



## **Health Insurance (Diagnostic Imaging Accreditation) Instrument 2020**

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I, GREG HUNT, the Minister for Health, make this legislative instrument under subsection 23DZZIAA(1) of the *Health Insurance Act 1973*.

Dated 23 March 2020

GREG HUNT

Minister for Health

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## 1 Name of instrument

This legislative instrument is the *Health Insurance (Diagnostic Imaging Accreditation) Instrument 2020*.

## 2 Purpose of instrument

This instrument establishes a scheme under which diagnostic imaging practices may be accredited for diagnostic imaging procedures.

## 3 Commencement

This instrument commences on 1 April 2020.

## 4 Authority

This instrument is made under subsection 23DZZIAA(1) of the Act.

## 5 Repeal of previous instrument

The *Health Insurance (Diagnostic Imaging Accreditation) Instrument 2010* is repealed.

## 6 Interpretation

Note: Unless a contrary intention appears, an expression used in this instrument has the same meaning as in the Act — see section 13 of the *Legislative Instruments Act 2003*. Terms that are defined in the Act and used in this instrument include the following:

- (a) approved accreditor;
- (b) base for mobile diagnostic imaging equipment;
- (c) diagnostic imaging accreditation scheme;
- (d) diagnostic imaging premises;
- (e) diagnostic imaging procedure;
- (f) diagnostic imaging service;
- (g) diagnostic imaging services table;
- (h) Medicare benefit;
- (i) proprietor.

(1) In this instrument:

*Act* means the *Health Insurance Act 1973*.

*adverse event* has the meaning given in subsection 16(1).

*applicant* means an applicant for accreditation of a diagnostic imaging practice under section 9, 10 or 11.

*desktop audit* means a review by an approved accreditor carried out other than in a diagnostic imaging practice to assess whether the diagnostic imaging practice meets the entry level standards or the standards in Schedule 1 or has MIAP approval.

**diagnostic imaging modality** means a set of diagnostic imaging procedures identified as a modality in Schedule 2.

**diagnostic imaging practice** means diagnostic imaging premises or a base for mobile diagnostic imaging equipment.

**entry level standards** means Standard 1.2, Standard 1.3 and Standard 1.4 in Schedule 1.

**initial decision** has the meaning given in subsection 18(1).

**Medical Imaging Accreditation Program** means the diagnostic imaging accreditation program that:

- (a) is jointly administered by NATA and RANZCR;
- (b) relates to the Version 11-2019 RANZCR standards as at 30 June 2019; and
- (c) provides diagnostic imaging practices with accreditation under the program for a period of no more than four years.

**MIAP approval** means accreditation under the Medical Imaging Accreditation Program.

**MIAP expiry date** means the date the diagnostic imaging practice's MIAP approval is due to end as most recently evidenced under subsection 11(2).

**NATA** means the National Association of Testing Authorities Australia, Australian Company Number 004 379 748.

**previous instrument** means the *Health Insurance (Diagnostic Imaging Accreditation) Instrument 2010*.

**prior accreditation** has the meaning given in section 8.

**RANZCR** means The Royal Australian and New Zealand College of Radiologists, Australian Company Number 000 029 863.

**re-accreditation** has the meaning given in section 8.

**reconsideration decision** has the meaning given in subsection 18(4).

**responsible accreditor** has the meaning given in section 7.

- (2) Unless the contrary intention appears, the standards in Schedule 1 apply in relation to a diagnostic imaging practice to the extent that services provided at the diagnostic imaging practice are diagnostic imaging services in respect of which a Medicare benefit is or is expected to be payable.

## 7 Responsible accreditor

- (1) The **responsible accreditor** for a diagnostic imaging practice is:
  - (a) the approved accreditor who last granted the diagnostic imaging practice accreditation under this instrument; or
  - (b) if, since the diagnostic imaging practice was last accredited under this instrument, the proprietor or an approved accreditor has notified Services Australia that an approved accreditor is the responsible accreditor for the

diagnostic imaging practice, the approved accreditor last notified to Services Australia.

- (2) Where:
  - (a) immediately before the end of the day on 31 March 2019 a diagnostic imaging practice was accredited under the diagnostic imaging accreditation scheme established by the previous instrument; and
  - (b) the approved accreditor who granted that accreditation is approved to accredit diagnostic imaging practices under this instrument,that approved accreditor is the **responsible accreditor** for the diagnostic imaging practice until an approved accreditor becomes the responsible accreditor in accordance with subsection (1).
- (3) The proprietor of a diagnostic imaging practice must ensure that the diagnostic imaging practice has a responsible accreditor at all times while it is accredited under this instrument.

## 8 When application can be made for re-accreditation

- (1) Where a diagnostic imaging practice is accredited under section 9, 10 or 11 (**prior accreditation**), it may apply for further accreditation under section 10 or 11 (**re-accreditation**) before the expiry date of the prior accreditation.
- (2) Where the application for further accreditation is made more than 6 months before the expiry date of the prior accreditation, the re-accreditation must commence within 6 months after the application date.
- (3) If a diagnostic imaging practice that has prior accreditation is granted re-accreditation before the expiry date of the prior accreditation, the prior accreditation ceases when the re-accreditation takes effect.

## 9 Accreditation against entry level standards

### *Accreditation*

- (1) The diagnostic imaging practice is an **entry level practice** if it has not had at any time accreditation under:
  - (a) this section or section 10 or 11; or
  - (b) section 8, 9 or 10 of the previous instrument; or
  - (c) the diagnostic imaging accreditation scheme established by the *Health Insurance (Diagnostic Imaging Accreditation) Determination 2008*.
- (2) The proprietor of an entry level practice may apply to an approved accreditor for accreditation of the diagnostic imaging practice under this section.
- (3) In considering whether or not to grant accreditation under this section the approved accreditor must assess the application against the entry level standards.
- (4) The approved accreditor must grant accreditation under this section if satisfied that the diagnostic imaging practice meets the entry level standards.
- (5) The proprietor of a diagnostic imaging practice that has accreditation under this section must:

- (a) ensure that the diagnostic imaging practice complies with the entry level standards; and
- (b) provide to the responsible accreditor the required evidence in relation to the entry level standards as specified in Schedule 1 on request by the responsible accreditor from time to time.

*Revocation*

- (6) Where a diagnostic imaging practice that has accreditation under this section does not continue to meet the entry level standards or satisfy a condition of accreditation, the proprietor must notify the responsible accreditor immediately after the proprietor becomes aware of the failure to meet the entry level standards or the condition of accreditation.
- (7) Where a diagnostic imaging practice has been accredited under this section for a period of two years, the responsible accreditor must revoke the accreditation of the diagnostic imaging practice.

## **10 Accreditation against standards**

*Accreditation*

- (1) The proprietor of a diagnostic imaging practice may apply to an approved accreditor for accreditation of the diagnostic imaging practice under this section.
- (2) In considering whether or not to grant accreditation under this section the approved accreditor must assess the application against the standards in Schedule 1.
- (3) The approved accreditor must grant accreditation under this section if satisfied that the diagnostic imaging practice meets the standards in Schedule 1.
- (4) The proprietor of a diagnostic imaging practice that has accreditation under this section must:
  - (a) ensure that, at all times, the diagnostic imaging practice complies with the standards in Schedule 1; and
  - (b) provide to the responsible accreditor the required evidence as specified in Schedule 1 on request by the responsible accreditor from time to time.

*Revocation*

- (5) Where a diagnostic imaging practice that has accreditation under this section does not continue to meet the standards in Schedule 1 or satisfy a condition of accreditation, the proprietor must notify the responsible accreditor immediately after the proprietor becomes aware of the failure to meet the standards in Schedule 1 or the condition of accreditation.
- (6) Where:
  - (a) a diagnostic imaging practice has accreditation under this section; and
  - (b) four years have passed since the diagnostic imaging practice was last accredited,

the responsible accreditor must revoke the accreditation of the diagnostic imaging practice.

## **11 Accreditation based on Medical Imaging Accreditation Program**

### *Accreditation*

- (1) The proprietor of a diagnostic imaging practice that has MIAP approval may apply to an approved accreditor for accreditation of the diagnostic imaging practice under this section.
- (2) The approved accreditor must grant accreditation under this section if the proprietor provides the approved accreditor with a document evidencing:
  - (a) that the diagnostic imaging practice has MIAP approval; and
  - (b) the date the diagnostic imaging practice's MIAP approval is due to end.
- (3) The proprietor of a diagnostic imaging practice that has accreditation under this section must ensure that the diagnostic imaging practice complies with the standards and requirements of the Medical Imaging Accreditation Program.

### *Notification*

- (4) The proprietor of the diagnostic imaging practice must notify the responsible accreditor of any renewal, revocation, lapsing, suspension or variation of the diagnostic imaging practice's MIAP approval.
- (5) Where a diagnostic imaging practice that has accreditation under this section does not continue to satisfy a condition of accreditation, the proprietor must notify the responsible accreditor immediately after the proprietor becomes aware of the failure to meet the condition of accreditation.

### *Revocation, variation and suspension*

- (6) Where:
  - (a) a diagnostic imaging practice has accreditation under this section; and
  - (b) the diagnostic imaging practice's MIAP approval lapses or is revoked under the Medical Imaging Accreditation Program,the responsible accreditor must revoke the accreditation of the diagnostic imaging practice.
- (7) Where:
  - (a) a diagnostic imaging practice has accreditation under this section; and
  - (b) the diagnostic imaging practice's MIAP approval is varied or suspended under the Medical Imaging Accreditation Program,the responsible accreditor must vary or suspend, as the case may be, the accreditation of the diagnostic imaging practice.
- (8) Where a diagnostic imaging practice has accreditation under this section on the MIAP expiry date, the responsible accreditor must revoke the accreditation of the diagnostic imaging practice.

## 12 Applications for accreditation

- (1) This section applies to an application for accreditation made under section 9, 10 or 11.

### *Application*

- (2) An application must:
  - (a) be made in writing to an approved accreditor; and
  - (b) be lodged by the proprietor of the diagnostic imaging practice or an employee of the proprietor; and
  - (c) specify the section under which accreditation is being sought (that is, whether under section 9, 10 or 11); and
  - (d) specify the diagnostic imaging practice that is to be granted accreditation; and
  - (e) specify the diagnostic imaging modalities for which the diagnostic imaging practice is to be granted accreditation.
- (3) An applicant must provide the approved accreditor with such information as the approved accreditor reasonably requires in support of the application.
- (4) An application must authorise the approved accreditor:
  - (a) to check the accuracy of the information provided by whatever means the approved accreditor sees fit; and
  - (b) to store and use the information for the purposes of Division 5 of Part IIB of the Act and for the purposes of this instrument.

### *Decision*

- (5) The approved accreditor must decide an application for accreditation in accordance with this instrument by:
  - (a) granting accreditation to the diagnostic imaging practice for the diagnostic imaging modalities for which accreditation was sought, with or without conditions; or
  - (b) granting accreditation to the diagnostic imaging practice for only some of the diagnostic imaging modalities for which accreditation was sought, with or without conditions; or
  - (c) refusing to grant accreditation.
- (6) The approved accreditor must assess an application for accreditation in accordance with the section under which accreditation is being sought.
- (7) Without limiting subsection (5), the conditions referred to in paragraphs (5)(a) and (b) may include a condition requiring the proprietor of the diagnostic imaging practice to notify the responsible accreditor of any changes that occur relating to the certifications or approvals affecting the diagnostic imaging practice, staff or equipment.

### *Notification*

- (8) As soon as practicable after deciding an application, the approved accreditor must notify the applicant in writing of the decision setting out:



- (a) the decision (specifying any conditions imposed); and
- (b) the reasons for the decision; and
- (c) a statement of the applicant's reconsideration rights under section 18; and
- (d) if the diagnostic imaging practice is granted accreditation for some or all of the diagnostic imaging modalities referred to in the application:
  - (i) the date from which the diagnostic imaging practice is accredited; and
  - (ii) the diagnostic imaging modalities for which accreditation is granted.

### **13 Diagnostic imaging modalities**

- (1) It is a condition of accreditation under this instrument that the proprietor of the diagnostic imaging practice notifies the responsible accreditor of any change in the diagnostic imaging modalities carried out by the diagnostic imaging practice.
- (2) After a diagnostic imaging practice has been granted accreditation the responsible accreditor may make a decision to vary a diagnostic imaging practice's accreditation so that the diagnostic imaging practice is accredited for additional or fewer diagnostic imaging modalities by written notice to the proprietor that sets out:
  - (a) the diagnostic imaging modalities for which the diagnostic imaging practice is accredited; and
  - (b) the reasons for the variation; and
  - (c) a statement of the proprietor's reconsideration rights under section 18.

### **14 Conditions of accreditation**

- (1) After a diagnostic imaging practice has been granted accreditation the responsible accreditor may impose conditions of accreditation on the diagnostic imaging practice by written notice to the proprietor that sets out:
  - (a) the terms of the conditions; and
  - (b) the reasons for imposing the conditions; and
  - (c) a statement of the proprietor's reconsideration rights under section 18.

Note: The power to impose a further condition after the grant of accreditation may be utilised where, for example, a diagnostic imaging practice loses a staff member with technical expertise and it is important that the diagnostic imaging practice recruits a replacement staff member with appropriate skills, training and experience.

- (2) It is a condition of accreditation under this instrument that the proprietor of the diagnostic imaging practice permits the responsible accreditor to, at any time:
  - (a) access and inspect the premises and equipment of the diagnostic imaging practice;
  - (b) access, inspect and copy documents, materials, books and records, however stored, in the custody or under the control of the proprietor, its officers, employees, agents or contractors; and
  - (c) require the provision of information by the proprietor, its officers, employees, agents or contractors;

for the purpose of the responsible accreditor determining whether the diagnostic imaging practice meets, or continues to meet, requirements for accreditation under this instrument.

## 15 Fees

- (1) Subject to subsections (2) and (3), an approved accreditor may charge proprietors the following fees for services the approved accreditor provides to diagnostic imaging practices:
  - (a) fees for work performed in receiving and processing applications under this instrument;
  - (b) fees for undertaking desktop audits;
  - (c) membership fees; and
  - (d) fees for re-issuing accreditation certificates.
- (2) An approved accreditor may not charge a separate fee for:
  - (a) work performed in considering taking action, or taking action, under section 16; or
  - (b) work performed in receiving and processing an application for reconsideration under section 18.
- (3) When charging fees, an approved accreditor must not discriminate against a diagnostic imaging practice on the basis of its geographic location.

## 16 Variation, suspension or revocation of accreditation

- (1) Subsections (2), (3) and (4) apply where one or more of the following events (an *adverse event*) occurs:
  - (a) the responsible accreditor considers that a diagnostic imaging practice that has accreditation under section 9 may no longer meet the entry level standards;
  - (b) the responsible accreditor considers that a diagnostic imaging practice that has accreditation under section 10 may no longer meet the standards in Schedule 1;
  - (c) the responsible accreditor considers that the proprietor of a diagnostic imaging practice that has accreditation under section 9, 10 or 11 may have breached or not fulfilled a condition of accreditation;
  - (d) the responsible accreditor becomes aware that a diagnostic imaging practice that was given accreditation under section 9 was not an entry level practice.
- (2) Where subsection (1) applies, the responsible accreditor must give the proprietor notice in writing giving details of:
  - (a) the adverse event or events to which the notice relates; and
  - (b) any material taken into account by the responsible accreditor in forming the view referred to in subsection (1),and allow the proprietor 28 days after receiving the notice to make written submissions, including in relation to rectification of the adverse event.
- (3) Within 28 days after the end of the 28 day period referred to in subsection (2) and after considering any written submissions made by the proprietor under subsection (2), the responsible accreditor, if satisfied that the standards are not met or that a condition of accreditation has been breached or not fulfilled or that the diagnostic imaging practice was not an entry level practice, must require the proprietor to rectify the breach of the standards or the failure to comply with the

condition or make a new application under section 10 or 11, as the case may be, within a nominated period.

- (4) If, after requiring the proprietor under subsection (3) to rectify the breach of the standards or breach or non-fulfilment of the condition or make a new application within a nominated period, the responsible accreditor is satisfied that the adverse event has occurred and has not been rectified, then the responsible accreditor must make a decision to vary, suspend or revoke the accreditation of the diagnostic imaging practice.
- (5) In spite of anything in subsections (1), (2), (3) or (4), the responsible accreditor may make a decision to immediately vary, suspend or revoke an accreditation where the responsible accreditor considers that there is a potential danger to public health or safety if the accreditation is not varied, suspended or revoked.
- (6) Where the responsible accreditor makes a decision to:
  - (a) vary or suspend the accreditation of a diagnostic imaging practice under subsection (4) or (5) or under subsection 11(7); or
  - (b) revoke the accreditation of a diagnostic imaging practice under this instrument,the responsible accreditor must notify the proprietor in writing of the decision setting out:
  - (c) the decision;
  - (d) the reasons for the decision; and
  - (e) a statement of the proprietor's reconsideration rights under section 18.

## **17 Date of effect of decisions**

- (1) Subject to subsection (2), a decision made under this instrument by an approved accreditor (including a reconsideration decision) takes effect on the day specified in the decision or, if a day is not specified, on the day on which the decision is made.
- (2) The following decisions (whether initial decisions or reconsideration decisions) do not take effect until the proprietor's rights to reconsideration by the responsible accreditor under section 18 (if any) and by the Minister in accordance with section 23DZZIAD of the Act are exhausted or have expired:
  - (a) a decision to impose a condition of accreditation under subsection 12(5) or 14(1) (other than a decision made on the ground that there is a potential danger to public health or safety if the condition is not imposed);
  - (b) a decision to refuse to grant accreditation to a diagnostic imaging practice that already has accreditation;
  - (c) a decision to grant, to a diagnostic imaging practice that already has accreditation, accreditation for only some of the diagnostic imaging modalities for which accreditation was sought;
  - (d) a decision to vary accreditation so that a diagnostic imaging practice is accredited for fewer diagnostic imaging procedures;
  - (e) a decision to suspend accreditation in whole or in part; and
  - (f) a decision to revoke accreditation in whole or in part (other than a decision made on the ground that there is a potential danger to public health or safety if the accreditation is not revoked).

## 18 Reconsideration of decisions

- (1) If an approved accreditor makes a decision under this instrument in relation to a diagnostic imaging practice (***initial decision***), the proprietor may apply to the approved accreditor who made the initial decision for reconsideration of the initial decision.
- (2) The application must be made in writing:
  - (a) within 28 days after the date of the initial decision; or
  - (b) if the approved accreditor is satisfied that special circumstances exist, within such further period (if any) as the approved accreditor, either before or after the expiration of that period, allows.
- (3) The proprietor must set out the reasons for the application and, in doing so, may provide new material for the approved accreditor to consider.
- (4) An approved accreditor:
  - (a) must, within 28 days after receipt of an application made in accordance with subsection (1); and
  - (b) may, on its own motion, whether or not the proprietor has applied for reconsideration, reconsider the initial decision and make a new decision (***reconsideration decision***):
    - (c) affirming the initial decision;
    - (d) varying the initial decision; or
    - (e) setting aside the initial decision and making a decision in substitution for it.
- (5) The approved accreditor must give a proprietor notice in writing of a reconsideration decision setting out:
  - (a) the decision;
  - (b) the reasons for the decision;
  - (c) a statement of the proprietor's reconsideration rights under section 23DZZIAD of the Act.

## 19 Transitional provisions

### *Accreditation under the previous instrument continues*

- (1) Where a diagnostic imaging practice was, immediately before the commencement of this instrument, accredited under section 8, 9 or 10 of the previous instrument, the practice is taken to have been accredited under the corresponding provision of this instrument:
  - (a) with the same end date; and
  - (b) for the same diagnostic imaging modalities; and
  - (c) subject to the same conditions; and
  - (d) if at that time the accreditation was under suspension, subject to the same suspension;as under the previous instrument.

*Application for accreditation made under previous instrument to be determined under that instrument*

- (2) Where:
- (a) the proprietor of a diagnostic imaging practice applied to an approved accreditor for accreditation of a diagnostic imaging practice under the previous instrument; and
  - (b) the approved accreditor had not yet decided the application immediately before the commencement of this instrument;

the approved accreditor must:

- (c) determine the application in accordance with the standards in force under the previous instrument immediately before the commencement of this instrument.

*Reconsideration of decisions under previous instrument*

- (3) Where:
- (a) an approved accreditor made a decision under the previous instrument in relation to a diagnostic imaging practice; and
  - (b) the proprietor made an application to the approved accreditor for reconsideration of the approved accreditor's decision; and
  - (c) the approved accreditor had not yet decided the application immediately before the commencement of this instrument;

the approved accreditor must reconsider the earlier decision and make a new decision in accordance with the standards in force under the previous instrument immediately before the commencement of this instrument.

# Schedule 1— Diagnostic Imaging Accreditation Scheme – Standards

(sections 9 and 10)

## Part 1—Organisational Standards

### Standard 1.1 Safety and Quality Manual Standard

The diagnostic imaging practice must prepare a comprehensive Safety and Quality Manual that includes all diagnostic imaging accreditation scheme (DIAS) related policies and addresses DIAS standards, including the title and /or names of the persons at the diagnostic imaging practice who develop, approve, implement, maintain, and review these policies.

#### Required Evidence

A documented Safety and Quality Manual for the diagnostic imaging practice which addresses the practice's:

- governance, policies and procedures regarding DIAS (Standard 1.1);
- registration and licensing of personnel (Standard 1.2);
- radiation safety and optimised radiation technique charts (Standards 1.3 and 3.2);
- diagnostic imaging equipment and servicing (Standards 1.4 and 1.5);
- healthcare associated infection policies and procedures (Standard 1.6);
- provision of diagnostic imaging services and reporting and recording image findings policies (Standards 2.1, 4.1 and 4.2);
- consumer consent and information policies (Standard 2.2);
- patient identification and procedure matching policies (Standard 2.3);
- medication management policies (Standard 2.4);
- diagnostic imaging protocols (Standard 3.1); and
- consumer and stakeholder feedback and complaints policies (Standard 4.3).

Evidence which demonstrates that mechanisms are in place to evaluate, audit, review and monitor each one of the Standards and their specific requirements.

### Standard 1.2 Registration and Licensing Standard (Entry Level Standard)

Staff, students, contractors or locums and any other practitioner eligible to provide or assist in the provision of diagnostic imaging services to the practice must provide evidence of and maintain all appropriate and current registration and/or licences to undertake diagnostic imaging procedures.

### Required Evidence

Copies of each registered health practitioner's Australian Health Practitioner Regulation Agency (AHPRA) registration documentation, or an AHPRA registration number which can be verified on the public register. These practitioners include:

- medical practitioners;
- dentists;
- medical radiation practitioners;
- nurses; and
- allied health practitioners (including podiatrists, osteopaths, chiropractors and physiotherapists).

Copies of the AHPRA registration documentation of each student who is registered on the AHPRA student register.

Where the practice provides imaging modalities that involve ionising radiation, copies of each registered health practitioner's Commonwealth, State or Territory radiation user licence (or similar), or a registration number which can be verified on the public register, if required in the relevant jurisdiction.

Copies of each non-registered health practitioner's Commonwealth, State or Territory radiation use licence, or a licence number which can be verified, if required in the relevant jurisdiction.

Where the practice provides ultrasound services, copies of each sonographer's statement of accreditation on the Australian Sonographer Accreditation Register (ASAR) or a registration number which can be verified on the ASAR register for the purpose of determining registration on the Services Australia Register of Sonographers.

Evidence that the registration status of practitioners is reviewed annually, in line with AHPRA's annual registration process.

### **Standard 1.3                      Radiation Safety Standard (Entry Level Standard)**

Where a diagnostic imaging practice uses ionising radiation, the practice must comply with the requirements of the relevant Commonwealth, State or Territory radiation safety legislation.

### Required Evidence

Copies of relevant Commonwealth, State or Territory Radiation Safety Regulator equipment licences and registrations (or similar) or registration numbers which can be verified.

Copies of radiation safety plans and all other relevant radiation safety documents required by Commonwealth, State or Territory radiation safety legislation, with evidence that they are reviewed a minimum of once per accreditation cycle.

#### **Standard 1.4                      Equipment Inventory Standard (Entry Level Standard)**

The diagnostic imaging practice must maintain a current diagnostic imaging equipment inventory demonstrating that relevant equipment used to provide diagnostic imaging services is registered with Services Australia and complies with specifications in the *Health Insurance Act 1973* and the *Health Insurance Regulations 2018*.

##### Required Evidence

A current, documented equipment inventory which includes:

- the name of item;
- manufacturer; and
- serial number (or other identifier).

A copy of the most recent DHS Location Specific Practice Number (LSPN) register equipment record.

#### **Standard 1.5                      Equipment Servicing Standard**

The diagnostic imaging practice must demonstrate that equipment used to acquire, manipulate, print or report images for diagnostic imaging procedures is safe and appropriate for its intended use.

##### Required Evidence

Records and service reports, demonstrating the equipment used to provide images is serviced according to manufacturer's guidelines by qualified persons and the requirements of applicable radiation safety legislation, including the:

- date of service, details and results of the service and the date of the next service; and
- actions taken at the practice in response to the results of the service.

A record of the service provider's qualifications is to be provided to the approved accreditor, however they do not need to appear on every service report. The service provider shall:

- hold a radiation use licence (or similar) for service and repair (if servicing ionising radiation equipment) issued by the Commonwealth, State or Territory regulator relevant to where the service is performed; and
- provide evidence of successful completion of a recognised service training course appropriate to the equipment being serviced.

##### NOTE:

A "service" in this context refers to "maintenance carried out at predetermined intervals, or according to prescribed criteria, and intended to reduce the probability of failure or the degradation of the functioning of an item" (AS/NZS 3551:2012 §1.4.36). A breakdown repair is not a service. The service frequency would normally be as defined by the medical equipment manufacturer however a variation can exist "supported by a documented rationale for the deviation" (AS/NZS 3551:2012 §6.4.2).

#### **Standard 1.6                      Healthcare Associated Infection Standard**

The diagnostic imaging practice must mitigate the risk of the transmission of infectious agents to patients, carers, healthcare workers, support staff and other visitors, by:



- a) identifying, assessing and managing and reporting the risk of the transmission of infectious agents;
- b) meeting the requirements specified in infection control guidelines/policies produced by Commonwealth, State and Territory government authorities;
- c) reporting, investigating, and responding to incidents at the diagnostic imaging practice arising from the transmission of infectious agents; and
- d) ensuring consumer-specific information on the management and reduction of healthcare associated infections is available at the point of care.

#### Required Evidence

A documented policy and procedure for preventing the transmission of infectious agents to patients and carers, healthcare workers, support staff and other visitors which includes the process for identifying, assessing and managing risks and reporting, investigating and responding to the transmission of infectious agents when they occur. (Standard 1.1)

Where relevant, documented quality improvement activities, which describe the actions taken in response to the transmission of an infectious agent(s).

Where ultrasound services are being provided, a documented policy for reprocessing ultrasound transducers that is consistent with national standards and guidelines relating to disinfection.

Copies of consumer-specific information on the management and reduction of healthcare associated infections.

## **Part 2—Pre-procedure standards**

### **Standard 2.1 Provision of Service Standard**

The diagnostic imaging practice must demonstrate that diagnostic imaging services are only undertaken where there is an identified clinical need and:

- a) upon receipt of an appropriate request from a medical practitioner or a practitioner who is able under the *Health Insurance Act 1973* to request services of that kind as a service for which a Medicare benefit is payable; or
- b) where the providing and reporting practitioner self-determines the service in accordance with requirements of the *Health Insurance Act 1973*.

#### Required Evidence

For practitioners providing requested services:

- the practice must have a documented policy and procedure in response to inappropriate requests for diagnostic imaging procedures. (Standard 1.1)
- a sample of de-identified requests documenting the clinical need for the diagnostic imaging procedures rendered at the diagnostic imaging practice.

For practitioners providing self-determined services:

- a sample of de-identified records documenting clinical need.

## **Standard 2.2 Consumer Consent and Information Standard**

Prior to a diagnostic imaging procedure being rendered, except in cases of emergency, the diagnostic imaging practice must ensure that:

- a) patients have access to information about the diagnostic imaging procedure;
- b) risks are advised to the patient or substitute decision maker;
- c) practice staff obtain and record relevant information about the patient's health status and individual patient risk factors;
- d) consent for each diagnostic imaging procedure is obtained from the patient or the substitute decision maker; and
- e) patient consent requirements reflect the risk attached to the diagnostic imaging procedure.

### Required Evidence

A documented policy and procedure for obtaining patient consent prior to a diagnostic imaging procedure being provided, ensuring that the consent requirements reflect the level of risk attached to each procedure. It is expected that practices obtain written patient consent prior to invasive or high risk procedures. (Standard 1.1)

A sample of de-identified records of consent obtained from the patient in respect of the diagnostic imaging procedure.

A sample of de-identified records documenting the patient's health status, relevant to the diagnostic imaging procedure being undertaken, with regard to:

- asthma;
- previous exposure to intravenous contrast;
- allergies;
- medical conditions such as diabetes, kidney disease or heart disease;
- pregnancy status;
- medications such as metformin hydrochloride;
- breastfeeding; and
- medical devices and implanted devices such as intra-cranial aneurysm clips, cardiac pacemaker, coronary stents, intra ocular foreign bodies and cochlear implants.

Examples of service specific information for the diagnostic imaging services available at the practice.

A sample of de-identified records must be provided which demonstrate that risks have been advised to the patient.

## **Standard 2.3 Patient Identification & Procedure Matching Standard**

The diagnostic imaging practice must ensure that all patients are correctly identified and matched to their intended procedure or treatment by:

- a) using at least three (3) approved patient identifiers to match a patient to their request or medical record from the time the patient presents and through all stages of the diagnostic imaging service and when transferring responsibility of care;
- b) correctly matching patients with their intended diagnostic imaging service and the anatomical site and side (if applicable) of the diagnostic imaging procedure;
- c) utilising the 'time-out' technique for high risk procedures, including confirming the patient's allergy status; and
- d) reporting, investigating, and responding to patient care mismatching events when they occur and implementing changes, where relevant, to reduce the risk of future incidents.

#### Required Evidence

A documented policy and procedure for matching patients to their intended diagnostic imaging procedure including the report for that procedure, through all stages of the service and when transferring responsibility of care. (Standard 1.1)

A sample of appropriately de-identified records documenting the use of three patient identifiers.

A documented policy and procedure which sets out the process for reporting, investigating and responding to patient care mismatching events when they occur.

Where relevant, documented quality improvement activities, which describe the actions taken in response to patient care mismatching events.

## Standard 2.4 Medication Management Standard

The diagnostic imaging practice must ensure that medication risks are managed by:

- a) correctly and safely storing, preparing and disposing of medications in accordance with manufacturer's guidelines and relevant Commonwealth, State or Territory requirements;
- b) identifying patients at risk from adverse reactions;
- c) administering medication safely, actively monitoring the effects of medication, and all relevant details recorded in the patient's records;
- d) personnel capable of providing timely and appropriate care in the event of an adverse reaction to medication; and
- e) reporting, investigating and responding to incidents arising from adverse reactions or medication mismanagement.

### Required Evidence

A documented policy and procedure describing the procedures for:

- storing, preparing and disposing of medications;
- identifying at risk patients;
- administering medications safely;
- monitoring and recording the effects of medication; and
- reporting, investigating, and responding to adverse reactions or medication mismanagement incidents when they occur.

A documented management plan which identifies the procedures for managing adverse reactions at the time they occur;

- the type and location of resuscitation equipment and associated drugs at the practice; and
- the personnel certified in basic life support and qualified to use resuscitation equipment and drugs. (Standard 1.1)

Where a practice performs examinations using contrast, a documented protocol which ensures the appropriate use and administration of contrast.

A sample of de-identified records for relevant diagnostic imaging procedures documenting the information collected about the patient's medication use and/or history regarding previous reactions to medications.

Example of records demonstrating managing adverse reactions at the time they occur.

Where relevant, documented quality improvement activities, which describe the actions taken in response to incidents related to medication management.

NOTE:

A 'medication' in this context refers to anything administered to a patient:

- to create or enhance a diagnostic quality image; and/or

- where imaging is used as part of an interventional procedure.

## **Part 3—Procedure standards**

### **Standard 3.1 Diagnostic Imaging Protocol Standard**

The diagnostic imaging practice must have documented protocols which describe the required projections, list of anatomy to be visualised, contrast injection requirements and/or positioning required for the acquisition of optimised quality images.

#### Required Evidence

Documented protocols for routine diagnostic imaging procedures or groups of diagnostic imaging procedures rendered at the diagnostic imaging practice, with evidence that they have been reviewed a minimum of once per accreditation cycle, which include all necessary information for the proper conduct of the examination taking into account any specifications for the required qualifications, experience and specialisation of the personnel. Where specific tasks are delegated to members of the imaging team, the protocols shall indicate any specific circumstances under which personnel shall seek further guidance and/or input from the supervising medical practitioner.

### **Standard 3.2 Optimised Radiation Technique Charts Standard**

A diagnostic imaging practice which uses ionising radiation must ensure that patient radiation exposure is kept as low as reasonably achievable (ALARA) by selecting equipment and techniques for diagnostic imaging procedures sufficient to provide the required clinical information.

#### Required Evidence

A technique chart, consistent with the ALARA principle, for each unit of ionising radiation equipment located at the diagnostic imaging practice.

Ionising radiation equipment where settings are entered manually:

- evidence must be supplied that demonstrates the settings have been reviewed and authorised by a qualified person, annually for each episode.

Ionising radiation equipment where settings are embedded in the software and operators select a protocol:

- evidence must be supplied that demonstrates the underlying settings have been reviewed and authorised by a qualified person annually.

For each item of screening fluoroscopy equipment:

- a copy of a log of screening times, and evidence that the log has been reviewed by a qualified person annually.

For each item of interventional angiography equipment:

- evidence that system generated dose metrics have been logged and reviewed by a qualified person annually. If the interventional angiography equipment is not capable

of generating dose metrics alternatively a copy of a log of screening times, and evidence that the log has been reviewed by a qualified person annually should be provided.

The practice must establish a program to ensure that radiation doses administered to a patient for diagnostic purposes are:

- a) annually compared with diagnostic reference levels (DRLs) for diagnostic procedures for which DRLs have been established in Australia; and
- b) if DRLs are consistently exceeded, reviewed to determine whether radiation protection has been optimised.

## **Part 4—Post procedure standards**

### **Standard 4.1                      Communicating Results and Reports Standard**

The diagnostic imaging practice effectively communicates the results of a requested diagnostic imaging procedure by:

- a) providing timely, clear and concise written reports which address the information:
  - requested by the requesting practitioner;
  - required by the diagnostic imaging service; and
  - that is necessary for the interpretation of the images;
- b) taking all reasonable steps to personally advise the requesting practitioner (or another practitioner where necessary) about urgent and unexpected findings; and
- c) responding to feedback and requests from requesting practitioners about the content or provision of reports and/or advice provided.

#### Required Evidence

A documented policy for the provision of reports to requesting practitioners and patients.  
(Standard 1.1)

A sample of de-identified imaging reports, consistent with the practice's documented policy for reporting.

Where relevant, documented quality improvement activities, which describe the actions taken in response to feedback from requesting practitioners.

#### **Standard 4.2 Findings of Self-Determined Services Standard**

When the service is a self-determined service, information about the findings of the diagnostic imaging procedure must be documented in a report and retained in the patient record.

##### Required Evidence

A sample of de-identified records documenting the image findings and that show that it has been retained in the patient records.

#### **Standard 4.3 Consumer and Stakeholder Feedback and Complaints Management Standard**

The diagnostic imaging practice must provide opportunities for, and respond to, feedback and complaints from consumers, requestors and all other stakeholders about the provision of a diagnostic imaging service.

##### Required Evidence

A documented policy for inviting, recording, managing and responding to feedback and complaints which is consistent with the principles of open disclosure and fairness, accessibility, responsiveness, efficiency and integration. (Standard 1.1)

Evidence of publicly accessible information for inviting, managing and responding to feedback and complaints which is consistent with the principles of open disclosure and fairness, accessibility, responsiveness, efficiency and integration.

Evidence of training practice staff in managing and responding to feedback and complaints.

A sample of de-identified feedback and complaints received and records of the actions taken.

## Schedule 2—Diagnostic Imaging Accreditation Scheme—Diagnostic Imaging Modalities

(section 6)

A diagnostic imaging modality is one of the following groups of diagnostic imaging procedures:

Modality	Relevant items in the diagnostic imaging services table	Medicare Code
<b>Ultrasound</b>	All items in <u>Group I1</u> .	<b>ULT</b>
<b>Computed Tomography</b>	All items in <u>Group I2</u> .	<b>CTG</b>
<b>Diagnostic Radiology including General Radiology (X-ray), Mammography, Angiography, Fluoroscopy and Orthopantomography (OPG)</b>	All items in <u>Group I3</u> .	<b>RAD</b>
<b>Nuclear Medicine Imaging</b>	All items in <u>Group I4</u> .	<b>NME</b>
<b>Magnetic Resonance Imaging (MRI)</b>	All items in <u>Group I5</u> .	<b>MRI</b>