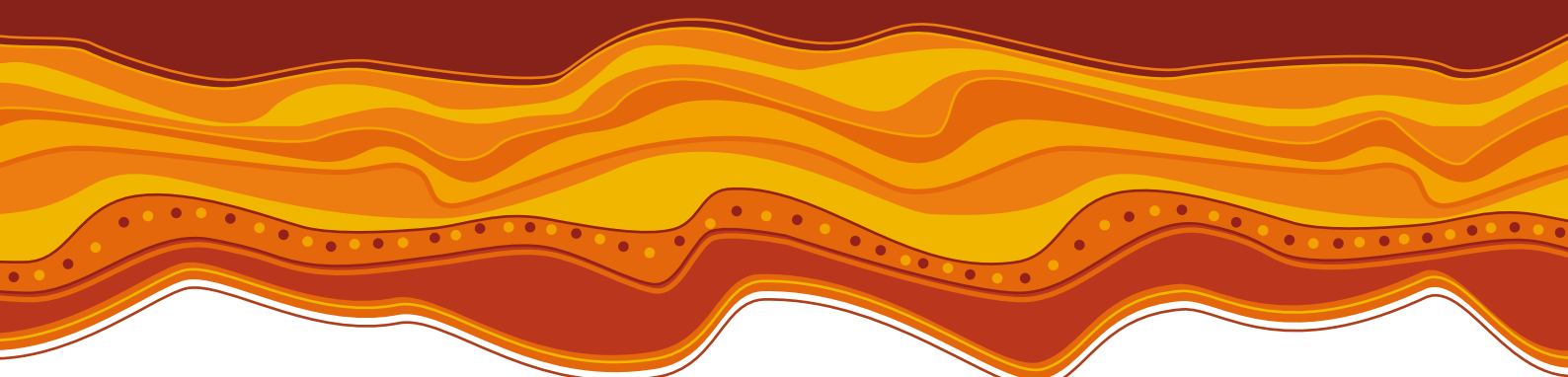




Application Guide

Meeting the Diagnostic Imaging Accreditation Standards



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Background

Standards

The standards that a diagnostic imaging practice is required to meet for Stage I accreditation are similar to those under which they currently operate in their particular State or Territory. The standards represent existing State and Territory regulatory requirements regarding the licensing and registration of staff, equipment and radiation safety. A copy of the standards can be accessed on the HDAAU website at: www.hdaau.com.au/diagnostic_imaging_accreditation/diagnostic_imaging_standards

Authorisation

Diagnostic imaging accreditation applicants must authorise the approved accreditor (HDAAU) to check the accuracy of information provided and to store and use the information for the purposes of the Scheme. HDAAU clients are asked for authorisation when they submit their application information; note, for sonographers this includes authorisation to verify the sonographers registration with the Department of Health and Ageing.

Certification of Accuracy

When submitting an application for diagnostic imaging accreditation, applicants are required to certify: *"...that the statements made and documents attached in this application are true and correct in every detail and the copies of all registration certificates and licences accompanying this application are true copies of original documents shown to me"*.

Terms and Conditions

HDAAU terms and conditions can be accessed by practices registered for accreditation with HDAAU from the website once logged into the secure onTrack area of www.hdaau.com.au



Part 1. Registration and Licensing Standards

Standard 1.1

The proprietor of a diagnostic imaging practice ensures that its staff or contractors and any other practitioners providing services to the practice have and maintain the appropriate and current registration and/or licence to undertake the diagnostic imaging procedures for which accreditation is sought in the State or Territory.

Explanation

Registration and Licensing

Standard 1.1 sets out the requirements for the registration and licensing of medical and non-medical personnel who either provide diagnostic imaging procedures and/or who interpret images for the site which is seeking accreditation. In Standard 1.1 the following applies:

1. Registration requirements generally relate to the qualifications of personnel.
2. Licensing requirements generally relate to an authorisation for a person to use or operate radiation producing diagnostic imaging equipment such as:
i) X-ray, ii) computed tomography, or iii) fluoroscopy equipment, in order to provide a diagnostic imaging procedure.

The term '*diagnostic imaging procedure*' is defined in legislation and generally means the procedure for capturing or producing images.

Subject to some exemptions, diagnostic imaging procedures generally need to be provided under the supervision of a medical practitioner who is able to monitor and influence the conduct of the imaging.

Medical and non-medical personnel covered by Standard 1.1 generally include:

- medical practitioners/specialists/dentists;
- radiographers and Licensed X-ray Operators;
- allied health professionals such as chiropractors, physiotherapists, podiatrists and osteopaths;
- sonographers;
- nurses; and
- medical physicists.

There are different requirements regarding the licensing and registration of staff in the States and Territories.

Sub-contracting Arrangements

Where reporting services are provided under sub-contracting arrangements (i.e. by a separate organisation), the proprietor of the LSPN site seeking accreditation is required to provide evidence of the registration of those practitioners providing the reporting service.

Where a LSPN site sub-contracts to another practice in the same jurisdiction to report on diagnostic imaging, the LSPN site can provide a certified copy of the reporting practice's diagnostic imaging accreditation certificate as evidence of the reporting practitioner's registration. If the LSPN site sub-contracts to another practice in an alternative jurisdiction, the LSPN site would need to provide certified copies of the reporting practitioners' registration certificates for the jurisdiction where the image is captured.

Sonographers

Legislation states that for the purposes of Medicare eligibility, ultrasound services can only be performed by a medical practitioner or a registered sonographer on behalf of a medical practitioner.

A registered sonographer is a person whose name is entered on the Register of Sonographers kept by the Medicare Australia CEO. The information contained on the Register of Sonographers held by Medicare Australia is the same information as held in the Australasian Sonographer Accreditation Registry (ASAR).

Applicants need to provide evidence of the registration of a sonographer (4 digit ASAR registration number) along with the full name of the sonographer.



Evidence Required for Standard 1.1

Registration and Licensing

When submitting evidence for Standard 1.1 the following evidence is required to be uploaded to the “My Application” area of www.hdaau.com.au or sent with a completed and signed Evidence Checklist to HDAAU:

1. Documentary evidence of registration certificates and licences for:

- Medical practitioners/specialists/dentists;
- Radiographers and Licensed X-ray Operators;
- Allied health professionals;
- Sonographers;
- Nurses; and
- Medical physicists

or

2. Where Registrations and Licences are held on a public register which can be verified by HDAAU, registration and licence numbers.

Note

Sonographers need to record the sonographers name and Australasian Sonographer Accreditation Registration number (four digit ASAR registration number).



Part 2. Safety Standards

Standard 2.1

The proprietor of a diagnostic imaging practice ensures that the practice complies with the requirements of the current State or Territory radiation safety legislation.

Explanation

Radiation protection

Standard 2.1 sets out the radiation safety requirements for:

- Radiation producing diagnostic imaging equipment such as radiographic, fluoroscopic, mammographic and computed tomography systems; **and**
- The premises where this equipment is located and used.

Sites providing ultrasound services only do not need to comply with this standard.

Explanation 2.1(a)

Radiation Safety

Radiation protection legislation varies between the jurisdictions and the relevant authorities in the jurisdictions are:

Australian Capital Territory

ACT Health

New South Wales

Department of Environment and Climate Change

Northern Territory

Department of Health and Community Services

Queensland

Department of Health

South Australia

Environment Protection Authority

Tasmania

Department of Health and Human Services

Victoria

Department of Human Services

Western Australia

Radiological Council

Some State and Territory radiation protection legislation requires that each piece of radiation producing diagnostic imaging equipment is registered for use with the relevant regulatory authority. In this situation a Certificate of Registration or similar¹ from the relevant regulatory authority is issued to the owner of the equipment after registration of: a) the equipment; b) its location; and c) ownership; occurs with that authority.

In addition, and where relevant, a Certificate of Compliance, or similar, may be issued by the relevant regulatory authority after an inspection of the equipment by an authorised person.

Explanation 2.1(b) and 2.1(c)

Radiation Management Plan

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code of Practise for Radiation Protection in the Medical Applications of Ionizing Radiation (2008) (the Code) establishes the regulatory requirements for the use of ionizing radiation in medicine.

The Code has been developed for adoption into State and Territory radiation safety legislation but has yet to be implemented. The Code is a guide to good practise to ensure that the risks of radiation exposure to patients, staff and other persons are as low as reasonably achievable.

The Code includes a requirement for a site with radiation producing diagnostic imaging equipment to develop, implement and regularly review a Radiation Management Plan.

Guidance about the preparation of a Radiation Management Plan is included in the Code.

¹ In Victoria legislation requires a Management Licence which specifies what activities can be carried out at the site and what radiation producing equipment is operating from the site.



Evidence required for Standard 2.1(a)

Radiation Safety

When submitting evidence for Standard 2.1(a) the following evidence is required to be uploaded to the “My Application” area of www.hdaau.com.au or sent with a completed and signed Evidence Checklist to HDAAU:

1. Current Certificate of Registration and Certificate of Compliance for the LSPN;
or
2. Current Certificate of Registration and Compliance Testing Sticker information.

Notes

Where a Certificate of Compliance is a condition of registering radiation producing diagnostic imaging apparatus, the applicant should provide both a current Certificate of Registration and a current Certificate of Compliance as evidence of compliance with Standard 2.1.

In some States and Territories a Certificate of Compliance may not be issued but the relevant regulatory authority affixes a Compliance Testing Sticker to verify compliance. The applicant can copy the information contained on the sticker and supply this as evidence.

Evidence required for Standard 2.1(b)

Radiation Plan (radiation producing equipment only)

When submitting evidence for Standard 2.1(b) the following evidence is required to be uploaded to the “My Application” area of www.hdaau.com.au or sent with a completed and signed Evidence Checklist to HDAAU:

1. The name of the Radiation Safety Officer responsible for radiation safety for the site;
and
2. A description of the responsibilities of the Radiation Safety Officer.

Evidence Required for Standard 2.1(c)

Radiation Plan (radiation producing equipment only)

When submitting evidence for Standard 2.1(c) the following evidence is required to be uploaded to the “My Application” area of www.hdaau.com.au or sent with a completed and signed Evidence Checklist to HDAAU:

1. A Radiation Management Plan in States and territories where the Code is required by legislation.



Part 3. Equipment Standards

Standard 3.1

The proprietor of a diagnostic imaging practice ensures that the practice maintains a current equipment inventory.

Explanation

Equipment

To be eligible to provide diagnostic imaging services under Medicare, sites with diagnostic imaging equipment must register that equipment with Medicare Australia. Registered sites and bases for mobile equipment are allocated a Location Specific Practice Number (LSPN).

Equipment to be registered with Medicare Australia which is relevant to the accreditation standards includes individual:

- ultrasound units and transducers;
- computed tomography units;
- angiography systems;
- general X-ray equipment;
- fluoroscopy equipment;
- mammography equipment; and
- orthopantomography equipment.

To maintain registration with Medicare Australia, sites must annually confirm or update equipment information. The following information is generally provided to Medicare Australia when registering diagnostic imaging equipment:

- serial number;
- model type/number;
- manufacturer (Company);
- date manufactured or date installed in Australia; and
- date operational.

Some diagnostic imaging equipment must meet specifications to be used for certain diagnostic imaging services provided under Medicare. For example:

- ultrasound machines used for urological ultrasound must be equipped with transducers of a frequency of 7.0 – 7.5 MHz;
- ultrasound machines for musculoskeletal ultrasound must be equipped with transducers of a frequency of 7.5 MHz or greater; and
- ultrasound machines used for vascular studies must be capable of colour doppler imaging.

Evidence Required for Standard 3.1 Equipment

When submitting evidence for Standard 3.1 the following evidence is required to be uploaded to the “My Application” area of www.hdaau.com.au or sent with a completed and signed Evidence Checklist to HDAAU:

1. Confirmation of the LSPN;
and
2. A current equipment inventory including:
 - Serial number; and
 - Model type/number; and
 - Manufacturer (Company); and
 - Date manufactured or date installed in Australia; and/or
 - Date operational.

Note

Examples of appropriate confirmation of the LSPN include, but are not limited to: (a) Medicare Australia LSPN Registration Form, or (b) confirmation letter, or (c) application for a LSPN, or (d) declaration, or (e) annual update form.



Part 4. Provision of Services Standards

Standard 4.1

Diagnostic imaging procedures are only undertaken at the diagnostic imaging practice where there is an identified clinical need and:

- (a) Upon receipt of a request from a medical practitioner or a practitioner specified in the Act for the purpose of requesting services of that kind and for which a Medicare benefit is payable; or
- (b) Where the practitioner interpreting the image is permitted to self determine the service for which a Medicare benefit is payable under the Act.

Explanation

Provision of Services Standards

Diagnostic imaging services are required to be clinically relevant before they are eligible for Medicare benefits. A clinically relevant service is a service that is generally accepted in the profession as being necessary for the appropriate treatment of the patient.

Requested services

Medicare benefits are not payable for services which are classified as requested services unless, prior to commencing the service, the medical practitioner providing the service receives a signed and dated request from a requesting practitioner.

The clinical relevance of a diagnostic imaging service rendered at the request of another practitioner, is determined by the requesting practitioner.

There are some exemptions regarding requested services. A written request will not be required for a requested service provided by a medical practitioner in a remote area if the medical practitioner has a remote area exemption². Also, a written request is not required in an emergency situation.

Written records must include the report on the requested diagnostic imaging service provided by a medical imaging practitioner. For ultrasound services, where the service was performed for or on behalf of a medical practitioner, the report must include the registered sonographer's name.

Self determined services

A written request is not required for the payment of Medicare benefits when the diagnostic imaging service is provided by or on behalf of a consultant physician or a specialist (other than a specialist radiologist).

The above means that a medical practitioner such as a cardiologist, urologist, vascular surgeon, ophthalmologist, obstetrician or a gynaecologist can provide a diagnostic imaging service after they have determined through clinical assessment of the patient that the service is required. These services are referred to as self-determined services.

New practices

Practices that commence operation after 1 July 2008 that are required to be accredited before they provide services under Medicare may not have at the time of applying for accreditation, actual patient requests and/or patient records as evidence of compliance with Standard 4.1. In these circumstances, an example of patient requests and/or patient records is required as evidence of intended compliance and a time limited accreditation is then able to be granted. After this the practice submits a sample of actual patient and practice records which needs to occur before expiry of the time limited accreditation. Where the documentary evidence demonstrates compliance with Standard 4.1, accreditation is granted until 30 June 2010.

² The definition of a remote area is one that is more than 30 km by road from:
a) a hospital which provides a radiology service under the direction of a specialist in the speciality of diagnostic radiology; and b) a free-standing facility under the direction of a specialist in the speciality of diagnostic radiology. A medical practitioner has to apply to Medicare Australia for a remote area exemption if he or she qualifies under the remote area definition.



Evidence Required for Standard 4.1

Provision of Services Standards

When submitting evidence for Standard 4.1 the following evidence is required to be uploaded to the “My Application” area of www.hdaau.com.au or sent with a completed and signed Evidence Checklist to HDAAU:

1. Ten depersonalised records of services provided on the 7 October 2008 clearly showing the following:
 - name of referrer; and
 - name of person capturing or reporting the image; and
 - clinical need; and
 - service sought.**or**
2. For new practices, all records as detailed in point 1 above on a date nominated by the accreditor (HDAAU).

Notes

If the practice provides less than ten services on the nominated date, the practice need only provide records for the number of services provided on that date.

If no services were provided on the 7 October 2008 the practice should provide the evidence on the first subsequent date that services were requested.

Where a practice provides more than one modality, the records should, where possible, represent all the modalities provided at the site.

Standard 4.2

The diagnostic imaging practice only substitutes diagnostic imaging procedures:

- **where appropriate for the diagnosis of a patient’s medical condition;**
and
- **where generally accepted on the basis of diagnostic imaging medical opinion;**
and
- **where permitted by the Act and subordinate legislation for the payment of a Medicare benefit for that service.**

Explanation

Service Substitution

Under certain conditions the practitioner providing a requested diagnostic imaging service may substitute the requested service for another service. This would occur when the clinical information provided in the request suggests that another service would be more appropriate to diagnose the patient’s condition.

A service cannot be substituted, however, unless the provider takes all reasonable steps to consult the requesting practitioner about the substitution of the service.

Practices which do not provide “requested services” do not need to comply with Standard 4.2.

Where a provider substitutes a service, the provider’s records must include information about the consultation or attempted consultation with the requesting practitioner and the date of the consultation or attempted consultation.

Evidence Required for Standard 4.2

Service Substitution

When submitting evidence for Standard 4.2 the following evidence is required to be uploaded to the “My Application” area of www.hdaau.com.au or sent with a completed and signed Evidence Checklist to HDAAU:

1. (Where the practice has substituted a requested diagnostic imaging service) evidence of consultations or attempted consultations regarding the substituted service with the requesting practitioner.
or
2. (If in the previous 12 months the practice has not substituted any requested diagnostic imaging service), a policy indicating when a service might be substituted and what procedures would be followed regarding a substituted service.

Notes

This record need not be additional to the records provided as evidence for Standard 4.1 if there is evidence in these records pertaining to substituted services.



Glossary of Terms

Base for mobile diagnostic imaging equipment

Premises, under a single business name, where diagnostic imaging equipment is ordinarily located when not in use and where the diagnostic imaging procedures carried out using the equipment are not carried out, or are more frequently carried out off the premises.

Diagnostic imaging modality

Refers to a set of diagnostic imaging procedures referred to in Schedule 2 of the Ministerial Determination.

Diagnostic imaging practice

Is a convenient term to cover a “diagnostic imaging premises” and a “base for mobile diagnostic imaging equipment”. These terms are defined in the Act.

Diagnostic imaging premises

A building, or part of a building, at which diagnostic imaging procedures are carried out under a single business name.

Diagnostic imaging procedure

Is the production of images such as X-rays, computed tomography scans, ultrasound scans, and magnetic resonance imaging scans for use in rendering “diagnostic imaging services”.

Diagnostic imaging service

An “R-type” or and “NR-type” service as defined on the diagnostic imaging services table prescribed under A44 of the Health Insurance Act 1973.

Diagnostic imaging proprietor

Is the person or government agency that has effective control of the premises or the base, the use of the diagnostic imaging equipment used at or ordinarily located at the premises, and the employment of staff connected with the premises or the base. Person means a natural person or incorporated body.

