



Australian Government

Department of Health

DIAGNOSTIC IMAGING ACCREDITATION SCHEME

**USER GUIDE FOR PRACTICES
APPLYING FOR ACCREDITATION**

Publication Information

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Revision history of the DIAS User Guide (2015 Version):

DATE REVISION/S APPROVED:	REVISION/S MADE TO:	TRIM REFERENCE:
15 February 2016	Text related to Standard 2.1 and Standard 2.2	D16-140076
2 July 2018	Text related to: <ul style="list-style-type: none"> • Standard 1.5: evidentiary requirements for service provider qualifications and licences, outlined in Advisory Statement 18/05. • Standard 2.1: an amendment to an explanatory note referenced regarding self-determined services, outlined in Advisory Statement 18/01. • Standard 2.2: consent requirements for transvaginal and transrectal ultrasound procedures, outlined in Advisory Statement 18/03. • Standard 3.2: information regarding Diagnostic Reference Levels for nuclear medicine and computed tomography, outlined in Advisory Statement 18/04. • Glossary: amendment to the definitions of "infectious agents" and "invasive imaging procedures", and the addition of the following terms and definitions: "equipment servicing agent", "recognised service training course", and "service provider". • Amendments to Appendix 1, and insertion of new Appendices 13A and 13B. 	D18-1485516

DATE REVISION/S APPROVED:	REVISION/S MADE TO:	TRIM REFERENCE:
21 April 2020	<p>Text related to:</p> <ul style="list-style-type: none"> • The Medical Imaging Accreditation Program: to ensure that from 1 April 2020 MIAP recognition under the DIAS is with reference to the Version 11-2019 RANZCR standards. • Standards 1.2, 1.3, 1.4, 1.5, 1.6, and 4.2: to ensure consistency with amendments set out in the <i>Health Insurance (Diagnostic Imaging Accreditation) Instrument 2020</i>. • Throughout the User Guide: amendments to restore broken hyperlinks and ensure document references are correct and up to date. • Standard 4.3: amended references in the guidance material to refer to the relevant incident and complaints management criteria in the current National Safety and Quality in Healthcare Standards. • Glossary: the addition of the term “Services Australia” to reflect the current name of the department formerly known as the “Department of Human Services”. 	

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INTRODUCTION

The Diagnostic Imaging Accreditation Scheme (DIAS) was established by the *Health Insurance Amendment (Diagnostic Imaging Accreditation) Act 2007* to ensure Medicare funding is directed to diagnostic imaging services that are safe, effective and responsive to the needs of health care consumers.

A diagnostic imaging procedure is defined in the *Health Insurance Amendment (Diagnostic Imaging Accreditation) Act 2007* as 'a procedure for the production of images (for example x-rays, computerised tomography scans, ultrasound scans, magnetic resonance imaging scans and nuclear scans) for use in the rendering of diagnostic imaging services'.

A diagnostic imaging service covers both the diagnostic imaging procedure and the reading and report generated for that procedure by the diagnostic imaging service provider.

All practices intending to render any diagnostic imaging services listed in Category 5 (Diagnostic Imaging Services Table), of the Medicare Benefits Schedule, for the purpose of Medicare benefits must be accredited under the DIAS. Practices that do not have accreditation cannot provide Medicare funded diagnostic imaging services. It is an offence under the *Health Insurance Act 1973* to provide a diagnostic imaging service without first informing patients that the practice is not accredited and that Medicare benefits are not payable.

Practices must have a registered, current Location Specific Practice Number (LSPN) with Services Australia. The LSPN is a unique number identifier, specific to the geographical site and practice, which must be included on all accounts, receipts and assignment of benefits forms. Each item of imaging equipment must be registered with Services Australia, including:

- Angiography systems;
- Computed tomography units (including eligible Cone Beam Computed Tomography units);
- Fluoroscopy equipment;
- Gamma cameras;
- General x-ray equipment;
- Magnetic resonance imaging units;
- Mammography equipment;
- Nuclear medicine equipment;
- Orthopantomography equipment;
- Positron emission tomography scanners; and
- Ultrasound units and transducers.

The Practice Accreditation Standards (the Standards) for DIAS were originally introduced in 2010. In 2015, the Standards were revised. The focus of the 2015 standards has been to enhance the 2010 standards, rather than developing new ones. The 2015 Standards will be implemented from 1 January 2016.

The DIAS Standards are divided into four parts:

- Part 1 Organisational Standards;
- Part 2 Pre-procedure Standards;
- Part 3 Procedure Standards; and
- Part 4 Post-procedure Standards.

It may be difficult for a new practice to meet the full suite of Standards, as records showing compliance may not be generated until the practice has been operating for a time. Practices entering the DIAS may choose to be accredited against either the entry level Standards or the full suite of Standards. Practices initially choosing to be accredited against the entry-level Standards have a period of two years to achieve accreditation against the full suite of Standards to retain their accreditation.

On the following page is a table listing each of the DIAS Standards and how each applies to either the entry level Standards or the full suite of Standards.

Once a practice has achieved accreditation against the full suite of Standards, the practice must seek re-accreditation to the full suite of Standards at four yearly intervals to maintain their accreditation.

Any non-accredited practice that was previously accredited must seek re-accreditation against the full suite of Standards and cannot apply for re-accreditation against the entry-level Standards.

Medical Imaging Accreditation Program

The Royal Australian and New Zealand College of Radiologists (RANZCR) delivers a voluntary accreditation program jointly with the National Association of Testing Authorities, Australia (NATA). Known as the Medical Imaging Accreditation Program (MIAP), this program is underpinned by the [Standards of Practice for Diagnostic and Interventional Radiology](#) which were developed by RANZCR to describe competence requirements for practices offering medical imaging services.

Practices participating in MIAP can seek recognition of their MIAP accreditation under the DIAS. Practices accredited after 1 April 2020 under MIAP must be accredited against the Version 11-2019 RANZCR standards in force as at 30 June 2019. This recognition will grant MIAP practices accreditation against the full suite of DIAS Standards until the date of the expiration of the recognised MIAP accreditation. By this date, practices will need to either provide their accreditor with evidence of renewal of MIAP accreditation or have been granted accreditation against the full suite of Standards.

	Entry Level Standards	Full Suite of Standards
PART 1 ORGANISATIONAL STANDARDS		
Standard 1.1 Safety and Quality Manual		✓
Standard 1.2 Registration and Licensing	✓	✓
Standard 1.3 Radiation Safety	✓	✓
Standard 1.4 Equipment Inventory	✓	✓
Standard 1.5 Equipment Servicing		✓
Standard 1.6 Healthcare Associated Infection		✓
PART 2 PRE-PROCEDURE STANDARDS		
Standard 2.1 Provision of Service		✓
Standard 2.2 Consumer Consent and Information		✓
Standard 2.3 Patient Identification & Procedure Matching		✓
Standard 2.4 Medication Management		✓
PART 3 PROCEDURE STANDARDS		
Standard 3.1 Diagnostic Imaging Protocols		✓
Standard 3.2 Optimised Radiation Technique Charts		✓
PART 4 POST PROCEDURE STANDARDS		
Standard 4.1 Communicating Results and Reports		✓
Standard 4.2 Findings of Self-Determined Services		✓
Standard 4.3 Consumer and Stakeholder Feedback and Complaints Management		✓

About this User Guide

This document has been designed as a step-by-step guide to support diagnostic imaging practices preparing a successful accreditation application under the 2015 DIAS Standards.

The User Guide contains explanations, examples, legislative obligations and statutory requirements, where applicable for each Standard. It also provides guidance on how to interpret each Standard and how an applicant can demonstrate their practice's compliance with each Standard.

Outside the accreditation cycle, the User Guide provides a powerful tool for identifying areas where a practice may improve the safety and quality aspects of their operations.

How to use this User Guide to prepare for accreditation

This document addresses each Standard individually with support for interpretation provided across three common areas:

- a) Intent of the Standard: in plain English, a short description of outcomes the Standard is looking to confirm.
- b) Evidence requirements: these are the assessment records and documents provided by the practice that Accreditors will be reviewing to determine compliance with each Standard.
- c) Preparing your accreditation application: this section provides guidance on the evidence required, links to templates and examples of the evidence, and links to websites that offer further information and assistance.

Evidence requirements are mandatory for practices seeking accreditation. For ease of reference, and to highlight their importance, evidence requirements are highlighted throughout this User Guide in blue shaded boxes. An example from Standard 1.3 is shown below:

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.

This User Guide is designed to outline the process that practices may follow to efficiently prepare for accreditation and achieve a successful accreditation application. Practices are encouraged to centrally collate documentation meeting required evidence as they work through this User Guide. This collection is then ready for submission to your Accreditor.

Appendices – templates and examples

Appendices include checklists of requirements, examples of submissions, and templates to assist practices develop their quality documentation.

All of the templates provided in the appendices are tools to assist practices address the required evidence. Practices should edit the content of the templates so that the final document accurately reflects day-to-day operations.

In particular, the accreditation checklist (**Appendix 1**) will indicate a practice's ability to demonstrate they have met the requirements of the Standards. Where gaps are identified, the checklist refers practices to the related Standard, and to further information in related Standards and in other Appendices.

Using the checklist in **Appendix 1**, practices can self-assess against each Standard. By completing the accreditation checklist, practices will either:

- confirm that their current documentation, including supporting records, meet accreditation requirements; or
- identify areas where documentation and records need to be further developed in order to meet accreditation requirements.

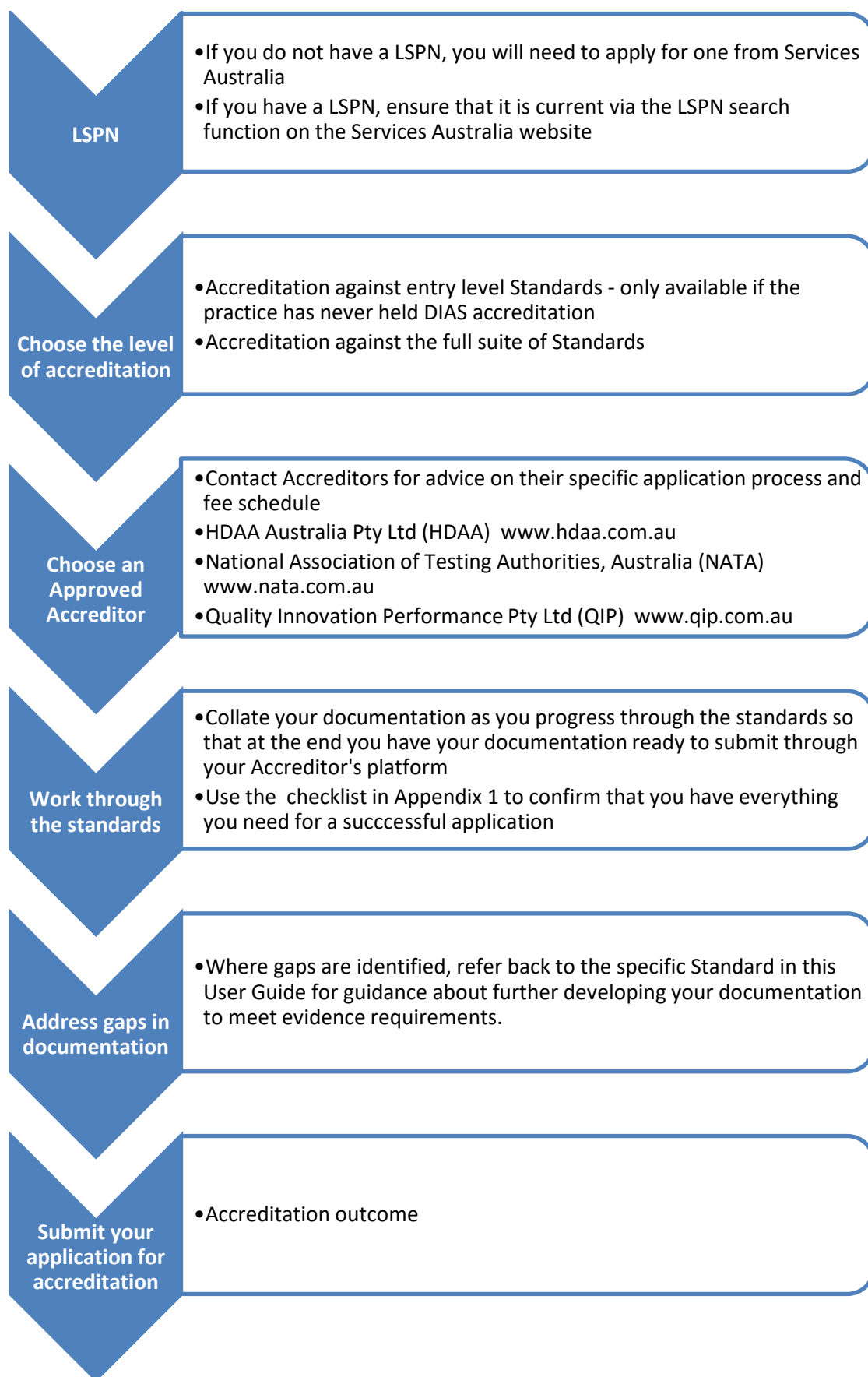
Example Safety and Quality Manual

To help with interpretation, the appendices include an example Safety and Quality Manual from a fictitious practice.

Appendix 2 provides an example Safety and Quality Manual, and **Appendix 3** is a template which practices can use to build their own Safety and Quality Manual. The example has been structured to meet accreditation requirements. Suggested headings are bolded in **orange** and represent inclusions that would cover the Standards. Prompts for the content under each heading are in **blue**, and should be replaced with the practice's policies and procedures.

On the following page is a six-step process suggested as a means of progressing through this User Guide and ensuring readiness to submit an accreditation application.

Six-step process to prepare for accreditation



Acknowledgements

The DIAS Standards are developed under the direction of the Department of Health, with advice and direction from the Diagnostic Imaging Advisory Committee, and up to 2015, the Monitoring and Implementation Committee.

The contribution of the following people in participating in the consultation process and/or reviewing sections of the 2010 User Guide for Practices Applying for Accreditation is gratefully acknowledged:

Mr James Abbott
Dr Bernie Bourke
Dr Fraser Brown
Mr Paul Carroll
Dr Bruce Chater
Dr Barry Elison
Professor Michael Feneley
Mr Sean Holmes
Dr Glenn McNally
Ms Stephanie Newell
Dr John O'Shea
Dr David Thiele
Ms Elaine Trevaskis
Ms Tracey Vitucci
Mr Anthony Wallace
Mr Christopher Whennan
Mr Andrew Wilmot

This 2015 version of the User Guide has been updated by the Diagnostic Imaging Accreditation Scheme Approved Accreditors, at the request of the Department of Health:

**HDAA Australia
Pty Ltd**
(HDAA)

**National Association of
Testing Authorities,
Australia**
(NATA)

**Quality Innovation
Performance Pty Ltd**
(QIP)

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.

Intent of the Standard

Good governance is about being transparent, accountable and effective, with clear lines of authority and decision-making. This applies to both corporate governance and clinical governance.

The DIAS Safety and Quality Manual Standard has been developed to closely align with the intent of Standard 1 of the National Safety and Quality Health Service Standards, *The Governance for Safety and Quality in Health Service Organisations Standard*, from the [Australian Commission on Safety and Quality in Healthcare \(ACSQH\)](#).

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.

Preparing your accreditation application

There are two key areas required to demonstrate your practice's ability to achieve this Standard.

1. The submission of a Safety and Quality Manual is central to the accreditation process.

Your Safety and Quality Manual should describe the policies governing your practice to ensure the safety and quality of the care provided to patients. It must include:

- policies and procedures to address each of the DIAS Standards; and
- who is authorised to review and approve your policies.

For some practices, sub-sections of the required evidence for Standard 1.1 may not be applicable. For example, radiation safety and optimised radiation technique charts, or medication management may not be relevant. In your accreditation application, you will

need to have a defensible rationale for not including any evidence against all sub-sections listed as a minimum requirement for the Safety and Quality Manual.

Policies and procedures must be regularly reviewed by your practice to ensure they are current, reflect any changes to legislation and ensure patient safety. The person(s) responsible for performing these reviews should be appropriately qualified to do so. The review period must not exceed once per accreditation cycle for most documents; a number of policies/procedures require annual review. The practice must ensure that each document is reviewed at an appropriate frequency.

For practices preparing a Safety and Quality Manual for the first time, an example Safety and Quality Manual is available in [Appendix 2](#). A template Safety and Quality Manual, available in [Appendix 3](#) has been provided so that practices can add their relevant policies, procedures and review processes for each of the Standards.

2. Standard 1.1 asks for evidence showing that mechanisms are in place to evaluate, audit, review and monitor each one of the Standards and their specific requirements.

In essence, the above processes are quality improvement activities. These activities are undertaken by a practice to demonstrate that the quality and safety systems in place are working effectively. Alternatively, where the systems are not working as intended, the practice should be identifying opportunities for improvement.

To implement quality improvement activities, the practice must identify:

- what they want to evaluate (e.g. procedures for recording patient consent);
- how it will be evaluated (e.g. internal audit);
- determine whether any changes need to be made (e.g. adding a consent field to the request form); and
- when and how will the changes be reviewed (e.g. follow up audit in 3 months).

These quality improvement activities can be performed in a variety of ways, such as internal audits, or review of incident reports and complaints. The types of activities undertaken should reflect the size and scope of the practice.

[Appendix 4](#) is a quality improvement register. This register can be used to record quality improvement activities across all Standards in a centralised location. It may also be provided with your application for accreditation demonstrating improvement activities undertaken by your practice. The quality improvement register can be used as follows to:

- describe actions taken in response to incidents (e.g. healthcare associated infection);
- describe actions taken in response to feedback;
- provide evidence of policy and procedure reviews;
- provide evidence of staff registration and licencing reviews;
- give a summary of audits; and
- recording action items from a management review.

The checklist in [Appendix 1](#) will help you to determine whether you have all of the necessary documents and records to meet this standard.

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.

Intent of the Standard

The intent of this Standard is to ensure that all personnel providing diagnostic imaging services are appropriately registered and licensed as required by existing Commonwealth, State and Territory regulatory requirements.

Personnel 'assisting' with imaging are those operating imaging equipment under the supervision of medical practitioners.

Medical personnel¹ and non-medical personnel² covered by this Standard can be staff or contractors, and may include:

- allied health professionals such as chiropractors, physiotherapists, podiatrists and osteopaths;
- dentists and dental specialists;
- medical practitioners/specialists;
- medical physicists;
- nurses;
- medical radiation practitioners (radiographers) and licensed x-ray operators;
- nuclear medicine technologists or technicians;
- sonographers; and
- students³.

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.

¹ 'Medical personnel' means any medical practitioner such as a radiologist, general practitioner, or medical specialist.

² 'Non-medical personnel' includes medical radiation practitioners (radiographers), nuclear medicine technologists/technicians, sonographers, nurses, dentists and allied health professionals such as chiropractors, physiotherapists, podiatrists and osteopaths.

³ Students are added to the AHPRA Student register, but are not issued with an AHPRA registration number. The AHPRA student register is not publically available. Education providers are required to notify their students that they have been successfully added to the AHPRA Student Register once this has been confirmed by AHPRA. Submission of this notification from the education provider to the student will meet the intent of the required evidence for students.

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.

Preparing your accreditation application

Standard 1.2 is required for both entry level and full suite accreditation.

There are three key areas required to demonstrate your practice's ability to achieve this Standard.

1. Evidence of registration

Practices must submit either:

- a) registration and licence numbers (where these can be verified on a public register, e.g. AHPRA or ASAR); or
- b) copies of the complete registration certificates or use licences (including conditions) where information is not available on a public register.

The table in [Appendix 5](#) provides guidance on the personnel required to provide Medicare funded services.

There are different requirements regarding the licensing and registration of staff in each jurisdiction.. [Appendix 6](#) outlines relevant legislation based on the jurisdictional location of your Practice.

Practices may also wish to read the Department of Health "[Strengthening the Provision of Quality Diagnostic Radiology Services Fact Sheet](#)" which details who can request and provide particular services.

Note: Legislation can be superseded. It is the responsibility of your practice to ensure that you are addressing the requirements of current legislation.

2. Evidence of Radiation Licensing

There are different requirements regarding the licensing and registration of staff in each jurisdiction. . [Appendix 6](#) outlines relevant legislation based on the jurisdictional location of your Practice.

3. Annual review of registration and licensing status

The final item is to perform an annual review to confirm currency of registrations and licensing for personnel. Records of this review must be kept.

The checklist in [Appendix 1](#) will help you to determine whether you have all of the necessary documents and records to meet this standard.

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.

Intent of the Standard

Practices using radiation emitting equipment or radiopharmaceuticals must demonstrate that they are complying with existing Commonwealth, State or Territory regulatory requirements. This Standard specifically relates to:

- Radiation producing diagnostic imaging equipment such as radiographic, fluoroscopic, mammographic, computed tomography and positron emission tomography systems;
- nuclear medicine practices and use of radiopharmaceuticals; and
- the premises where examinations using radiation emitting equipment and/or radiopharmaceuticals are performed.

Note: This standard is not applicable to sites that provide only non-radiation services (ultrasound or magnetic resonance imaging (MRI)).

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.

Preparing your accreditation application

Standard 1.3 is required for both entry level and full suite accreditation.

There are three key areas required to demonstrate your practice's ability to achieve this Standard.

1. Submission of relevant radiation safety regulatory requirements including, but not limited to:
 - premises licence;
 - possession licence;
 - equipment licences;
 - compliance certificates (may be required for equipment and/or premises); and
 - registrations (either copies of original documents or details that can be verified on a public register).

Radiation safety legislation varies between jurisdictions. To determine which Commonwealth, State or Territory Radiation regulatory requirements apply to your practice and the authority responsible see [Appendix 6](#).

2. Submission of a radiation safety plan (may also be known as radiation management plan, or similar), if applicable.

The [Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation \(2008\) \(RPS 14\)](#) provides guidance on the preparation of a radiation safety plan. If you are not sure whether or not you are required to have a radiation safety plan (however named) you should check with your Commonwealth, State or Territory regulator who will be able to give

you the information that you need; also check the conditions of your management/possession license which may state that you are required to have a radiation safety/management plan.

Some jurisdictions may also require a Radiation Safety Officer, also known as the Responsible Person in RPS 14.

If you need a template to assist you with your radiation safety plan, you can find one in Schedule A of RPS 14.

Other codes, standards and guidelines that may be cited in radiation licenses:

- RPS No. 14.1 - [Safety Guide for Radiation Protection in Diagnostic and Interventional Radiology \(2008\)](#)
- RPS No. 14.2 - [Safety Guide for Radiation Protection in Nuclear Medicine \(2008\)](#)
- RPS No. 10 - [Code of Practice and Safety Guide for Radiation Protection in Dentistry \(2005\)](#)
- RPS No. 19 - [Code of Practice for Radiation Protection in the Application of Ionizing Radiation by Chiropractors \(2009\)](#)

Radiation safety legislation varies between jurisdictions. To determine which Commonwealth, State or Territory Radiation regulatory requirements apply to your practice, see [Appendix 6](#). This appendix also lists the authority responsible for radiation safety in each jurisdiction.

3. The final requirement for this standard is evidence that your Radiation Safety Plan has been reviewed in the last accreditation cycle, i.e. once during the two year entry level accreditation, and once every four years thereafter.

The checklist in [Appendix 1](#) will help you to determine whether you have all of the necessary documents and records to meet this standard.

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*.

Intent of the Standard

To be eligible to provide diagnostic imaging services under Medicare, sites with diagnostic imaging equipment must register that equipment with Services Australia. A specific item of equipment can only be registered to one LSPN at a time. Both Services Australia and the practice's accreditor must be notified of changes to equipment.

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 Services Australia Location Specific Practice Number (LSPN) register equipment record.

Preparing your accreditation application

Standard 1.4 is required for both entry level and full suite accreditation.

There are two key areas required to demonstrate your practice's ability to achieve this Standard.

1. Submission of a diagnostic imaging equipment inventory that includes at a minimum the name of the item, manufacturer, and serial number (or other unique identifier). For practices preparing an inventory for the first time, a template is provided in [Appendix 7](#). An example of how this can be used can be found as an attachment to the example Safety and Quality Manual ([Appendix 2](#)).
2. Submission of evidence that the equipment used to perform diagnostic imaging procedures is registered on the Location Specific Practice Number Register:
 - a) for new practices entering the Scheme, provide a copy of the LSPN Registration Form, including the section listing your equipment details; **OR**
 - b) a current copy of the annual LSPN Declaration and/or Update Details Form from Services Australia including the section that lists your equipment details; **OR**
 - c) LSPN Equipment List available from Services Australia.. Check with Services Australia for the current procedure for [obtaining your list](#). To support practices gather their required evidence, [Appendix 8](#) is provided as a sample display of evidence for a site with only ultrasound equipment.

The checklist in [Appendix 1](#) will help you to determine whether you have all of the necessary documents and records to meet this standard.

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.

Intent of the Standard

Equipment performance is critical to the quality and safety of diagnostic procedures. At all times, equipment used for diagnostic imaging procedures must be able to produce images of diagnostic quality for all clinical conditions.

The focus of this Standard is to ensure the optimal performance of equipment. Preventive maintenance must be undertaken by appropriately qualified and trained service personnel in accordance with the manufacturer's recommendations for each item of equipment.

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 are 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).

Preparing your accreditation application

There are two key areas required to demonstrate your practice's ability to achieve this Standard.

1. Records of preventive maintenance services

Practices must retain copies of all preventive maintenance servicing reports and practice records for each item of equipment. The following information must be included:

- Date of service;
- Details of the service;
- Results of the service;
- Date or timeframe for the next service; and
- Actions taken by the practice in response to the results of the service.

Preventative maintenance records must be provided for equipment registered to the

practice's LSPN, such as ultrasound equipment (excluding transducers), CT equipment, nuclear medicine imaging equipment including PET, diagnostic radiology equipment (including x-ray, OPG, angiography, fluoroscopy and mammography equipment), and MRI. Preventative maintenance records should be provided for contrast injectors, if used in the provision of diagnostic imaging services.

2. Service provider qualifications and licensing

For each service provider who attends your practice you must submit copies of the following documentation:

- Qualifications;
- Radiation use license(s) (or similar); and
- Evidence of successful completion of a recognised service training course appropriate to the equipment being serviced.

It may not always be practical or possible to seek confirmation of qualifications from the person providing the service at the time of the service. Practices are strongly advised to make arrangements to obtain these records when booking services, or negotiating service contracts.

A record of service provider qualifications may alternatively be provided in a Letter of Attestation, confirming that the service providers used are appropriately trained in accordance with the manufacturer's guidelines for the type of equipment being serviced; and where applicable to the type of equipment being serviced, licenced to service and repair ionising radiation equipment located at your practice.

If a Letter of Attestation is used as an alternative form of evidence it must:

- be on business letterhead
- include the manufacturer and model of the equipment to be serviced and the radiation safety licencing details of each service provider
- state that the requisite licencing and training records have been sighted and can be produced on request, and
- be signed and dated by an individual with the authority to attest to the information provided.

A template Letter of Attestation to assist with the collection of the required evidence from your equipment servicing agent/s, regarding service providers, is included in [Appendix 13A](#).

When a practice collects the required evidence of the qualifications and licencing of service providers from their equipment servicing agent in the form of a Letter of Attestation, the practice should provide the template letter to their equipment servicing agent well in advance of the date for submission of their application for accreditation or reaccreditation.

If an equipment servicing agent provides false or inaccurate information about the qualifications and licencing of their service providers in a Letter of Attestation, they would be legally responsible for any repercussions arising from those claims.

Practices which employ their own service providers may also provide the required evidence in the form of a Letter of Attestation. A template for this purpose is provided in [Appendix 13B](#).

Practices should note that an accreditor may not accept a Letter of Attestation if it is not in the format specified above. Similarly, an incomplete Letter of Attestation will not meet the evidentiary requirements of Standard 1.5.

The checklist in [Appendix 1](#) will help you to determine whether you have all of the necessary documents and records to meet this standard.

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.

Intent of the Standard

Infection control risks will vary in different diagnostic imaging environments. Patients may become infected while receiving care, and health care workers may be at risk while they work.

The aim of this Standard is to ensure that appropriate infection control measures are in place to reduce the incidence and risk of infection, and prevent infection transmission.

The DIAS Healthcare Associated Infection Standard has been developed to be closely aligned to the intent of Standard 3 of the National Safety and Quality Health Service Standards, *Preventing and Controlling Healthcare Associated Infections* from the [Australian Commission on Safety and Quality in Healthcare \(ACSQH\)](#).

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.

Preparing your accreditation application

There are five key areas required to demonstrate your practice's ability to achieve this Standard.

1. Healthcare associated infection policies and procedures

Practices must have a documented policy and supporting procedures addressing the risk of healthcare associated infection and the transmission of infectious agents that include:

- a) Identifying, assessing and managing risks; and
- b) Reporting, investigating and responding to incidents.

Section 2.2 in the National Health and Medical Research Council [Australian Guidelines for the Prevention and Control of Infection in Healthcare 2019](#) provides more detailed information and examples of risk assessment processes in relation to infection prevention and control.

2. Records describing actions taken in response to the transmission of infectious agents.

These may be records showing how the practice handled and investigated transmission events or 'near misses'. Entries in the Quality Improvement Register ([Appendix 4](#)) may meet this requirement.

3. Practices providing ultrasound services must provide a policy for reprocessing ultrasound transducers that is consistent with national standards and guidelines relating to disinfection.

Semi critical medical devices may be used to perform diagnostic imaging services. A semi critical medical device means a therapeutic device that, when used as recommended by its manufacturer:

- a) makes contact with healthy intact mucous membranes of the human body; and
- b) does not ordinarily enter normally sterile areas of the body.

These devices, when disinfected, must be subjected to at least a high level disinfection process. Practices should refer to the Therapeutic Goods Administration [Guidelines for the Evaluation of Disinfectants](#) for further information about the requirements for high level disinfection methods.

If you are unsure whether the disinfectant you use meets this requirement, ask your supplier for a copy of the ARTG public summary for the product. If compliant, the intended use will include "high level disinfection".

4. Consumer-specific information about HAI risk minimisation

The practice must have information aimed at their patients describing how healthcare associated infection (HAI) risks are minimised at the practice. This could include measures such as posters, leaflets, web pages etc. This information must be available at the point of care. Brochures that may be useful can be found on [NHMRC website](#).

5. Standard 1.1 requires that you evaluate, audit, review and monitor each standard and its specific requirements. This can be done by a range of approaches such as audits, management reviews, or improvement records. There is a suggested review schedule in the example Safety and Quality Manual ([Appendix 2](#)) which can be used in conjunction with the accreditation checklist ([Appendix 1](#)) to support planned reviews of all standards at required intervals.

The checklist in [Appendix 1](#) will help you to determine whether you have all of the necessary documents and records to meet this standard.

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*.

Intent of the Standard

Medicare funded services listed in Category 5 (Diagnostic Imaging Services Table) of the Medicare Benefits Schedule are intended to be applied only to patients where there is a defined clinical question that imaging can answer. Medicare benefits are not payable for health screening services.

The intent of this Standard is to ensure the clinical need for the diagnostic imaging procedure has been established. For a referred service this is demonstrable through clear and documented communication between the referrer and the practice in the form of a valid request form. Where the Practitioner is permitted to self-determine, the same obligation to clearly document the clinical need remains, however, this is usually documented in patient records.

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.

Preparing your accreditation application

Evidence requirements are different for requested and self-determined services. Practices are strongly encouraged to document whether or not they provide requested and/or self-determined services in their Safety and Quality Manual.

Requested Services

Requested services are those under which a permitted health practitioner has requested that an imaging practice perform a diagnostic imaging service.

There are three key areas required to demonstrate your practice's ability to achieve this Standard if you perform requested services.

1. The practice must have a documented policy and procedure describing how inappropriate requests are handled.

2. Practices must submit 3-5 de-identified request forms for each modality demonstrating that an identified clinical need was documented.

Information about the recommended method for de-identifying records can be found in [Appendix 9](#).

3. Standard 1.1 requires that you evaluate, audit, review and monitor each standard and its specific requirements. This can be done by a range of approaches such as audits, management reviews, or improvement records. There is a suggested review schedule in the example Safety and Quality Manual ([Appendix 2](#)) which can be used in conjunction with the accreditation checklist ([Appendix 1](#)) to support planned reviews of all standards at required intervals.

The checklist in [Appendix 1](#) will help you to determine whether you have all of the necessary documents and records to meet this standard.

Self-determined Services

As described in the Medicare Benefits Schedule, explanatory note IN.0.7, services are classified as self-determined when rendered:

- By a consultant physician or specialist, in the course of that consultant physician or specialist practicing his or her specialty (other than a specialist in diagnostic radiology); or
- To provide additional services to those specified in the original request and the additional services are of the type that would have otherwise required a referral from a specialist or consultant physician.

There are two key areas required to demonstrate your practice's ability to meet this Standard if you perform self-determined services.

1. Practices must submit 3-5 de-identified patient records for each modality, demonstrating that an identified clinical need was documented.

Information about the recommended method for de-identifying records can be found in [Appendix 9](#).

2. Standard 1.1 requires that you evaluate, audit, review and monitor each standard and its specific requirements. This can be done by a range of approaches such as audits, management reviews, or improvement records. There is a suggested review schedule in the example Safety and Quality Manual ([Appendix 2](#)) which can be used in conjunction with the accreditation checklist ([Appendix 1](#)) to support planned reviews of all standards at required intervals.

The checklist in [Appendix 1](#) will help you to determine whether you have all of the necessary documents and records to meet this standard.

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.

Intent of the Standard

Patients have a right to receive information, ask questions, and raise concerns about their health care. Effective communication between the patient and the practice is fundamental to informed decision-making for both parties.

The purpose of this Standard is to ensure that:

1. Information concerning the proposed diagnostic imaging procedure is accessible to patients (or their substitute decision maker) prior to the service, and is easily understood so they can make informed decisions on risks and benefits and this information is subject to regular and ongoing review.
2. Practices have obtained patient health information relevant to determining clinical risk for the proposed procedure,
3. Consent is obtained from the patient or substitute decision maker prior to each and every examination.
 - Consent for procedures that are not considered to pose a high risk may be verbal or written, as determined by the practice, but it must be obtained and recorded.
4. Where the proposed diagnostic imaging procedure represents a high risk to the patient, written/signed consent must be obtained.

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.

Preparing your accreditation application

There are six key areas required to demonstrate your practice’s ability to achieve this Standard.

1. The practice’s policy and procedures for obtaining appropriate patient consent and providing information to consumers about the service and its risks must be included in the Safety and Quality Manual.

It is expected that the diagnostic imaging practice which undertakes the examination is responsible for ensuring:

- a patient or substitute decision maker has received sufficient, appropriate information to make an informed decision, including information about the potential risks and benefits of the proposed examination;
- a patient or substitute decision maker has given valid consent prior to the examination being undertaken; and
- relevant evidence of the consent is appropriately documented.

It is expected that practices obtain written patient consent prior to invasive or high risk procedures; and it is the responsibility of the practice to determine the level of risk associated with each procedure. Written consent from a substitute decision maker is also recommended where doubt exists about the patient’s capacity to consent.

An invasive procedure is broadly defined for the purposes of the DIAS as ‘a procedure requiring insertion of an instrument or device into the body through the skin or a body orifice for diagnosis or treatment’⁴. An exemption from the requirement for written consent to be obtained for an invasive procedure has been provided for the following procedures:

- the insertion of an IV cannula,
- the performance of low risk transvaginal or transrectal ultrasound. Note that where transvaginal or transrectal ultrasound procedures are performed, verbal informed consent must be obtained from the patient or substitute decision maker and evidence of this consent recorded. For high risk procedures, such as those which use transvaginal or transrectal scanning as imaging guidance (e.g. for biopsies) or are otherwise high risk for the individual patient, written consent must still be obtained from the patient or substitute decision maker.

⁴ Stedman’s Medical Dictionary 26th edition (1995)

2. De-identified copies of 3-5 examples of documented consent (verbal or written) must be provided for each modality.

Consent obtained may be written or verbal, as determined by the practice, but consent must be obtained for each examination.

- Implied consent is not permitted. A practice cannot assume that a patient has consented to an imaging examination on the basis that they have arrived at the practice with a request form.
 - Verbal consent is appropriate for low risk procedures where the procedure is explained to the patient, giving them an opportunity to proceed or decline to undertake the procedure. Verbal consent must be recorded for each examination. The practice must determine how they will record this consent. This should be described in the procedure.
3. De-identified copies of 3-5 examples demonstrating that the patient's health status relevant to the imaging procedure has been collected.

Practices must document a patient's health status where it may affect the risk assessment of the patient for the proposed procedure.

For example, if planning a procedure which uses contrast, this would include capturing, at minimum, information on asthma, allergies, pregnancy status and breastfeeding. For a plain x-ray, this information is likely to be limited to pregnancy status for women of child-bearing age.

Pregnancy status as stated by the referring practitioner is usually not a sufficient record that pregnancy status has been checked.

Information about the recommended method for de-identifying records can be found in [Appendix 9](#).

4. Practices must ensure information on specific diagnostic imaging procedures is accessible at the practice. Information may be provided in hardcopy or electronic formats. Suitable information could be developed in-house, or obtained from a credible source such as the [InsideRadiology website](#).
5. De-identified copies of 3-5 examples demonstrating that risks associated with the procedure have been advised to patients.

It is the responsibility of the practice to determine the level of risk associated with each imaging procedure.

For procedures determined to be of very low, or no risk to the patient, risks do not need to be advised. Practices should document these procedures in their Safety and Quality Manual.

Note: Invasive procedures are defined in the glossary. Unless an exception applies and has been described in the explanatory material for Standard 2.2 in this user guide, practices must obtain written consent from the patient for these procedures.

Information about the recommended method for de-identifying records can be found in [Appendix 9](#).

6. Standard 1.1 requires that you evaluate, audit, review and monitor each standard and its specific requirements. This can be done by a range of approaches such as audits, management reviews, or improvement records. There is a suggested review schedule in the example Safety and Quality Manual (Appendix 2) which can be used in conjunction with the accreditation checklist (Appendix 1) to support planned reviews of all standards at required intervals.

Appendix 10 is an example of a form for ensuring that practices meet the minimum requirements for obtaining and recording information regarding a patient's health status, risk advice and consent.

The checklist in Appendix 1 will help you to determine whether you have all of the necessary documents and records to meet this standard.

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.

Intent of the Standard

An essential part of receiving safe care is ensuring that the right care is provided to the right person. This is achieved by:

1. Ensuring all patients are correctly identified.
2. Ensuring the patient is matched with their:
 - intended diagnostic imaging service;
 - anatomical site; and
 - anatomical side.
3. Use of a time-out for high risk procedures.
4. Demonstrating continuous improvement processes resulting from any mismatching events.

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.

Preparing your accreditation application

There are five key areas required to demonstrate your practice's ability to achieve this Standard.

1. Submission of a documented policy and associated procedures for matching patients to their intended diagnostic imaging procedure; an example Patient Identification and Procedure Matching policy can be found in **Appendix 2**.

The policy and procedures must address:

- The identifiers that are approved at the practice; consideration should be given to whether the approved identifiers are unique to the patient, and whether they would assist in reducing the risk of misidentifying two similar sets of identifiers;
 - That three identifiers must be confirmed through all stages of the service, including, but not limited to:
 - On the request;
 - At the point of imaging;
 - On each worksheet (where worksheets are used);
 - On the report; and
 - When transferring responsibility of care.
 - That the patient is matched to their intended procedure; and
 - Time out process for high risk procedures.
2. De-identified copies of 3-5 examples for each modality demonstrating the use of 3 identifiers.

Practices may wish to adopt appropriate protocols developed by the [Australian Commission on Safety and Quality in Health Care](#) and add these to their Safety and Quality Manual.

Information about the recommended method for de-identifying records can be found in [Appendix 9](#).

3. Submission of a documented policy and associated procedures for investigating patient identification mis-match incidents. The procedure must include:
- How the incident is recorded;
 - Who the incident is reported to;
 - How the incident is investigated;
 - What is the response to the outcome of the investigation, for example, depending on the circumstance responses could include:
 - Recording the quality improvement register;
 - Contacting the requesting physician;
 - Correspondence with the patient;
 - Issuing an amended report;
 - Updating medical records;
 - Changing procedures; and
 - Escalating the incident to senior management or sentinel reporting.
4. Provide records describing actions taken in response to patient mis-match events.
5. Standard 1.1 requires that you evaluate, audit, review and monitor each standard and its specific requirements. This can be done by a range of approaches such as audits, management reviews, or improvement records. There is a suggested review schedule in the example Safety and Quality Manual ([Appendix 2](#)) which can be used in conjunction with the accreditation checklist ([Appendix 1](#)) to support planned reviews of all standards at required intervals.

The checklist in [Appendix 1](#) will help you to determine whether you have all of the necessary documents and records to meet this standard.

[Appendix 2](#) (Safety and Quality Manual example) includes an example of a policy on patient identification and procedure matching that addresses the requirement of a process for reporting, investigating and responding 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.**

Intent of the Standard

Medication management is a key area of risk for practices, and requires appropriate risk mitigation strategies. Patient harm may result if the wrong medication is administered, or the right medication is used incorrectly. Medications may also have adverse and unintended side effects.

The purpose of this Standard is to ensure practices have strategies in place for managing medication risks.

Medications that are used during interventional radiology procedures and those required to create or enhance diagnostic quality images fall within the scope of this standard.

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.

Preparing your accreditation application

Which medications are within the scope of DIAS?

- Anything that is used to create or enhance diagnostic quality images is within scope. This includes contrast, and may include medications such as saline, buscopan, beta blockers and local anaesthetic. If the medication must be used to obtain diagnostic quality images then it is included.
 - Anything that is administered to a patient as part of an interventional radiology procedure such as steroids, sedatives, local anaesthetics. Further information on what is considered to be an interventional radiology procedure can be found at the website of the [Interventional Radiology Society of Australia](#).

Note: If your practice does not store, prepare, dispose or administer medications in regard to diagnostic imaging services provided under Medicare, then this should be documented in the practice Safety & Quality Manual. You do not need to do anything further under this Standard and can now proceed to Standard 3.1.

There are six key areas required to demonstrate your practice's ability to achieve this Standard.

1. Submission of a documented medication management policy, and associated procedures covering all elements contained in the required evidence:
 - 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.

An example demonstrating how this information can be structured in a policy and a procedure to meet required evidence can be found in the example Safety and Quality Manual [Appendix 2](#).

2. Submission of a documented management plan for managing adverse reactions covering all elements contained in the required evidence:
 - 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.

An example demonstrating how this information can be structured in a policy and a procedure to meet required evidence can be found in the example Safety and Quality Manual [Appendix 2](#).

3. A documented protocol for the appropriate use and administration of contrast must be provided.

This protocol, where relevant, should be consistent with the RANZCR [Guidelines for the use of iodinated contrast](#), and the RANZCR [Guidelines on the use of gadolinium-containing MRI contrast agents in patients with renal impairment](#).

This protocol should also:

- describe the risks that need to be advised to patients;
 - describe the consent procedure;
 - identify the dose and type of iodinated contrast to be administered;
 - determine the situations when the radiologist supervising the procedure is to be contacted;
 - identify who is permitted to administer contrast;
 - describe the need for a medical practitioner to be immediately available to attend to the patient in the event of an emergency or complication of contrast injection;
 - describe the information that needs to be recorded in the patient file (type of contrast, dose/volume administered and route of administration, adverse reactions);
 - describe the length of time patients are required to stay at the practice after the procedure; and
 - describe the correct storage conditions for the contrast.
4. De-identified records documenting patient's medication use, history, and health status information that could increase risk. You will be required to submit 3-5 samples of such records for each modality.

A template for a Health Status, Risk and Consent form is in [Appendix 10](#).

Note: Records of patient health status may have already been supplied with the evidence requested for standard 2.2.

5. Provide records demonstrating the management of adverse reactions.
6. Standard 1.1 requires that you evaluate, audit, review and monitor each standard and its specific requirements. This can be done by a range of approaches such as audits, management reviews, or improvement records. There is a suggested review schedule in the example Safety and Quality Manual ([Appendix 2](#)) which can be used in conjunction with the accreditation checklist ([Appendix 1](#)) to support planned reviews of all standards at required intervals.

The checklist in [Appendix 1](#) will help you to determine whether you have all of the necessary documents and records to meet this standard.

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.

Intent of the Standard

The intent of this Standard is to ensure that practices adopt a consistent approach to imaging studies and deliver optimal images for diagnostic purposes.

Practices should have clear and detailed protocols describing the steps for performing an imaging study, including the required projections and/or manoeuvres. Practices must have documented protocols for all routine examinations performed.

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.

Preparing your accreditation application

There are two key areas required to demonstrate your practice's ability to achieve this standard.

1. Practices must submit protocols for all routine diagnostic imaging procedures.

Protocols must include all necessary information for the proper conduct of the examination, including at a minimum:

- Required projections;
- List of anatomy to be visualised;
- Contrast injection requirements;
- Positioning required;
- Any specification for the required qualifications, experience and specialisation of personnel*; and
- Instances when personal attendance, direct supervision or indirect supervision by a medical practitioner would be required.

* This may be covered by a statement within your Safety and Quality Manual under the policy addressing standard 1.2.

Consideration should also be given to including the following:

- Patient preparation instructions;
- Post procedure instructions;
- The range of diagnostic equipment available;
- Standard views;
- Specialised views;
- Use of gonad protection; and

- Ultrasound worksheets.
2. Protocols must be reviewed to keep them current and reflecting the needs of the practice and their patients. There must be evidence that each protocol has been reviewed at least once in the last accreditation cycle, i.e. once during the two year entry level accreditation, and once every four years thereafter.

Sample protocols are included in the example Safety and Quality Manual [Appendix 2](#).

The checklist in [Appendix 1](#) will help you to determine whether you have all of the necessary documents and records to meet this standard.

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.

Intent of the Standard

Note: Standard 3.2 only applies to practices using ionising radiation. Therefore practices that provide only ultrasound services or only MRI services do not need to comply with this Standard.

It is the intent of this Standard to ensure practices adopt a consistent approach to imaging studies that achieves optimal images for diagnostic purposes while also adhering to the ALARA principle of keeping radiation exposure as low as reasonably achievable.

The settings (technique charts, embedded settings, dose metrics and screening times) used on radiation emitting equipment must be reviewed and authorised by a qualified person on an annual basis.

A 'Qualified Person' must be defined by each practice by title or by name and described in the Safety and Quality Manual. The Qualified Person is expected to be a radiologist, medical physicist or senior radiographer.

Metrics for radiation dose administered by the practice for a specific study type on a given imaging device are used to determine a facility reference level (FRL – which may also be referred to as a 'practice reference level', PRL). The FRL is compared with diagnostic reference levels (DRL) for those study types where a DRL has been established in Australia. The objective of a diagnostic reference level is to help avoid excessive radiation dose to the patient that does not contribute additional clinical information to the medical imaging study.⁵

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.

⁵ IAEA Radiological Protection for Medical Exposure to Ionizing Radiation; IAEA: Vienna, 2002

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.

Preparing your accreditation application

Note: Evidence in this section depends on the type of equipment used.

There are five key areas required to demonstrate your practice's ability to achieve this standard.

1. Submit a technique chart for each unit of radiographic equipment.
2. Where settings are required to be manually entered:

Submit evidence that each technique chart has been reviewed and authorized by the qualified person annually for equipment

OR

Where equipment has settings embedded in software and operators select a protocol:

Submit evidence showing that the underlying embedded settings have been reviewed and authorised by the qualified person annually.

3. For each item of fluoroscopy equipment, the practice must submit the log of screening times for each item of equipment. Evidence must be available showing that the screening log has been reviewed by a qualified person annually. A template that may be used by practices to create a Screening Log is in [Appendix 11](#).

Note: Where fluoroscopy equipment is capable of generating dose metrics, it is acceptable to provide evidence that the dose metrics have been reviewed annually by a qualified person.

Useful information about reducing patient x-ray exposure during fluoroscopy can be found on the [IAEA Radiation Protection of Patients](#) website.

4. For each item of interventional angiography equipment, evidence must be available showing that the dose metrics have been reviewed by a qualified person annually. Where the interventional angiography equipment is not capable of recording dose metrics, the practice must submit the log of screening times for each item of angiography equipment, along with evidence showing that the screening log has been reviewed by a qualified person annually.
5. Practices providing examinations for which Diagnostic Reference Levels (DRLs) have been published in Australia must have a program to compare FRLs to the published DRL annually.

DRL comparison evidence

DRLs are published by ARPANSA, and are available on their [website](#). DRLs have been published for CT and for nuclear medicine, including the CT portion of SPECT/CT and PET/CT. The requirement to compare FRLs to published DRLs only applies to practices performing these procedures. As further DRLs for other modalities are published, these too must be compared annually.

As of 1 July 2018, CT DRLs have been published for three age ranges: baby/infants (0-4 years), children (5-14 years), and adults (15+ years), for eight anatomical regions for adults (only three for infants and children). Nuclear medicine DRLs have been published for a wide range of adult protocols in general nuclear medicine and PET, including the CT component of SPECT/CT and PET/CT. At this time there are no DRLs for paediatric nuclear medicine imaging scans and no requirement to conduct annual audits of such protocols.

A practice performing procedures for which DRLs have been established must develop a program for calculating a FRL and collecting data to annually compare the FRL to the corresponding DRL. The process for calculating the FRL should be documented along with the comparison procedure. A process for regularly reviewing the procedure and the audit outcomes should also be documented. Where a FRL exceeds the relevant DRL, a review of the imaging protocol to ensure that radiation protection of patients is optimised should occur.

For nuclear medicine services, if a fixed administered activity is specified in the imaging protocol, a note of the relevant DRL should be included in the protocol; and where a value above the DRL is considered appropriate, a brief statement of the justification should also be recorded. However, if the imaging protocol specifies that the administered activity is adjusted according to the physical characteristics of the patient (e.g. weight, body-mass index) then a FRL should be determined from the actual administered activities for a sample of patients.

Similarly, for comparison against the DRLs for the CT component of SPECT/CT and PET/CT, a FRL should be determined from the dose-length product for a sample of patients. The DRLs for the CT component of such procedures only apply to scans taken for the purposes of attenuation correction or anatomical localisation of features in the isotope imaging sequence. Fully diagnostic CT scans must be compared against the relevant diagnostic CT DRLs.

ARPANSA provides several resources to help facilities conduct dose audits, however practices can use any method to review and record their data against the DRLs, provided all required information is provided. Facilities may take advantage of the free Multi-Detector Computed Tomography (MDCT) online survey program published by ARPANSA which records details of up to 20 imaging events for each protocol type and returns an automated report comparing the facility data against the published DRL. Similarly, templates from ARPANSA are available to aid in the collation of nuclear medicine dose data, as there is currently no online survey program to submit this information. Information about the DRL Modality Surveys, the login page for the online survey and templates for nuclear medicine dose data can be found on the [ARPANSA website](#).

The checklist in **Appendix 1** will help you to determine whether you have all of the necessary documents and records to meet this standard.

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.

Intent of the Standard

This Standard applies to practices that provide imaging services in response to requests from referring practitioners; it is not applicable to practices that only provide self-determined services. Practices who provide both requested and self-determined services must meet the requirements of both Standards 4.1 and 4.2.

Across the health care system there is evidence of harm to patients arising from ineffective or incomplete communication between healthcare practitioners. Such instances can lead to incorrect treatment, delays in diagnosis, life threatening adverse events, increased health care expenditure and increased hospital stays.

The intent of this Standard is to ensure timely and effective communication between practices and referrers, to achieve optimal patient outcomes.

This Standard also addresses the practice's policy regarding the provision of reports to patients.

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.

Preparing your accreditation application

There are four key areas required to demonstrate your practice's ability to achieve this Standard.

1. Submission of a documented policy for the provision of reports to requesting practitioners; an example demonstrating how a policy may be structured to meet the required evidence is found in [Appendix 1](#).

The policy must include how the reporting physician communicates unexpected or urgent findings to the requesting practitioner. The types of findings that would be considered 'unexpected' or 'urgent' should be defined, as should the manner of the communications.

The practice's policy must include the provision of reports to patients. The policy should consider aspects such as:

- Whether the practice will provide reports directly to patients;
 - The circumstances under which reports may be provided; and
 - How the patient can request a copy of the report.
2. Submission of de-identified reports that are consistent with the practices policy on the provision of reports to requesting practitioners; 3-5 samples of such reports for each modality.

Note: It is preferable that the reports submitted under this Standard match the 3-5 sample requests provided by practices as required evidence for Standard 2.1. This will allow accreditors to assess consistency in the process of receiving a diagnostic imaging request through to reporting the findings of the diagnostic imaging procedure undertaken.

Reports should be de-identified – the recommended manner of de-identification is shown in [Appendix 9](#).

3. A documented process for receiving feedback from requesting practitioners, and where appropriate, initiating quality improvement activities; [Appendix 4](#) (Quality Improvement Register) centralises quality improvement activities across all Standards. This improvement action register can be provided as evidence of documented quality improvement activities describing actions taken in response to feedback received from requesting practitioners.
4. Standard 1.1 requires that you evaluate, audit, review and monitor each standard and its specific requirements. This can be done by a range of approaches such as audits, management reviews, or improvement records. There is a suggested review schedule in the example Safety and Quality Manual ([Appendix 2](#)) which can be used in conjunction with the accreditation checklist ([Appendix 1](#)) to support planned reviews of all standards at required intervals.

The checklist in [Appendix 1](#) will help you to determine whether you have all of the necessary documents and records to meet this standard.

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.

Intent of the Standard

This Standard only applies to practices that provide self-determined services; it is not applicable to practices providing imaging services in response to requests from referring practitioners. Practices who provide both requested and self-determined services must meet the requirements of both Standards 4.1 and 4.2.

The provision exists under the Medicare Benefits Scheme for some specialist physicians to self-determine. Services are classified as self-determined when rendered:

- By a consultant physician or specialist, in the course of that consultant physician or specialist practicing his or her specialty (other than a specialist in diagnostic radiology); or
- Under a pre-existing diagnostic imaging practice exemption.

Required Evidence

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

Preparing your accreditation application

There are two key areas required to demonstrate your practice's ability to achieve this standard.

1. Your practice must submit 3-5 de-identified patient records documenting the image findings for self-determined services.

These records should be de-identified (see [Appendix 9](#) for information about de-identifying records), and may be the same records provided to demonstrate the clinical reason for the imaging (Standard 2.1) patient consent and risk (Standard 2.2) and the use of patient identifiers (Standard 2.3).

2. Standard 1.1 requires that you evaluate, audit, review and monitor each standard and its specific requirements. This can be done by a range of approaches such as audits, management reviews, or improvement records. There is a suggested review schedule in the example Safety and Quality Manual ([Appendix 2](#)) which can be used in conjunction with the accreditation checklist ([Appendix 1](#)) to support planned reviews of all standards at required intervals.

The checklist in [Appendix 1](#) will help you to determine whether you have all of the necessary documents and records to meet this standard.

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.

Intent of the Standard

The purpose of this Standard is to ensure practices actively encourage feedback from patients, carers, requestors and other stakeholders, and provide opportunities for people to comment on their healthcare.

There are a number of publications outlining the responsibilities of practices when communicating with patients.

Patients seeking or receiving care through diagnostic imaging practices have the right to comment in relation to services received. These rights are described in the [Australian Charter of Healthcare Rights](#), published by The Australian Commission of Safety and Quality in Health Care.

Patients also have the right to have an open discussion regarding adverse events which may have caused harm to the patient during their time in the imaging practice. The Australian Commission of Safety and Quality in Health Care (ACSQHC) [Australian Open Disclosure Framework](#) is designed to enable health service organisations and clinicians to communicate openly with patients when health care does not go to plan. It is designed so that patients are treated respectfully after adverse events.

The DIAS Standard 4.3 Consumer and Stakeholder Feedback and Complaints Management has been developed to align with the intent of Criteria 1.11-1.12 (Incident management systems and open disclosure) and 1.13-1.14 (Feedback and complaints management) of the National Safety and Quality Health Service Standards, [Clinical Governance Standard](#), from the Australian Commission on Safety and Quality in Healthcare (ACSQHC).

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 publically 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.

Preparing your accreditation application

There are five key areas required to demonstrate your practice's ability to achieve this Standard.

1. Submission of a documented policy for inviting, recording, managing and responding to feedback and complaints. The policy should address feedback from referrers, patients and other stakeholders such as patient family members or carers.

Stakeholder feedback and complaints provide practices with an opportunity to:

- evaluate the current performance of their diagnostic imaging service;
- inform solutions on improving services delivered; and
- build confidence and trust with patients, thus fostering better relations with patients.

Feedback can be collected in any manner that works for your practice, and could include methods such as ad hoc feedback forms, interviews or surveys.

An example of how a policy may be structured to meet the required evidence is found in [Appendix 2](#).

2. The practice must have publically available information about how and why it collects feedback. This information should be consistent with the [Australian Privacy Principles](#) which describe how entities manage personal information in an open and transparent way.
3. Records showing that personnel at the practice have been trained in feedback and complaints handling.
4. Submit 3-5 de-identified records of feedback and/or complaints received by the practice, including records of actions taken by the practice in response to the feedback.

These records should be de-identified (see [Appendix 9](#) for information about de-identifying records).

A template is provided in [Appendix 12](#) that can be used to develop your practice's feedback form.

The quality improvement register ([Appendix 4](#)) can be used to log the feedback received and track the actions undertaken.

5. Standard 1.1 requires that you evaluate, audit, review and monitor each standard and its specific requirements. This can be done by a range of approaches such as audits, management reviews, or improvement records. There is a suggested review schedule in the example Safety and Quality Manual ([Appendix 2](#)) which can be used in conjunction with the accreditation checklist ([Appendix 1](#)) to support planned reviews of all standards at required intervals.

The checklist in [Appendix 1](#) will help you to determine whether you have all of the necessary documents and records to meet this standard.

GLOSSARY

TERM	DEFINITION
ALARA principle	ALARA is an acronym for “As Low As Reasonably Achievable”. This is a radiation safety principle for minimizing radiation doses by employing all reasonable methods, economic and social factors being taken into account.
Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)	A Commonwealth Government agency charged with responsibility for protecting the health and safety of people, and the environment, from the harmful effects of ionising and non-ionising radiation.
Australian Sonographer Accreditation Register (ASAR)	ASAR accredits, and re-accredits on a regular basis, ultrasound programs offered by various institutions, and establishes the criteria against which these programs and any future Australian and New Zealand programs are judged. In addition a register of accredited and student sonographers is maintained and their continuing professional development (CPD) activities monitored and recorded.
Department of Health	The Department which seeks to promote, develop, and fund health and aged care services for the Australian public. This is achieved through strengthening evidence-based policy advice, improving program management, research, regulation and partnerships with other government agencies, consumers and stakeholders.
Diagnostic Imaging Accreditation Scheme	The Scheme is designed to ensure Medicare funding is directed to diagnostic imaging services that are safe, effective and responsive to the needs of health care consumers.
Diagnostic imaging procedure	The procedure for capturing or producing images.
Diagnostic imaging service	The entire procedure including the report. Under Medicare, the report itself is considered the service, and includes all processes that were required to produce the report (i.e., the actual imaging). The Service can only be provided by a medical practitioner.
Diagnostic quality image	An image that is of sufficient quality and detail to see all of the structures that are critical in answering the clinical question.

TERM	DEFINITION
Equipment servicing agent	An organisation or business entity which employs or contracts service providers who undertake preventative maintenance.
HDAA Australia Pty Ltd (HDAA)	One of three approved accreditors of the Diagnostic Imaging Accreditation Scheme.
High Risk	The assessed risk associated with an imaging examination for a specific patient determined by considering the patient's health status and the planned imaging procedure. Where the risk for a patient is high, written consent must be obtained prior to imaging.
Incident	Includes an error, a near miss or any adverse event relating to patient care, or patient, visitor or staff safety.
Infectious agents	A pathogen capable of entering the body, surviving in, multiplying, and potentially causing disease.
Interventional imaging procedures	Procedures such as joint injections, biopsies, and catheterisation using imaging guidance (usually X-ray, ultrasound and CT). Further information on what is considered to be an interventional radiology procedure can be found at the website of the Interventional Radiology Society of Australia .
Invasive imaging procedures	A procedure requiring insertion of an instrument or device into the body through the skin or a body orifice for diagnosis or treatment.
Location Specific Practice Number (LSPN)	Number issued by Services Australia to <ul style="list-style-type: none"> • identify the site where the diagnostic imaging procedure is undertaken; and • register the type of equipment used or stored at the practice.
Medical personnel	Medical practitioner such as a radiologist, general practitioner, or medical specialist.
Medicare Benefits Schedule	The listing of Medicare services funded by the Australian government.

TERM	DEFINITION
Medication - falling within the scope of DIAS	<ul style="list-style-type: none"> Anything that is used to create or enhance diagnostic quality images is within the scope. This includes contrast, and may include medications such as saline, buscopan, beta blockers and local anaesthetic. If the medication must be used to obtain diagnostic quality images then it is included. Anything that is administered to a patient as part of an interventional radiology procedure, such as steroids, sedatives, local anaesthetics etc.
National Association of Testing Authorities, Australia (NATA)	One of three approved accreditors of the Diagnostic Imaging Accreditation Scheme.
Non-Medical personnel	Includes radiographers, sonographers, nurses, dentists and allied health professionals such as chiropractors, physiotherapists, podiatrists and osteopaths.
Nuclear Medicine Physician	<p>A medical practitioner credentialed by the Joint Nuclear Medicine Credentialing and Accreditation Committee (JNMCAC) of the Royal Australasian College of Physicians and the Royal Australian and New Zealand College of Radiologists.</p> <p>Credentialed Nuclear Medicine Physicians are entitled to provide Medicare funded nuclear medicine services. More information can be found on the Australasian Association of Nuclear Medicine Specialists website.</p>
Patient Identifier	Information used for the purposes of patient identification which may include: patient name (family and given name/s); date of birth; address; medical record number etc. Identifiers should be personal to the patient, and different practices may choose to collect different identifiers to suit their patients and practice.
Practitioner	A health care professional such as a doctor, nurse, imaging technologist, sonographer or pharmacist.
Qualified Person	For Standard 3.2: "Qualified Persons" may include radiologists, senior experienced radiographers, or medical physicists and other personnel who have direct authority and responsibility for the imaging performed, and can authorise the doses delivered to patients at the practice. Service personnel would not be considered appropriate.

TERM	DEFINITION
Quality improvement activity	Actions taken within the practice to review and enhance the quality of a process and/or diagnostic imaging service; may be undertaken proactively, or in response to an error, slip, incident, complaint or audit finding.
Quality Innovation Performance Pty Ltd (QIP)	One of three approved accreditors of the Diagnostic Imaging Accreditation Scheme.
Radiation medical practitioner	The medical practitioner responsible for the overall conduct of the procedure involving the exposure of the patient to ionising radiation. Generally a specialist in radiology (radiologist).
Recognised service training course	A training course generally accepted in the industry as appropriate for the equipment being serviced and the preventative maintenance activities of the service provider.
Record	A document, database (however kept), photograph or other pictorial representation or image which documents an event or finding. A blank form is not a record.
Referrer	A registered medical practitioner, dentist or other health professional who is entitled to refer individuals for imaging examinations. See also Requesting practitioner.
Requesting practitioner	A medical practitioner or other practitioner permitted to request a diagnostic imaging service under the <i>Health Insurance Act 1973</i> . See also Referrer.
Royal Australian and New Zealand College of Radiologists (RANZCR)	Professional organisation promoting the science and practice of the medical specialties of Radiology and Medical Imaging (Diagnostic and Interventional) and Radiation Oncology in Australia and New Zealand.
Sample	A subset of records selected by the practice to submit as evidence in an accreditation application to an accreditor.
Self-determined Services	Imaging services provided by a specialist physician in the pursuit of their specialty for their own patients. Radiologists generally cannot self-determine services.
Service (of equipment)	“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).

TERM	DEFINITION
Service provider	The individual who carries out preventative maintenance on diagnostic imaging equipment.
Services Australia	The Commonwealth department which administers Medicare.

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