this figure applied to a single treatment fraction, or in the case of multi-fraction treatments, the entire course of a patient's treatment regime. The Committee was of the opinion that centres should be encouraged to report incidents involving even minor dose variations as these reports served an educational purpose.

DESCRIPTION OF INCIDENT	ACTION TAKEN
On 21 July 2008 an 84 year-old female patient received a repeat CT scan during the investigation of a pulmonary embolism. She had received an identical scan on 8 July 2008. On 21 July the second scan was performed to investigate a shadow noticed on a previous chest radiograph. The report had stated that the physician requesting the scan on July 21 was unaware that the patient had received an earlier CT scan, and had this been known the second scan would not have been performed. The patient received a total effective dose of approximately 8 mSv as a result of the unnecessary scan.	In response to the incident, the centre amended its time-out form to include the question "When did you last have a CT scan?" Clerical staff were also instructed to check for previous or future bookings in the radiology information systems to avoid unnecessary bookings.
An unintended irradiation of a patient occurred at a Melbourne hospital on 8 August 2008. The incident involved an incorrect high resolution CT scan of the spine on a 56 year-old male patient. Two patients with the same name had presented to the medical imaging department and the wrong patient was selected for the scan. The cause of this incident was the failure of the radiographer to identify the patient correctly. The total effective dose received by the patient due to the unnecessary scan was approximately 6.4 mSv.	The hospital conducted an investigation into the incident. In response to the incident the hospital has decided to introduce an additional step in its ID protocol - when the name, date of birth, and address, are confirmed the radiographer is to tick each unique identifier on the request slip and sign to confirm that this has been done. This step essentially utilises the request slip as a time-out form. The hospital will also emphasise to staff the importance of adhering to the ID protocol and it will hold education sessions about this issue. An audit assessing compliance with the protocol will be routinely conducted.
An incorrect CT chest scan was performed on a 77 year-old female patient. The patient reported to the medical imaging department at a Melbourne hospital for a CT procedure and her request form was processed. Another request form was also found with a patient name which appeared to be that of the patient. The handwriting on the second request form was slightly illegible and the request was erroneously taken by the radiographer as being for the first patient. As a consequence, the patient was scanned for the correct procedure (CT adrenal study) and also received a CT chest scan which was not requested. The total effective dose received for the unnecessary extra scan was approximately 4 mSv.	In response to the incident, the imaging department has advised that requests will no longer be accepted without a patient's date of birth and/or address. The hospital has also reminded its radiographers to check the date of birth. The Committee requested that the Radiation Safety Team write to the imaging department to recommend that they implement a time-out procedure by adopting the Department's generic time-out form.

DESCRIPTION OF INCIDENT	ACTION TAKEN
A 24 year-old female patient underwent an abdominal/pelvis CT scan on 7 August 2008 at a private medical imaging practice. The resulting report indicated an intrauterine fluid collection that appeared to be a gestational sac. It was subsequently confirmed that the patient was pregnant at the time of the procedure with the gestational age being approximately 7 weeks. Prior to the procedure, the patient had indicated that she did not believe she was pregnant. The scan consisted of 2 scout views, and one helical scan. The patient received an equivalent uterine dose of approximately 34 mSv.	In response to the incident, the Safety Committee of the practice requested that a report be prepared detailing the estimated dose to the foetus and the associated risks to the foetus for all incidents involving an unplanned exposure to a pregnant female. The Committee requested the Radiation Safety Team to write to the practice advising that staff at the practice be reminded of the importance of determining whether females of child bearing age are pregnant. It was important to do so in a manner that did not cause offence.
A 68 year-old female patient was administered 880 MBq ^{99m}Tc MDP, intended for a bone scan. The patient was told to return to the nuclear medicine department approximately four hours after the administration. The instructions given to the patient about returning for the scan were not sufficiently clear to her and she went home which was 2.5 hours away. All attempts made by staff to contact the patient in time for the scan failed. As a result, the process had to be repeated.	The total effective dose to the patient as a result of the administration is estimated to be approximately 5 mSv. In response to the incident, the hospital has reemphasised to staff that patients must be given written instructions about returning for a scan post administration.
A CT scan was performed on the wrong patient in a Melbourne hospital on 4 August 2008. This incident occurred because two patients with identical first names and surnames had been staying in the same ward. One of these patients required an abdominal CT scan; however the other patient was taken for the scan. The total effective dose to the patient as a result of the scan was approximately 8 mSv.	The Committee recommended the implementation of a time-out policy within the hospital.

DESCRIPTION OF INCIDENT	ACTION TAKEN
An incident occurred at a Melbourne hospital on 7 October 2008, involved a nuclear medicine scan being performed on an incorrect patient due to the wrong patient identification label being attached to the request form for the procedure. The patient was administered 1030 MBq ^{99m}Tc Sestamibi. The total effective dose received by the patient because of the administration was estimated to be approximately 10.6 mSv.	The Committee recommended the implementation of a time-out policy within the hospital.
A request was written by a medical practitioner for a CT scan of a 74 year old male patient. The practitioner had intended for the scan to be performed in 5 to 6 months but it was performed immediately due to a misinterpretation by a radiographer. The total effective dose to the patient as a result of the scan was approximately 2.8 mSv.	The Committee reviewed a copy of the practitioner's notes on the request and agreed that the intentions were ambiguous. They could have been interpreted as requiring an immediate scan or a scan 5 to 6 months later.
A 63 year old female patient underwent a gated cardiac blood pool scan at a Melbourne medical imaging centre. Pyrophosphate (pyp) was injected, followed by 830 MBq of ^{99m}Tc (in pertechnetate form) as is standard procedure at the centre. During imaging, however, it had been discovered that the blood cells had not been labelled by the pertechnetate and no diagnostic information was obtained. The procedure was repeated the next day (10/10/08) using 1,066 MBq of pertechnetate and an acceptable image was obtained from this scan. It had been thought that the failed labelling was due either to the pyp not being administered at all, or being injected into tissue rather than the bloodstream. The patient received a total effective dose of approximately 14 mSv as a result of the failed scan.	The Committee requested that the outcomes of the investigation into the incident by the centre be forwarded to the Committee.

DESCRIPTION OF INCIDENT	ACTION TAKEN
An incident involving the incorrectly targeted radiotherapy treatment of a patient occurred at a Victorian hospital on 3 and 5 November 2008. There had been a mismatch between the position marked by tattoo on the patient as the isocentre for the treatment and the isocentre position on the treatment plan. A possible discrepancy had first been noticed at the first treatment session. The treatment sheet had shown the isocentre to be set at 8 cm inferior to the suprasternal notch but the tattoo was observed to be located 13 cm inferior to the suprasternal notch. The therapists who were performing the first treatment fraction agreed that a documentation error was the most plausible explanation for the discrepancy and chose not to query the radiation therapists who had simulated that patient as to the correct location of the isocentre. The report had stated "a 5 cm error in tattoo placement seemed a remote likelihood when compared with the likelihood of an arithmetic error". The discrepancy was reported in the centre's 'RiskMan' system, and treatment continued until the second fraction. Further discussion had ensued regarding the 'RiskMan' report between radiation therapists, and it was realised that an error had been made.	Investigations by Radiation Safety Team revealed that up to twelve radiation therapists had been involved in the treatment of the patient, and that this may have contributed to the incident. The Committee was advised that the hospital had devised a risk reduction action plan that included: • checking of all landmarks and tattoos by the senior CT radiation therapist according to the tattooing and land marking protocol; • use of land mark and tattoo stickers during all simulation/CT planning sessions; • verification of discrepancies of landmarks to tattoos by senior planning therapist; and • use of kilovoltage on-board imaging for all chest treatments, rather than megavoltage imaging. Radiation Safety Team circulated a summary of the incident and its causes to other radiotherapy centres.
An 81 year-old female patient underwent a CT scan of the facial bones and brain at a Melbourne hospital at 11.30 pm on 2 November 2008. After the scan, the referral form for the scan was left in the CT 'to be done' slot, the patient's details were not removed from the daily running CT whiteboard and the scan was not verified in the radiology information system. At the midnight shift change for radiography staff, there was inadequate communication between incoming and outgoing staff regarding the patient's scan. As a result, the patient was later brought back to the radiology department and the scan was repeated unnecessarily. The patient received a total effective dose of approximately 2.1 mSv as a result of the repeated scan.	The hospital reinforced its policy that once a patient has undergone a CT scan the procedure should be signed off in the radiology information system. The Committee advised the Radiation Safety Officer of the hospital that the use of a whiteboard to manage the patient schedule compromised the effectiveness of using a radiology information system.

DESCRIPTION OF INCIDENT	ACTION TAKEN
A non-English speaking 25 year old female patient was referred for an abdominal CT scan at a medical imaging practice on 6 November 2008. With the use of a translator it was noted on the contrast form that she was currently breastfeeding but that she was not currently pregnant. The patient was advised to express breast milk for her baby and return to conduct the procedure. The patient had returned to the centre for the scan. Due to the patient's inability to speak English, the radiographer did not ask the patient prior to the scan whether or not she may be pregnant. During the scan images through the uterus clearly revealed the presence of a foetus and the procedure was immediately stopped. The data acquired from the scanner indicated that the entire uterus had been scanned. It was subsequently determined that the foetus was approximately 17 weeks old at the time of the procedure. The uterus was exposed to an equivalent dose of approximately 21 mSv as a result of the procedure.	The Committee agreed that the patient should have been asked if she was menstruating and given a pregnancy test upon a response in the negative. The Committee noted that a telephone interpreter could have been used to overcome language difficulties.
A 34 year old female patient underwent a CT scan of the kidneys, ureter, and bladder. Subsequent to the scan, the patient discovered that she was pregnant. She contacted the medical imaging practice where she had had the scan on October 29 2008 to advise them. The gestational age was approximately 3.5 weeks at the time of the scan. At the time of the scan the patient indicated that she was not pregnant. The patient had been incorrectly advised by her GP to consider terminating the pregnancy because of the incident. The Committee was advised that she had since seen a different GP and has been referred to an obstetrician to manage the pregnancy. The foetus received an effective dose of approximately 8.5 mSv.	The medical imaging practice advised the patient not to terminate the pregnancy immediately upon being informed of the GP's advice. The Radiation Safety Officer (RSO) for the medical imaging practice was advised that questioning female patients of child-bearing age as to their last menstruation may help alert staff to the possibility of pregnancy. The RSO was also advised that the general practitioner who advised that the pregnancy should be terminated should receive counselling regarding risks of radiological procedures and communication of those risks.

DESCRIPTION OF INCIDENT	ACTION TAKEN
Six failed nuclear medicine scans occurred at the nuclear medicine centre of a Melbourne hospital. All six scans had been intended to utilise ^{99m}Tc-hydroxymethylene diphosphonate (HDP) but in each instance the scans showed free ^{99m}Tc uptake and no diagnostic information could be obtained. The activity administered to the patients had varied from 794 to 850 MBq. In all six instances the injected radiopharmaceutical had been reconstituted using the same vial of HDP bone agent and ^{99m}Tc, both supplied by the same company. Failure to achieve the correct uptake appeared to have been caused by the particular vial of HDP bone agent used. A manufacturing fault had been suspected as the cause. The company that supplied the agent was advised of the suspected defective product. There exists the further possibility that there was no HDP in the vial, although this is very unlikely. The NMT involved could not recall checking the vial for contents prior to reconstitution. The patients received approximately 10 to 11 mSv effective dose as a result of the failed scans.	The Committee recommended that the medical imaging company that operated the nuclear medicine centre be advised that centres reconstituting radiopharmaceuticals on-site have an obligation to perform quality control on these products before use.
An unintended CT scan was performed on a patient at a Melbourne hospital. The scan was requested for an 85 year-old female patient. A referral slip was faxed from the emergency department to the medical imaging department and the scan was performed correctly. The following day the patient was asked by the referring physician if she had undergone a CT scan. The patient responded that she had only had x-rays. The physician sent a copy of the original referral to the medical imaging department and a second scan was subsequently performed. After the scan had been completed the radiographer involved had realised that the same procedure had been performed previously on the patient. The referring physician was contacted and he admitted that he did not adequately follow up on the first scan. The patient received an effective dose of approximately 10.4 mSv as a result of the scan.	The Committee sought clarification as to whether the referral for the second scan had been a copy of the original referral, or a second referral form had been created. Correspondence with the Radiation Safety Officer (RSO) of the hospital indicated that the referral for this scan was faxed the day after the request was written. As a result, the Radiation Safety Team wrote to the RSO, advising that referral forms that are faxed should be labelled both with the word “FAXED” and with the date.

DESCRIPTION OF INCIDENT	ACTION TAKEN
On 24 November 2008, the Department's Radiation Safety Team was advised by a Melbourne company that they could not locate two sealed sources containing ^{241}Am with an activity of approximately 3.7 GBq each. The sources had been in storage after having been removed from two gauges used to determine the level of fluid in bottles and cans. The company believed the loss occurred on or about 13 November 2008 when a load of surplus metal was consigned to a scrap metal merchant. The possibility exists, however, that the source may have left the company's premises by another route, e.g. to landfill. The company that lost the source believed the loss to be accidental disposal rather than theft.	An extensive search of the scrap metal merchant's stock and investigation of other possible routes by which the sources may have left the company's premises did not result in the sources being found. It appears that the most likely scenarios are that the sources were eventually melted together with a large volume of other scrap metal or were disposed of to landfill and covered over with inert material. In either case, the sources would not present a significant hazard to anyone. The sources have been declared as lost in the licence database maintained by the Department.
A utility vehicle that was transporting a nuclear moisture/density gauge (NMDG) was involved in a collision with another vehicle in rural Victoria. As a result of the collision, the NMDG ended up in an irrigation channel that ran beside the road.	Officers from the Radiation Safety Team attended the scene of the incident to respond to the incident and provide advice to emergency service personnel on site. The NMDG was transported in accordance with legislative requirements and was not damaged as a result of the incident. It was transported to the premises of the company that owned the NDMG by an employee of the company.
At 9:30 am on Monday 16 February 2009, an employee of a geotechnical engineering company telephoned the Radiation Safety Team (RST) of the Department and reported the theft of one of the company's nuclear density/moisture gauges (NDMG) from the secured underground car park of the residence of a company employee. The driver of the utility advised that the ^{137}Cs source rod was locked in the shielded position and the transport case was locked. A person in the neighbouring apartment of the utility driver stated that he witnessed the theft and would be able to identify the men who stole the NDMG as he had seen them a number of times at the apartment buildings.	The driver of the utility reported the theft to the local Police. The RST has advised the State Emergency Response Officer (Victoria Police) and the Australian CBRN Data Centre of the Australian Federal Police of the theft. RST also advised other jurisdictions and the Australian Radiation Protection and Nuclear Safety Agency of the theft. The stolen NDMG was returned to the car park of the employee's residence on 18 March 2009.

DESCRIPTION OF INCIDENT	ACTION TAKEN
On 6 February 2009 six patients at a Melbourne hospital were administered with ^{99m}Tc in which the injectate following injection had a biodistribution consistent with unlabelled ^{99m}Tc. The Committee had been advised of a similar incident that occurred at another hospital on 8 December 2008. The Committee was advised that the two incidents appeared to be related, as the supplier of the HDP pharmaceutical had received six reports of defective product, all having the same batch number. The Committee thought it was unusual that only some vials from a batch would be defective, as it would be expected that, if there was a problem with a batch, the whole batch would be affected. The supplier did not believe the batch was defective, and it was their policy not to issue a product recall unless instructed to do so be their USA-based supplier.	The Committee recommended that the Radiation Safety Team write to all nuclear medicine centres performing reconstitution of radiopharmaceuticals to advise them that they should undertake quality control testing of the product prior to administration. The Committee also recommended that the Radiation Safety Team determine which other centres may have been affected by the defective product.
A nuclear medicine technologist at a Melbourne hospital obtained a blood sample from a 58 year-old male patient for a cell labelling study. The blood was labelled and injected back into the same patient. The technologist failed to observe the nuclear medicine department's patient identification policy. During the injection the technologist realised that the procedure had been performed on the wrong patient. The injection of the labelled blood ceased immediately upon this realisation. It had been estimated that approximately 174 MBq of ^{99m}Tc was injected into the patient. The patient received an effective dose of approximately 1.9 mSv as a result of the administration.	The technologist concerned was counselled by the chief nuclear medicine technologist about the importance of thoroughly verifying patient identity. The technologist conceded that she had made a mistake, and had been remorseful and concerned for the patient's welfare. The Committee recommended that the Radiation Safety Team write to the hospital to stress the importance of staff following established patient identification protocols.

DESCRIPTION OF INCIDENT	ACTION TAKEN
A 53 year old female patient was prescribed palliative radiotherapy to the paraaortic region. During the planning for the treatment, the isocentre was shifted 20 cm inferior to its originally proposed position, from the chest to the abdomen. This fact was not recorded on the electronic treatment sheet at the completion of planning. Part of the data had been entered when the plan was given to the charge panning therapist for checking. It had been intended that the rest of the data entry be completed at a later stage. Prior to the first treatment fraction an electronic portal image had been taken to verify the positioning of the patient. Verification was done via image overlay. It had been noted by the Chief Radiation Therapist that this mode was more suitable for detecting smaller variations, and was not as likely to pick up major geographical errors such as had occurred in this case. The first (posterior) treatment field was completed and the machine was being repositioned for the second (anterior) field. At this point the treating therapist noticed the coordinates and realised that the isocentre location was not correct.	The Committee reviewed a root cause analysis report relating to the incident. It was agreed that the 'auto-assist' image overlay mode should not have been used to verify patient positioning prior to treatment, as this mode can make comparison difficult due to the low quality of the portal images and difficulty distinguishing landmarks. A side-by-side comparison of images would have been preferable. The Committee noted that the report indicated that the last check prior to treatment had been performed by a radiation therapy student, rather than a qualified radiation therapist. It appeared that there was a need to reinforce the policy of performing double checks on patient setup prior to treatment. The Committee noted the risk reduction plan provided.
A 36 year-old female patient was referred for a non-urgent thoracic spine CT scan. When the patient was asked by the radiographer if there was any chance that she could be pregnant, she answered that she was "fairly sure" that she wasn't pregnant. The patient was told that the medical imaging centre involved would require her to undergo a pregnancy test. The patient replied that she was a nurse, was sure that she wasn't pregnant and wanted the examination on the day and didn't want to come back at a later date. The radiologist and radiographer acquiesced to performing the examination. The patient later became aware that she was approximately six weeks pregnant at the time of procedure, and contacted the clinic to advise them of this. The effective dose to the embryo was approximately 0.22 mSv.	An incident information sheet was forwarded to the medical imaging centre.

DESCRIPTION OF INCIDENT	ACTION TAKEN
A 10 year-old male patient was scheduled to have a lung perfusion study after a cardiac catheter procedure that was to have been performed in the cardiology department of a Melbourne Hospital. The cardiac catheter procedure did not go ahead on the day that it had been scheduled to be performed. The nuclear medicine department was not informed that the cardiac intervention had not taken place as planned. After the patient was asked about their "procedure" the previous day, the parents and nursing staff did not mention that the cardiac catheter procedure had not gone ahead. The patient was administered with 80 MBq ^{99m}Tc-9 macro-aggregated albumin (MAA). It was subsequently realised that this had not been required. The Committee noted that the person managing the patient's case should have been aware that the patient did not have the cardiac catheter procedure, and should have requested that the nuclear medicine procedure be cancelled. The Committee requested to see the hospital's follow up report regarding the incident when it was available.	The Radiation Safety Team wrote to the Hospital in question requesting that a report on their investigation into this incident be forwarded to them.
A 12 year-old female patient developed radiation tissue reactions as a result of fluoroscopy performed during a procedure involving the placement of a pulmonary artery stent. The screening time required to complete this procedure was significantly greater than had been expected due to difficulties in the placement of the stent. The procedure took place on 7 April 2008 with a follow-up procedure on 28 April 2008. The skin entrance dose to the patient for the first procedure was approximately 14 Gy. The dose for the follow-up procedure on 28 April 2008 was approximately 2.3 Gy. The incident had not been reported until almost a year after it occurred. There was an apparent reluctance to report the incident and provide further information. Reported details of the symptoms caused were vague. It was also not clear who was using the fluoroscopy equipment during the procedure so there could be no way of knowing whether they held a use licence.	The Radiation Safety Team wrote to the hospital involved requesting information regarding the follow-up of the case, and processes that the hospital has in place to reduce radiation exposure to patients during interventional fluoroscopy procedures.

DESCRIPTION OF INCIDENT	ACTION TAKEN
A 55 year-old female patient developed radiation effects (erythema) as a result of fluoroscopy performed during a coronary interventional procedure on 17 March 2009. The skin entrance dose to the patient was approximately 15 Gy. In a follow-up procedure on 24 March 2009 the dose was approximately 1.5 Gy (8.6 minutes screening time).	The Radiation Safety Team wrote to the hospital involved requesting information regarding processes that the hospital has in place to reduce radiation exposure to patients during fluoroscopy procedures.
A company advised the Radiation Safety Team that the results of a wipe test conducted on the ^{241}Am source capsule of a fixed industrial radiation gauge at the company's plant indicated that the source capsule had leaked a small amount of radioactive material. The wipe test recorded a reading of 4000 Bq (about 0.00001% of the source's activity). The radioactive material had also been detected on a gasket that was part of the gauge housing and that was in contact with the source. Two officers from the Radiation Safety Team attended the site in response to the report and conducted an investigation, including radiation surveys to ensure that no area was contaminated with ^{241}Am.	The gauge was placed in storage awaiting disposal of the source and the gauge housing.
A patient received a skin entrance dose of approximately 690 mGy during an interventional angiography procedure on 25 March 2009. On 8 April 2009 the patient underwent a further procedure and received a skin entrance dose of approximately 6.1 Gy. The dose received by that patient appeared to have been the cause of an itchy redness on the patient's upper back.	The Radiation Safety Team wrote to the hospital regarding the incident, asking for details of the organisation's processes for incident investigation, follow-up, and corrective action.

DESCRIPTION OF INCIDENT	ACTION TAKEN
A 78 year-old male patient underwent an angiography procedure on 11 May 2009 for a mesenteric embolisation. The skin entrance dose recorded for this procedure was approximately 16 Gy. The high dose was attributed to a long screening time, high frame rate, and many acquisitions being used. The Committee noted that the report implied that a cardiologist had performed the procedure, and there was concern that the individual may have selected an inappropriately high frame rate that would have contributed to the high dose. This raised questions as to competency requirements for different types of fluoroscopy procedures. The Committee was advised that at the present time, use licences authorised the use of fluoroscopy apparatus for imaging during diagnostic and interventional cardiac procedures, and did not specify different types of fluoroscopy procedures.	The Radiation Safety Team wrote to the hospital regarding the incident, asking for details of the organisation's processes for incident investigation, follow-up, and corrective action.
The Committee was informed that the Minister for Health had received correspondence from a radiologist at a Melbourne Hospital alleging improper practices regarding the use of the new 320 slice Toshiba CT scanner at the hospital. The radiologist alleged that the scanner was being used to screen asymptomatic persons.	This incident raised a number of issues that were investigated by the Radiation Safety Team.