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Written by:	William Bartolo, Bartolo Safety Management Service The Radiation Safety Committee
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Background

Any research involving diagnostic procedures must have a Radiation Medical Practitioner (Radiologist or Medical Specialist for human research; veterinarian or veterinary radiologist for animal research) as a named investigator on the project, if live human subjects or animal subjects are involved.

Personnel involved in diagnostic or interventional radiology procedures could receive a radiation exposure principally from scattered radiation from the volunteer, animal or patient being examined. In normal circumstances no-one, other than the animal or patient, should be exposed to the primary X-ray beam, but such exposure could occur unintentionally.

Members of the public (for example, the mother of a paediatric patient, or the owner of a veterinary patient such as a dog or horse) may need to be in an Imaging Room while a diagnostic or interventional radiology procedure is taking place and could also receive a radiation exposure.

University personnel or members of the public in adjoining areas will be adequately protected as long as the required radiation shielding has been installed as required in RMP Section 15.

In addition, a medical physicist is required to provide Human Research Ethics and Animal Ethics Committees with a radiation dose estimation and risk assessment for any research studies that involve the research subjects receiving an exposure from ionizing radiation, for humans in accordance with the requirements of <u>RPS8 (ARPANSA 2005)</u>.

Responsibilities

The Radiation Medical Practitioner (Radiologist or Medical Specialist) or veterinarian or veterinary radiologist for animal research

The abovenamed person is responsible for the clinical management of the animal or patient undergoing a diagnostic or interventional radiology procedure. This includes the decision to proceed with a radiology procedure based on the specialist's knowledge of the potential risks and benefits of the procedure, taking into account the clinical information, and the sensitivity and specificity of the procedure.

The Referrer

The referrer of the patient for a research diagnostic procedure needs to be satisfied that the procedure is justified being aware that the patient will receive a radiation exposure. The referral must state the clinical question that the diagnostic procedure is intended to answer and the research reason for this exposure. The referral should also alert the radiation medical practitioner when the referrer is aware that a female patient or patient is pregnant or is breast-feeding. The referral may be in hard copy or electronic form.



The Radiographer

The radiographer is responsible for performing diagnostic radiology procedures as prescribed by the radiation medical researcher or practitioner in accordance with the University's written standard protocols.

This will include:

- correctly identifying the patient, the procedure and the site to be examined;
- following established imaging protocols to ensure optimal data acquisition and analysis;
- performing quality assurance procedures for instrumentation and image quality.

The Radiology Medical Physicist

A radiology medical physicist is required to assess, verify, and approve the research procedure and is to be readily available for consultation (in person, by phone, or through the internet) on optimisation of medical exposures, including clinical dosimetry and quality assurance, and to give advice on matters relating to radiation protection.

The radiology medical physicist works closely with the radiologists and radiographers in the optimisation of clinical studies – through image acquisition, analysis, and display optimisation, and ongoing oversight of the quality control of equipment.

In addition, a medical physicist is required to provide Human Research Ethics and Animal Ethics Committees with a radiation dose estimation and risk assessment for any research studies that involve the research subjects receiving an exposure from ionising radiation, in accordance with the requirements of RPS8 (ARPANSA 2005).

The Radiation Safety Committee

The RSC will oversee and provide advice on radiation safety within facilities performing diagnostic or interventional radiology.

Procedure

Procedures to Minimise Radiation Exposure

The radiation dose to the operator or a member of the public can be minimised by prudent positioning relative to the X-ray tube, patient and/or structural shielding. Where there is no structural shield and the operator has to remain in the room during general radiography, such as with mobile radiography, the operator should stand:

- at least two metres away from the X-ray tube; and
- outside the primary beam.

In these circumstances the operator should wear a protective apron.

Where a person is required to be present in a controlled area during an X-ray exposure, such as in a fluoroscopy suite, that person should not remain any closer to the patient or the X-ray tube than is necessary. The operator should ensure that any person who is required to remain in the room during the radiation exposure wears protective clothing or stands behind protective shields.



The design of all radiology suites should include a protected area in which the operator's console is located. The operator's console should be the only area within the radiology suite that radiography and remote-controlled fluoroscopy systems (usually over-table X-ray tube systems) are operable.

Personal Protective Equipment

Aprons, thyroid shields and other personal protective devices should meet the requirements of the EPA Policy on x-ray protective clothing. From NSW Policy on x-ray protection clothing:

A1.1.3 Aprons and gloves must have radiation attenuation of not less than 0.3 mm lead equivalence at 100 kVp.; A1.1.4 Aprons must cover the full width of the front of the body from the throat to within 10 cm of the knees, as well as the sides of the body. Wrap-around types of aprons must cover from the scapulae to below the buttocks. Fastenings must be provided to keep aprons closed.1 Refer to part A3 for different types of x-ray protective clothing. Where aprons have two overlapping front panels the total of the two panels when worn correctly must not be less than 0.3 mm in lead equivalence at 100 kVp.

Operators and other staff should use thyroid shields in all fluoroscopy, cardiology, and interventional radiology suites. Relevant staff should be provided with protective gloves for use during all radiological procedures in which the hands and forearms may be in the primary beam.

All personal protective clothing should be clearly labelled with its lead equivalence and a unique identification number as specified by AS/NZS 4543.3.2000, and examined under fluoroscopy at least annually to confirm its shielding integrity. If damage to an apron is seen or suspected, it must be reported to the Facility Manager and Radiation Safety Committee, and the apron immediately removed from service until its shielding integrity can be checked.

Protection of Relatives and Carers

- Any relatives of the patient or patient should be discouraged from entering the room during an examination unless they are required to assist with the examination. If they insist, they must be asked to stand at least 2m away from the patient and must wear a protective apron.
- Any person aiding an examination (e.g., restraining the patient) shall use a protective apron and avoid facing the direct primary beam. If their hands are near the primary beam, they should be provided with protective gloves.
- When children are to be examined, parent participation should be encouraged, and adequate protection provided to the parents, along with clear instructions as to the parent's role.

DENTISTRY

Besides all the above requirements for general radiology and any of the other requirements of RPS 10, the following excerpt from <u>ARPANSA RPS No.10</u> is to especially be considered and included in all routines:

`Most protective aprons no longer contain lead, but are an alloy of high atomic number materials. References to aprons apply to all personal protective clothing.'



Clinical Assessment of the Need for Radiography

The nature and extent of an actual or a suspected dental condition, its early detection, treatment and response to treatment must be the primary determining factors in submitting the patient to radiographic examination.

Radiology must not be used as a substitute for a clinical investigation, and therefore radiography must not be undertaken until a medical history has been taken and a clinical examination has established the need for a radiological examination, unless an emergency situation dictates otherwise.

Radiology is a most valuable aid to oral diagnosis, but it must be employed in accordance with the dental and general health needs of the individual patient.

Research Projects Involving the Irradiation of Humans

Where a project is to be undertaken for research purposes on humans the research must conform to generally accepted ethical and scientific principles.

To be medically justified, the information gained must be used to affect the care of people discovered to have a particular condition. For each project, there must be full compliance with the NHMRC's National Statement on Ethical Conduct in Research Involving Humans (1999) and the requirements of ARPANSA's <u>Code of Practice for Exposure of Humans to Ionising Radiation for Research Purposes</u>, Radiation Protection Series Publication No. 8 (2005).

Such projects must be so designed that the frequency of radiographic examinations and the number of images per examination is the minimum necessary, and every effort must be made to provide the individual patient with some direct benefit from the examinations made.

VETERINARY

Diagnostic radiology must only be undertaken if:

- (a) there is a clear indication for the procedure; and
- (b) it can be done without undue radiation hazard.

Only people who are essential to a procedure are permitted to be present during radiological examinations.

Each person present during a radiological examination must be:

- properly instructed to enable them to understand their part in the proposed procedure; and
- where practicable, positioned behind a protective screen.

Each person who is unable to position themselves behind a protective screen must:

- wear a protective apron, thyroid shield and lead glasses; and
- remain as far as practicable from:
 - (i) the primary X-ray beam,
 - (ii) the animal, and
 - (iii) the X-ray tube assembly.

Adequate facilities and devices must be available to ensure:



- physical control over the animal; and
- protection of the operator.

Radiography must only be carried out using an appropriate X-ray machine that satisfies the relevant requirements of Schedule B, <u>ARPANSA RPS 17.</u>

Radiography may be considered in two categories:

- radiography within a defined X-ray room or area. A defined X-ray room or area must have sufficient shielding to ensure that no person can receive a radiation dose in excess of the relevant radiation protection limits specified in RPS1;
- or
- b. radiography outside a defined X-ray room or area when a mobile or portable X-ray machine is taken to the animal. An X-ray examination must not be carried out outside a defined X-ray room or area unless it is not practicable to bring the animal to that room or area.

For further information and controls please refer to ARPANSA RPS 17 Schedule B.

The handling and exposure of the animals must comply with the Animal Research Act 1985 and also the Australian code of practice for the care and use of animals for scientific purposes.

Documentation

None

Audit

The integrity of protective aprons to be audited at least on an annual basis. Staff radiation exposures to be reviewed quarterly.

References and relevant links

NSW Health Policy Directive Correct Patient, Correct Procedure, Correct Site

ARPANSA. Radiation Protection in Dentistry. RPS Publication No. 10, December 2005

Safety Guide for Radiation Protection in Diagnostic and Interventional Radiology (RPS 14.1) ARPANSA 2008

Radiation Protection in Veterinary Medicine. RPS No. 17. ARPANSA. July 2009 – EPA policy on x-ray protective clothing

Animal Research Act 1985 No 123 Animal Research Regulation 2010.



Date	Revision No.	Author and Approval
Dec 2014	Version 1	William Bartolo, Bartolo Safety Management Service
May 2016	Version 2	William Bartolo, Bartolo Safety Management Service
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REVISION & APPROVAL HISTORY