STANDARD OPERATING PROCEDURE FOR
MAMMOGRAPHY EXAMINATIONS

ALBURY WODONGA HEALTH

WODONGA CAMPUS
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GLOSSARY OF TERMS IN THIS STANDARD OPERATING PROCEDURE:

**Australian Health Practitioner Regulation Agency (AHPRA):**
The Health Professional council area regularity body who’s function is maintaining and publishing a public register of properly qualified members of the professions. They approve and uphold high standards of education and training and investigating complaints and taking appropriate action.

**ALARA:**
As Low As Reasonably Achievable:
Radiation must be kept As Low As Reasonably Achievable (ALARA). The principle that radiation exposures must be reduced to the lowest level that can reasonably be achieved.

**CPD:**
Continuous Professional Development

**LMP:**
Last Menstrual Period.
By convention, pregnancies are dated in weeks starting from the first day of a woman's last menstrual period (LMP). If her menstrual periods are regular and ovulation occurs on day 14 of her cycle, conception takes place about 2 weeks after her LMP.

**Operator:**
Radiology technicians, technologists, and sonographers fall within the broad scope of a radiography profession. Using radiation in the form of x-rays, magnetic resonance imaging and ultrasound, radiographers assess, diagnose and treat patients for a variety of injuries and diseases. Often part of a medical or surgical team, radiographers are typically involved in initial patient evaluation and testing, providing diagnostic and evidentiary data for Physicians.

**PACS:**
Picture Archiving and Communications System:
A network of computers used by radiology departments that replaces film with electronically stored and displayed digital images. It provides archives for storage of multimodality images, integrates images with patient database information, facilitates laser printing of images, and displays both images and patient information at work stations throughout the network. It also allows viewing of images in remote locations.

**RIS:**
Radiology Information System.
A RIS is a computerised database used by radiology departments to store, manipulate, and distribute patient radiological data and imagery. The system generally consists of patient tracking and scheduling, result reporting and image tracking capabilities. RIS complements Hospital Information Systems (HIS), and is critical to efficient workflow to radiology practices.
Radiation (Ionising):
Radiation that produces ionisation in matter. Examples are alpha, beta, gamma and x-radiation and neutrons. When these radiations pass through the tissues of the body, they have sufficient energy to damage DNA.

Radiation Medical Practitioner:
A radiologist is a physician who reads and interprets digital images, or x-rays, of patients obtained through a variety of cameras, machines, and imaging equipment. The radiologist uses this information to help diagnose the patient and consult with the treating Physician to develop a course of treatment.

Referral or Request Form:
A request for a diagnostic imaging examination or procedure usually requires the completion of a written request or referral form, via which key information is communicated to the imaging facility from the referring Practitioner.

Radiation Medical Practitioner:
A radiologist is a physician who reads and interprets digital images, or x-rays, of patients obtained through a variety of cameras, machines, and imaging equipment. The radiologist uses this information to help diagnose the patient and consult with the treating Physician to develop a course of treatment.

RSO:
Radiation Safety Officer
The appointed person to advise AWH Management and Executive on all matters relating to radiation safety with the Organisation. In this case the RSO is the Practice Manager.
INTRODUCTION:
Standard Operating Procedures (SOPs) are succinct formal documents designed to achieve consistency by specifying standard practice in performing those functions.

AIM:
This document covers all practical issues required to comply with Code of Practice for Radiation Protection in Medical Applications of Ionizing Radiation 2008.

PURPOSE AND SCOPE:
The purpose of this SOP is to describe the process of radiation for any patient undergoing an x-ray examination.
The SOP will cover:
- Procedure for identification of individuals undergoing mammographic examination or procedure.
- Procedure for making enquires of females of childbearing age.
- Procedure for clinical handover in Medical Imaging.
- Procedure for justification / authorisation of a mammographic examination.
- Procedure for the assessing of the patient radiation dose.
- Procedure for setting and monitoring dose.
- Procedure for accidental or unintended radiation exposure.
- Procedure for Ensuring that all Operators understand the Principles of Dose Reduction.
- Procedure for the Provision of Mammography Protocol and Standard Exposure Factors.
- Systems of Work for Operators.

This SOP will be followed by all staff involved in the use of mammography equipment. All members of staff who use radiation, or are in any way involved with its use, shall do so only in accordance with State Registrations. Staff who work with radiation shall exercise reasonable care, use any protective equipment provided, report any defect in such equipment, wear any radiation monitors provided and undertake any training deemed necessary.

ROLES AND RESPONSIBILITIES:
Key roles and responsibilities are defined in the Code:
- **The Responsible Person (Management Licence Holder):** the person who has the overall management responsibility of the radiation source or practice.
- **The Medical Radiation Practitioner:** the person responsible for the justification and optimisation of the medical procedure involving the exposure of the patient to ionizing radiation.
- **The Operator:** the person who exposes the patient to ionizing radiation.
PROCEDURE FOR IDENTIFICATION OF INDIVIDUALS UNDERGOING A MAMMOGRAPHY EXAMINATION:

PURPOSE:
To ensure the correct identification of patients prior to exposure.

SCOPE:
All mammography examinations.

RESPONSIBILITIES:
The operator initiating the exposure is responsible for ensuring the final check of patient identity has been made before proceeding. The operator checking patient identity will adhere to this procedure.

PROCEDURE:
- The operator must undertake a positive patient identification (PPI) check and therefore they must ask the patient to state their name, address and date of birth. These details must be checked against the request form and if there are any discrepancies these must be investigated before undertaking the examination. *(Refer to Annex 1)*
- If the operator is satisfied that they have the correct patient they will sign the 'Time Out' stamp on the referral. This will be scanned into the patient's records on Radiology Information System (RIS) for reference.
- For patients unable to communicate through illness, physical or mental disability or language barrier, check identification bracelets or ask an escorting relative, carer or interpreter. A positive identification must be given.
- If there is no escort or identification bracelet on a patient, who is unable to give their details, contact the referring department and ask for someone who can identify that patient, such as a nurse or relative, to visit and identify the patient. The person who checks the patient identity will sign the request form in the “time out” stamp.
- A history of any previous relevant mammogram investigations should be taken from the patient prior to carrying out the new procedure to correlate the clinical detail provided on the radiology request form to that patient. The RIS and Picture Archive and Communication System PACS should be checked in every patient contact to ensure up to date records and any previous radiology or information.
FLOW CHART FOR THE PROCEDURE OF POSITIVE PATIENT IDENTIFICATION (PPI) UNDERGOING A MAMMOGRAPHY EXAMINATION

1. Medical Imaging with referral and details entered/confirmed onto RIS

2. Patient enters mammography Room Positive Patient Identification (PPI) performed

   - PPI criteria satisfied
     - PPI 'Time Out' documentation performed
     - Examination undertaken subject to justification
   - PPI criteria NOT satisfied
     - Additional information required from alternate source
     - PPI criteria NOT satisfied
     - Examination not performed
PROCEDURE FOR MAKING ENQUIRES OF FEMALES OF CHILDBEARING AGE:

PURPOSE:
To prevent unnecessary irradiation of a foetus from a medical exposure by ensuring enquiries with regard to pregnancy are made in an appropriate and consistent manner.

SCOPE:
All women of childbearing age who are to undergo mammography examinations.

RESPONSIBILITY:
The operator initiating the exposure is responsible for ensuring the final check of pregnancy has been made before proceeding. The operator checking pregnancy will adhere to this procedure. (Refer to Annex 2)

PROCEDURE:
The operator will require the outpatients to complete and sign the Pregnancy Questionnaire that will include questions on pregnancy and LMP (Refer to Outpatient Pregnancy Questionnaire (Females Aged 12 - 55 Years) Radiation Form). For inpatients, the requesting doctor will complete a pregnancy information section as part of the Request Form. If the patient states that she is NOT pregnant following choosing one of the reasons in the table below then proceed with the exposure. The patient should sign the Pregnancy Questionnaire and this needs to be scanned into the patient’s file on the RIS.

Do you meet one of the following criteria? It is not necessary to say which one:

- Not sexually active
- Tubal Ligation
- Hysterectomy
- Post-Menopausal
- Partner has had a vasectomy
- Negative Pregnancy Test (BHCG)
- Currently Menstruating
- Mirena / Implanon

- If the patient states that she IS pregnant consult with the Radiologist to check if the procedure may be safely deferred. The Radiologist may contact the referrer directly or delegate the task to the operator.
- If the procedure cannot be deferred justification can only be approved by the Medical Radiation Practitioner. If the outcome of the decision is that the procedure is justified and must proceed due to its nature, then Radiation in Pregnancy consent form (Refer to Radiation in Pregnancy Consent Form) should be administered by the Medical Radiation Practitioner. Risks vs benefits should be concisely explained to the pregnant patient.
- For patients unable to communicate through illness, physical or mental disability or language barrier, all questions relating to pregnancy will be addressed to an escorting relative, carer or interpreter.
FLOW CHART FOR PROCEDURE OF ASSESSING WOMEN OF CHILDBEARING AGE

Female Patient of Child Bearing Age (12 - 55 yrs)

Pregnancy status questionnaire.
Is the patient pregnant?

No (criteria satisfied)

Proceed (status documented)

Area of examination

Area other than pelvis

Proceed with lead shielding

> 10 days from LMP

Rebook when status verified

Do you meet one of the following criteria?
It is not necessary to say which one:
- Not sexually active
- Tubal Ligation
- Hysterectomy
- Post-Menopausal
- Partner has had a vasectomy
- Negative Pregnancy Test (BHCG)
- Currently Menstruating
- Mirena / Implanon

Urgent

Consult with Medical Radiation Practitioner

Pelvis

Non Urgent

Follow 10 Day Rule

< 10 Days from LMP

Pregnancy test to be organised

Proceed if examination justified

Consult with Medical Radiation Practitioner
PROCEDURE FOR CLINICAL HANDOVER:

PURPOSE:
The aim of this procedure is to ensure continuity of patient care and safety.

SCOPE:
Inter-departmental patient transportation.

RESPONSIBILITY:
All staff

PROCEDURE:

- Ensure that clinical handover is performed in accordance with AWH Clinical Handover Policy. (Refer AWH Clinical Handover Policy)  
- Ensure adherence to the ISBAR chart (Refer Annex 3)
- Any incidents relating to clinical handover are reported in the Incident Management System.
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<tr>
<th>I</th>
<th>Introduction</th>
<th>Identify yourself &amp; role to the patient and attending nurse</th>
<th>Identify yourself to the nurse</th>
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| S | Situation and Status | Communicate to the patient and nurse what examination has been requested. If applicable ensure preparation requirements have been fulfilled. | Communicate patient information  
☐ Presenting problem  
☐ Current status  
☐ Medications reviewed  
☐ Mobility  
☐ Cognitive status,  
☐ NFR status  
☐ Alerts | Communicate to nurse what examination has been performed |
| B | Background | What is the clinical background or context  
☐ Relevant past history  
☐ Co-morbidities  
☐ Recent issues- health and social |  |
| A | Assessment | ☐ Assessment findings  
☐ Current clinical status  
☐ Current vital signs | ☐ Peri-examination information eg. Cannula re-sited, contrast extravasation, unsatisfactory bowel preparation |
| R | Recommendations Repeat information to confirm understanding | Communicate patient requirements  
☐ Immediate needs- meds, monitoring, O2, PAC etc  
☐ Ask the patient if they have any questions | Communicate post examination patient requirements  
☐ Ask the patient if they have any questions |
PROCEDURE FOR JUSTIFICATION / AUTHORISATION OF A MEDICAL EXPOSURE:

PURPOSE:
The Department of Health Victoria requires every medical exposure to be justified and authorised in advance, in accordance with clause 3.3.3 of the Code. This procedure states how that justification takes place and how the operators conducting a medical exposure are made aware of the fact that justification has occurred. Justification of X-ray examinations is a wide and varied entity. To provide justification criteria for all examinations is unrealistic.

SCOPE:
All Mammography examinations.

RESPONSIBILITY:
It is the responsibility of the Medical Radiation Practitioner to authorise each exposure (generically) only if it is justified. It is the responsibility of the operator to effect a medical exposure only once authorisation has been obtained.

PROCEDURE:
- Medical Radiation Practitioners are entitled provide generic justification for mammography examinations. When justifying a medical exposure, consideration should be given to the following points:
  - The objectives of the exposure.
  - The direct health benefit to the individual.
  - The individual detriment the exposure may cause.
  - The benefits and risks of alternative techniques which may meet the objectives with less or no detriment.

- The following matters will demand special attention:
  - Exposures on medico-legal grounds.
  - Exposures with no direct health benefit to the individual being exposed.
  - Exposure of females who are, or may be pregnant.
  - Urgent / out of hour’s exposures.
  - Children.
  - The Operator may consider the examination to be generically justified provided that:
    - There is generic justification according to the protocol (Refer to document Generic Justification of mammography examinations) AND
    - There is clinical question
    - The clinical question can be answered by the examination

If sufficient clinical information is not made available by the referrer the Radiology Request Form will be returned in the cases of non-urgent referrals. In the case of urgent referrals the Medical Radiation Practitioner will arrange for the referrer to be contacted to obtain the relevant information. The practitioner will arrange for the non-urgent Radiology Request Forms to be returned with a tick chart.
The examination must not proceed until the operator has either *(Refer to Annex 4)*:
- Determined that the examination is generically justified OR
- Had the examination justified individually and set a specific protocol by the Medical Radiation Practitioner.
- In both cases there must be documented evidence ie signature of the individual who has deemed the examination justified. This is then to be scanned into the patient's file on the RIS

- The Operator is entitled to refer the process to justification on an individual basis by the Radiation Medical Practitioner at any time.
Medical Practitioner

Referral received from Medical Practitioner

Generic Justification
A clinical question is asked that can reasonably be answered by the examination

Insufficient clinical notes → Justified → Uncertain

Approval
Performed by Operator in accordance with guidelines established by the Radiation Medical Practitioner

Not Approved
Operator requests justification on individual

Justified

Insufficient Clinical Notes

Justification by Radiation Medical Practitioner Assessment performed by the Radiation Medical Practitioner in accordance with requirements of section 3.2 of the Code

Justified

Insufficient

Uncertain

Insufficient Clinical Notes

Cannot be justified

Approval
Performed by the Radiation Medical Practitioner in accordance with Section 3.2

PREGNANT PATIENTS REQUIRE JUSTIFICATION THE RADIATION MEDICAL PRACTITIONER WHERE THE PRIMARY BEAM WILL IRRADIATE THE FOETUS DIRECTLY

Examination Proceeds
Justification documented in patient’s file on RIS
PROCEDURE FOR REVIEW OF JUSTIFICATION PROTOCOLS:

PURPOSE:
The Department of Health Victoria requires every medical exposure to be justified and authorised in advance, in accordance with clause 3.3.3 of the Code. This procedure states the process for review of generic justification protocols.

SCOPE
All generic justification protocols for mammography examinations

RESPONSIBILITY:
It is the responsibility of the Medical Radiation Practitioner in conjunction with the Chief Radiographer to ensure that all generic justification protocols are reviewed regularly.

PROCEDURE:
- The generic justification protocols should be reviewed by the Radiation Medical Practitioner every 12 months.
- The generic justification protocols should be reviewed on the installation of new software or equipment.
- The generic justification protocols should be reviewed by request of the Radiation Medical Practitioner at all other times.
PROCEDURE FOR THE DOCUMENTATION OF THE PATIENT DOSE:

PURPOSE:
To detail how patient dose indicators are recorded for each mammography.

SCOPE:
Covers all mammography examinations.

RESPONSIBILITY:
It is the responsibility of the operator who initiates the exposure to ensure that the appropriate patient dose indicator is recorded.

PROCEDURE:
- The mammography equipment will automatically document dose related information on the patient’s images which are stored and available of PACS.
PROCEDURE FOR MONITORING DOSE: QA

PURPOSE:
To perform review of trends and to take corrective action if discrepancies are discovered.

SCOPE:
Observation of mammography statistics. Discrepancies may indicate equipment fault or the need to adjust protocols.

RESPONSIBILITY:
The Mammography Team Leader will investigate excessive doses and implement corrective action. The Mammography Team Leader may delegate this role as appropriate.

PROCEDURE:
- At least every six months the Mammography Team Leader will perform a patient dose audit and provide a report.
- The Mammography Team Leader will review the results to establish where discrepancies exist.
- The Mammography Team Leader will investigate excessive doses and implement corrective action.
PROCEDURE FOR MONITORING REJECT ANALYSIS OF MAMMOGRAPHY IMAGES:

PURPOSE:
To identify the procedure for the provision of reject analysis for the purpose of quality assurance.

SCOPE:
The Mammography Team Leader is responsible for analysis of all reject x-ray images.

PROCEDURE:
- The reason for image rejection is to be recorded and classified.
- Data is recorded and reject analysis is to be performed every 3 months.
- A report of the reject analysis is to be reported to the RSO.
- Any trends are to be investigated and addressed.
PROCEDURE FOR ACCIDENTAL OR UNINTENDED RADIATION EXPOSURE:

PURPOSE:
To ensure that all accidental and unintended exposures to patients or participants are properly investigated and recorded.
To ensure that reportable incidents are reported to the appropriate authority.

SCOPE:
Covers all Mammography examinations.

PROCEDURE:
- Any member of staff who suspects that an accidental, unnecessary or unintended exposure has occurred will, as soon as possible, record relevant information and report full details of the incident to the RSO and record the incident on VHIMS. The RSO will arrange for an investigation to be carried out immediately as per the Radiation Management Plan. *(Refer to Radiation Management Plan – OTH0061)*.
- Patients who undergo a procedure that was not intended, as a result of mistaken identification or other procedural failure, and consequently have been exposed to an ionising radiation dose, must be considered as having received an unintended dose of radiation.
- If the person reporting the incident has reason to believe it was caused by a radiation equipment fault, that person will advise other staff not to use the suspect equipment until it has been checked. The RSO will arrange for an assessment of the equipment to be made and will not allow it to be used for medical exposures until it is demonstrated that its performance is reliable and within recommended QA standards.
PROCEDURE FOR ENSURING THAT ALL OPERATORS UNDERSTAND THE PRINCIPLES OF DOSE REDUCTION:

PURPOSE:
This is to ensure Radiation Dose should be managed and minimized following As Low As Reasonably Achievable (ALARA) principle.

SCOPE:
All staff using the Mammography Equipment should follow to procedure to reduced radiation exposure.

PROCEDURE:
- Departmental staff meetings, during which radiation protection information is disseminated, are held regularly and minuted. These meetings include Practice Manager Meetings, Directorate Meetings and general staff meetings.
- The identity of the patient is checked prior to any radiation exposure.
- All equipment is subject to regular preventative maintenance and independent radiation safety and performance assessment.
- Mammography equipment faults are logged and reported to the Chief Radiographer / RSO.
- All staff receive appropriate in-house training on the operation of equipment.
- All untoward incidents are reported to the RSO and logged on VHIMS.
- All radiation incidents are reported and investigated.
- The cause of radiation incidents are reviewed and appropriate action taken to minimise the risk of recurrence.
- Care is taken at all times whilst examining patients to select the most appropriate examination settings and operate it in accordance with manufacturer’s instructions and operate in accordance with manufacturer’s guidelines.
PROCEDURE FOR THE PROVISION OF MAMMOGRAPHY PROTOCOLS AND STANDARD EXPOSURE FACTORS:

PURPOSE:
To identify the procedure for the provision of imaging protocols and the setting of standard exposure factors.

SCOPE:
All Mammographic examinations.

PROCEDURE:
- Standard imaging protocols are agreed by the Medical Radiation Practitioner and the Chief Radiographer. No alterations can be made to these protocols without consent of the Medical Radiation Practitioner.
- Standard exposure factors for each type of X-ray examination are stored within the mammography equipment's programme lists and documented with Justification Protocols for Mammography (OTH0069).
- Any adjustment to the programmed exposure factors must be authorised by the Mammography Team Leader.
SYSTEMS OF WORK FOR MAMMOGRAPHERS:

- Only AHPRA registered staff trained to operate the Mammography Equipment are permitted to do so.
- Do not enter the mammography room if the mammography warning light is illuminated.
- All doors must be closed during the mammography examination.
- All exposure parameters are to be checked prior to performing the mammography examination.
- PPE must be worn by any individual (other than the patient) who is present in the mammography room, unless protected by the lead lined screen, whilst an exposure is occurring.

Annexes:

Related AWH Documents:

Accreditation Standards:

Other Relevant Information:

References:

Contact Point: Medical Imaging.

In consultation with:

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