Australian Commission on **Safety and Quality** in Health Care

DIAS
Diagnostic Imaging Accreditation Scheme

Overview of the Medical Imaging Accreditation Scheme

The Medical Imaging Accreditation Scheme (MIAS) is the mechanism by which the Department of Health, Disability and Ageing can ensure imaging providers delivering Medicare Based Services are providing safe and high-quality patient care. This overview explains how the MIAS operates and the accreditation requirements and processes that apply to imaging providers.

About the Commission

The Australian Commission on Safety and Quality in Health Care (the Commission) is responsible for formulating and administering model national healthcare safety and quality accreditation schemes for healthcare services, including imaging providers.

The Commission's role in accreditation includes:

- providing national coordination of accreditation, and ensuring policies and procedures are in place to keep the accreditation process effective and transparent
- monitoring accrediting agencies' performance and identifying issues requiring further support
- overseeing accreditation in a wide range of health settings and work right across the health system to ensure expected standards of safety and quality continue to be met
- publishing assessment outcomes data and maintaining registers of accredited services as part of our commitment to public reporting.

National Medical Imaging Standards

Under the MIAS, imaging providers will be required to provide evidence that they meet the National Medical Imaging Standards (Imaging Standards). The Imaging Standards provide a framework to support imaging providers to implement a continuous cycle of patient safety and

quality improvement activities. This ensures imaging providers have safety and quality systems that minimise the risk of harm and improve patient care.

Imaging providers adopt a risk management approach to determine their improvement and implementation strategies. These strategies depend on the imaging provider size, service type, and context.

Accreditation

Accreditation provides assurances to the community that imaging providers meet the expected standards for safety and quality. It is a formal process where health services are assessed against nationally recognised standards.

The accreditation scheme must have sufficient rigour to be of value to imaging providers and provide assurances to the community. The scope of assessment requires flexibility to consider the complexity associated with the imaging provider.

The MIAS has three modes of assessment - virtual, onsite and hybrid. Depending on the assessment category, these may occur as announced or short notice assessments. The categories and modes of assessment for the MIAS are provided in **Table 1**.

Table 1. Imaging provider type and assessment mode

Service group	Characteristics	Assessment mode	Assessment schedule
Group 1	Self-referred ultrasound imaging	Virtual	• Announced assessment • Three-year accreditation cycle
Group 2*	Practices that provide services involving only one imaging modality	Virtual	• Short notice assessment • Three-year accreditation cycle
Group 3*	Practices that provide services involving only one imaging modality	Hybrid	• Announced assessment • Three-year accreditation cycle
Group 4	Practices that provide services involving more than one imaging modality	Hybrid	• Announced or short notice assessment • Three-year accreditation cycle
Group 5	Imaging providers approved for sampling	Onsite and Virtual 50% of sampled sites will be assessed onsite, 50% virtually	• Announced assessment • Three-year accreditation cycle
Group 6	Imaging services operated in facilities already accredited to	Onsite	• Assessed to the NSQHS Standards

	national safety and quality standards	and Medical Imaging Module • Short notice assessment aligned with the NSQHS assessment cycle • Three-year accreditation cycle

* Single modality practices can elect to be in group 2 or group 3

Assessment modes

Currently under DIAS, imaging providers are accredited by a desktop assessment. Providers are required to upload documentation that demonstrates compliance with the process-based DIAS Standards.

Safety and quality standards have evolved since DIAS was introduced in 2008, recognising that process standards assess what should occur in a healthcare setting, but do not evaluate the outcomes of those processes. The Imaging Standards place greater emphasis on continuous quality improvement embedded into day-to-day practice. Assessment therefore requires evidence from multiple sources to verify that documented systems and processes are implemented in practice.

Accreditation to the Imaging Standards will be by virtual, hybrid or onsite assessment (outlined in **Box 1**). These assessment modes allow assessors to consider different sources of evidence, such as documentation, interviews and observations of practice, providing a more comprehensive assessment of whether the Imaging Standards are met.

The assessment mode assigned to a practice will apply throughout the accreditation process, including final assessment or any mandatory reassessment.

Box 1. Assessment modes

Virtual assessment involves assessing an imaging provider using digital or remote means to view the imaging provider, comprising observations and interviews with the workforce, consumers and carers. The independent assessment team attends the imaging provider remotely to evaluate its compliance with the Imaging Standards.

Hybrid assessment involves assessing imaging providers using a combination of virtual and onsite assessments. The onsite assessor/s observe operations, practices and facilities, while the virtual assessment focuses on interviews and document review. For further guidance on virtual and hybrid assessment see **Appendix 1.**

Onsite assessment involves assessing imaging providers using a physical visit to observe the imaging provider and interview the workforce. The independent assessment team examines the operations, practices and facilities of the imaging provider, conducts interviews with the workforce, consumers and carers, and verifies the authenticity and accuracy of documentation provided by the imaging provider. For further guidance on onsite assessment see **Appendix 2.**

Short notice assessment involves the imaging provider being notified 10 business days prior to the assessment date. Health services may voluntarily choose to be assessed at short notice, or it may be a requirement of licencing or funding contracts.

Unlike an announced visit, a short notice assessment may occur at any time during the three-year accreditation cycle. Short notice assessment transfers the focus of assessment from a prepared state to the examination of the day-to-day systems, processes and care delivery, reducing the administrative burden of preparing for an accreditation visit.

Imaging providers electing to be assessed at short notice, may identify up to 20 business days per accreditation cycle for exclusion from a short notice assessment (see **Box 2**). Days which an imaging provider does not routinely provide imaging services are not counted as excluded dates. The imaging provider is responsible for informing the accrediting agency if the days of usual business change.

Box 2. Excluded dates: key points

- Imaging providers may request up to 20 business days per accreditation cycle be excluded from short notice assessments.
- Excluded dates are to be calculated based upon 'days of usual' business, on which the entire service is operational.
- Submissions to an accrediting agency of excluded dates should provide a rationale and supporting evidence to confirm that performing a short notice assessment on these dates would directly impact consumers, or that consumers of the service would be unavailable.
- Excluded dates will not be accepted where a mandatory repeat assessment is required. These are scheduled assessments that must occur within the specified timeframe.

Rural and remote practices

Imaging providers located in remote communities or small rural towns as per the Modified Monash Model (MM5-MM7), may apply for a virtual announced assessment. Applications are submitted through the approved accrediting agency and are subject to Commission approval, following a risk assessment of the practice.

Interim accreditation

New practices may apply for interim accreditation. Interim accreditation must be obtained before the practice can offer Medicare eligible services.

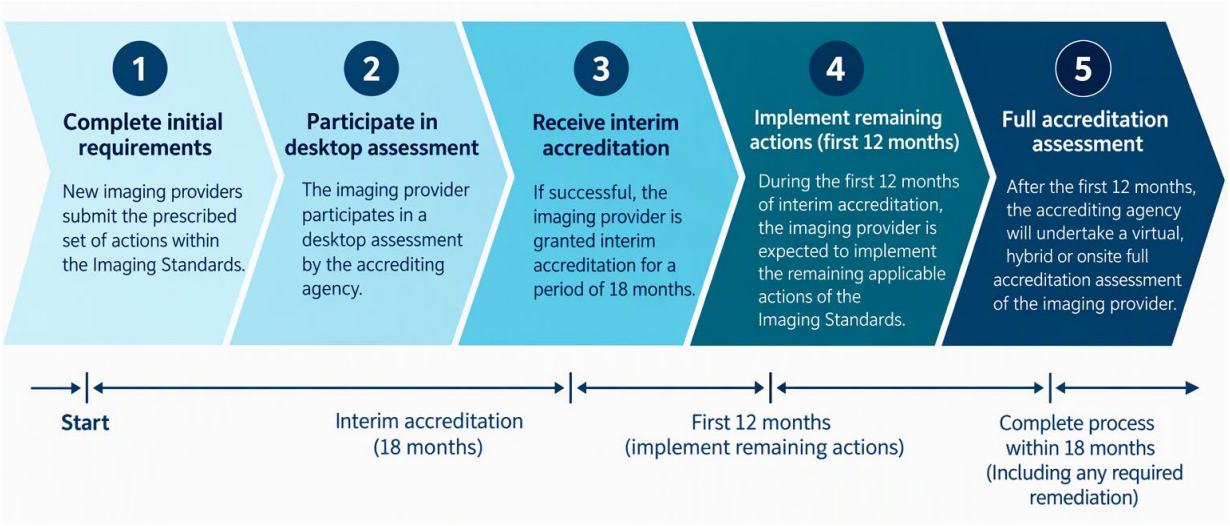
New practices are required to implement a prescribed set of actions from the Imaging Standards and undergo a desktop assessment. Practices that successfully complete this assessment will be granted interim accreditation for 18 months.

Within the first 12 months of the interim accreditation period, the practice must implement all remaining applicable actions of the Imaging Standards. The accrediting agency will then undertake a full accreditation assessment, which may be conducted virtually, onsite or using a hybrid approach.

The full assessment process (outlined in **Figure 1**.), including the resolution of any identified non-conformities or required remediation, must be completed within the 18-month interim accreditation period.

Successful imaging providers will transition to the three-year accreditation cycle, starting from the date of full accreditation.

Figure 1. Interim accreditation timeline



Sampling

Sampling is a structured way for accrediting agencies to assess a selected number of an imaging provider's practices, under a single governance structure, instead of assessing every single practice. To ensure consistency, the Commission has developed a sampling methodology (**Table 2**) to be applied by all accrediting agencies when assessing eligible imaging providers.

Table 2. Sampling Methodology

Number of practices	Required Assessments	Example
Up to 5	Every practice to be assessed	
6 to 20	5 practices, plus one-third of the remaining practices (rounded up)	If 15 practices: • 5 practices automatically assessed • one third of 10 rounded up is an additional 4 practices • total number of practices sampled would be 9
21 to 99+	10 practices, plus one-quarter of the remaining practices (rounded up)	If 40 practices: • 10 practices automatically assessed • One quarter of 30 rounded up is an addition 8 practices • Total number of practices sampled would be 18

100 or more	May apply to the Commission to cap the number of practices assessed	If 140 practices: • 10 practices automatically assessed • One quarter of 130 rounded up is an additional 33 practices • Total number of practices sampled would be 43 • Imaging provider applied to cap assessed practices at 35.

The following rules will apply when selecting the assessment practices.

1. The accrediting agencies will take into consideration factors such as (but not limited to):
   - previous assessment results
   - time elapsed since the practice was last assessed
   - information from incident reports, complaints and external reports, including their severity and frequency
   - performance trends and key quality indicators
   - insights gained through discussions with the organisation and practice (including, but not limited to, the complexity and diversity of service provision at each practice)
   - the provision of higher-risk or more complex services, such as interventional procedures, magnetic resonance imaging (MRI), computed tomography (CT) and nuclear medicine services.

   The sample should include an appropriate mix of service types and modalities, including higher-complexity services where relevant.
2. 75 percent (rounded up) of imaging practices assessed are to be selected based on a risk assessment by the accrediting agency.
3. 25 percent of practices assessed are to be selected at random, ensuring a representative sample of the service assessed.
4. Sample practices are to be selected by the accrediting agency without input or influence from the imaging provider.

The Commission will consider exemptions to the rules on a case-by-case basis where the availability of staff and patients is unpredictable and therefore requires some prior planning, or advanced notice is a requirement of entry to the practice.

Imaging providers seeking an exemption from the sampling methodology must write to the Commission via their approved accrediting agency. The Commission, in collaboration with regulators, decide on these applications.

Accrediting agencies are to notify the imaging provider of the practices to be assessed at least ten days prior to assessment. Remote or very remote practices, as defined by the ASGS-RA classification, should be notified at least 6 weeks prior to assessment.

Accreditation to multiple sets of standards

All the Commission's National Safety and Quality Standards are written with deliberate alignment in both structure and intent. Where multiple sets of Standards are applicable to an organisation's service delivery, dual accreditation is possible due to this alignment. Healthcare services are required to implement a foundational set of Standards in full, such as the National Safety and Quality Primary and Community Healthcare Standards (Primary and Community Healthcare Standards) or National Safety and Quality Health Service (NSQHS) Standards. The requirements for the additional Standards are mapped against the foundational standards to identify:

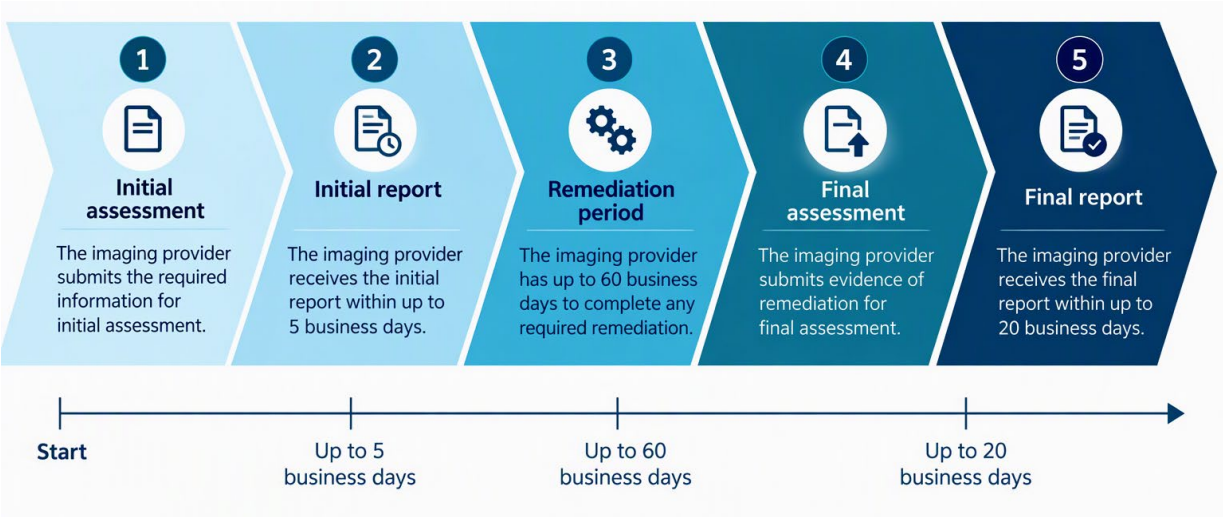
- actions that are duplicated/already addressed through implementation of the foundational Standards
- the small number of additional actions that are specific to the service delivery and will need to be implemented in addition to the foundational Standards.

The additional actions form the basis of 'National Safety and Quality Modules'. Imaging providers that undertake accreditation to other National Safety and Quality Standards, or that operate under the same clinical governance framework as a health service accredited to those Standards, may complete the **Medical Imaging Module**. This module is assessed concurrently with the Primary and Community Healthcare Standards or NSQHS Standards in a single assessment process. It contains the actions unique to medical imaging and removes any actions that are duplicated in the foundational set of Standards. This approach is designed to reduce accreditation burden.

Assessment process

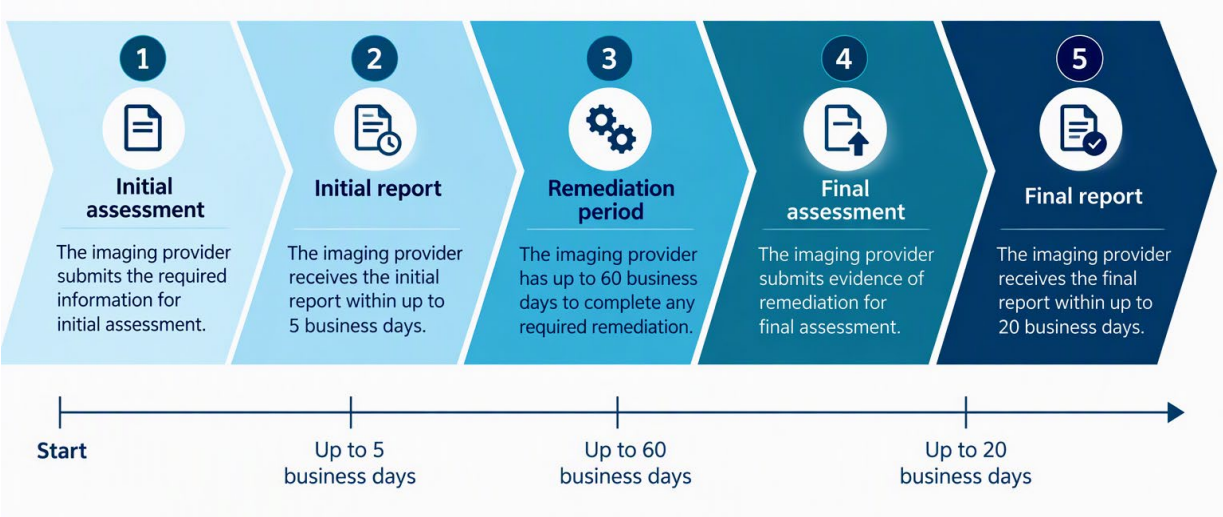
An assessment process can take between one to four months, dependent on whether a remediation period is required. It involves an **initial assessment**, with an initial report provided within 5 business days. If all the relevant actions of the Standards are met (**Figure 2**), the approved accrediting agency has 20 business days to finalise the outcome report and issue an accreditation award to the imaging provider.

Figure 2. Assessment process – accreditation at initial assessment



If, at initial assessment, one or more actions of the Standards are not met (**Figure 3**), the imaging provider has a remediation period of up to 60 business days before a **final assessment** occurs. This assessment is to confirm the requirements of the Standards are fully met. The approved accrediting agency has 20 business days from the final assessment to finalise recommendations, provide an outcome report and grant accreditation where appropriate.

Figure 3. Assessment process – remediation required at initial assessment



To support the sector to transition to the Imaging Standards, imaging providers accredited under DIAS will have a remediation period of up to 90 business days (instead of 60 business days) for the first accreditation cycle.

Significant risk

A significant risk is one where there is a high probability of a substantial and demonstrable adverse impact for a patient if not mitigated and is sufficiently serious to warrant an immediate response.

Where a significant risk is identified:

1. the assessor must immediately notify the imaging provider and accrediting agency
2. the imaging provider must identify and implement immediate controls and develop an action plan
3. the accrediting agency must notify the Commission and relevant regulator within 48 hours and provide the action plan
4. the imaging provider must complete the agreed actions by final assessment.

While the focus is on risks to patients, other significant risks may also be identified, including risks to the workforce.

Assessment rating scale

During an accreditation assessment, actions will be rated as:

- **met** – where all requirements are found to be fully met
- **met with recommendations** – where the requirements of an action are found to be largely met with the exception of a minor part of the action or location in the organisation, where additional implementation is required
- **not met** – where part or all of the requirements of the action are found to have not been met
- **not applicable** – where evidence is provided that the action is not applicable to the service provided.

Further information about the application of the rating, reporting and follow-up requirements are provided in **Appendix 3**.

Mandatory reassessment

Practices with a large number of actions rated ‘not met’ or ‘met with recommendations’ at initial assessment are unlikely to have sufficient time during the remediation period to fully embed all the changes required by the time accreditation is awarded. In these situations, a mandatory reassessment of an accredited imaging provider is required. **Box 3** outlines the mandatory reassessment criteria.

Box 3. Reassessment criteria

At the initial assessment, either:

- **16 percent** or greater assessed actions rated as not met or met with recommendations
- **5 or more** actions from the Clinical Governance Standard rated as not met.

Reassessment must occur within six months of awarding of accreditation and is conducted as an onsite assessment. At reassessment, all actions from the previous assessment rated met with recommendations and not met are reassessed.

The accrediting agency will notify the imaging provider of any not met actions and provide them with a report within five business days of the reassessment.

Where all actions are either met or met with recommendations, the imaging provider’s accreditation will be retained. The accreditation expiry date awarded following the original assessment remains unchanged.

There is a remediation period of 60 business days in which not met actions can be addressed. During this time, the imaging provider is to implement changes to ensure compliance with actions and may provide evidence to its accrediting agency to demonstrate compliance. At the end of the remediation period there is a final reassessment, that may be onsite. For an imaging provider to retain its accreditation, all actions must be met or met with recommendations.

Accreditation outcome appeal

Imaging providers can appeal their accreditation assessment outcome to their accrediting agency and the Commission. **Box 4** outlines the criteria that must be met for the Commission to review an appeal.

Box 4. Criteria for Commission appeals

An imaging provider **can appeal** to the Commission where:

- their accrediting agency did not comply with
    - the relevant accreditation policy/legislation
    - Commission fact sheets or advisories
- there is evidence that
    - a conflict of interest has been identified
    - the imaging provider was not afforded due process to appeal its accreditation assessment outcome with their accrediting agency.

The Commission **will not consider appeals** when the imaging provider:

- did not allow sufficient time, or comply with the reasonable directions of the accrediting agency to finalise the assessment before the accreditation expiry date
- is transferring between accrediting agencies.

The imaging provider submitting an appeal to the accrediting agency, or directly to the Commission, must do so within **20 business days** of receiving its final assessment report. Where an appeal has first been made to the accrediting agency, any appeal to the Commission must be submitted within **20 business days** of the accrediting agency's determination. Appeals must be submitted in writing and include executive approval. The Commission will provide a determination within 20 business days of receiving all information required to review the appeal.

Extension of an accreditation expiry date

Requests for an extension of an accreditation expiry date may be submitted to the Commission by the imaging provider or through the approved accrediting agency. The Commission will consider extensions where:

- risks have been identified that prevent a hybrid or virtual assessment from taking place
- natural disaster, fire, accident, or an emergency has occurred that lead to damage or restricted access to the practice
- the imaging provider’s operational priorities have changed, and clinical operations have temporarily ceased or relocated
- there have been changes in governance structures, such as acquisition or transfer of operations
- recent personal hardship or tragedy has been experienced by key workforce personnel, which has or is likely to significantly impact the operations over an extended period. This includes but is not limited to severe illness or death.

Transitioning between accrediting agencies

From time to time, imaging providers may wish to change the accrediting agency they have engaged to conduct accreditation assessments. Imaging providers may change their accrediting agency provided they:

- have signed a contract with the receiving accrediting agency before or immediately following cancellation of their client agreement with the initial accrediting agency
- maintain the existing accreditation cycle and schedule of assessment
- have no outstanding obligations to the initial accrediting agency.

Imaging providers cannot routinely transfer accrediting agencies during an assessment cycle (between an initial and final assessment). In these circumstances the Commission will consider requests on a case-by-case basis.

Out-of-cycle assessment

During the accreditation cycle, imaging providers may undergo changes for various reasons. Some changes can significantly increase the risk of patient harm, in which case, a review of compliance with standards may be necessary. Examples of these changes include:

- change of ownership and governance of an imaging provider
- changes or prolonged gaps in key leadership or executive positions across a number of positions
- significant increase in complexity of the scope of the service provision
- relocation to new facilities
- merger of one or more practices or imaging providers.

Appendices

Appendix 1 - Guidance on virtual and hybrid assessments

Virtual and hybrid assessments **cannot** be conducted when:

- there has been a report of a significant risk
- privacy, security, due process or impartiality cannot be guaranteed
- it is not feasible due to the limited availability, connectivity or performance of technology.

Before a virtual or hybrid assessment, the imaging provider must:

- provide assessors with a time limited clearance to the relevant programs and areas in the practices ICT systems
- provide assessors with a security briefing or instructions, if required
- ensure ICT devices are fully operational and charged
- nominate an ICT support person to be responsible for the integrity of the ICT system during the assessment
- ensure the nominated ICT support person is available to the assessors throughout the assessment
- provide the practices key contact details and obtain the assessors contact details
- agree to a contingency plan with the accrediting agency in the event the assessment cannot be finalised as scheduled.

During the virtual or hybrid assessment, the imaging provider must

- obtain permission from consumers involved in the assessment and provide them with information on the virtual assessment processes
- note that a general wide sweep of the camera does not require permission and is equivalent to an assessor being on site
- ensure all relevant documents are readily available or easily accessible.

After a virtual or hybrid assessment, the imaging provider must

- revoke assessors ICT and security access
- evaluate the effectiveness of the virtual assessment and provide feedback to the accrediting agency.

Information and communications technology systems

The imaging provider:

- ensures the ICT equipment being used during assessments
    - can be moved on a stable surface, such as a trolley to all locations where the assessment is to occur
    - has the camera facing forward when it is moved through a practice
    - complies with infection prevention and control requirements for equipment being moved between clinical areas
    - is fully charged and includes a backup power supply
- cannot use virtual backgrounds for assessments, as these reduce the likelihood of opportunistic observation of practice and environment
- ensures the ICT systems have the functionality to enlarge documents so they can be read by assessors.

Appendix 2 - Onsite assessment

How will assessments be planned?

Accrediting agencies will commence planning for the visit well in advance of the assessment. This allows time for security and IT systems to be arranged. Assessments must commence **at least** four months prior to the current accreditation expiry date. Imaging providers may work with their accrediting agency to find a suitable date.

Evidence provided to the accrediting agency prior to an assessment can help to prioritise the assessment schedule. Assessors will require access to governance documents and IT systems. There is no requirement to create presentations or provide additional documentation that is not generated as a part of usual business or delivery of patient care.

Timetabling will depend upon the size of the assessment team, number of practices to be visited and their geographic location. Prior to an assessment, it will be important to provide assessor teams with staff rosters and to communicate material changes so this can be taken into account on the day (such as key personnel, restrictions to clinical areas, or cancelled or changed theatre lists).

What will happen on the day of the assessment?

The aim of the assessment is for assessors to examine day-to-day practice.

Assessors will use an assessment framework called PICM which supports assessors to comprehensively evaluate each component of safety and quality systems in a service. This method provides a structure for conducting assessments based on evidence of actual performance from observations, interviews and records. It enables assessors to view aspects of the patient journey and identify how clinical governance and safety and quality systems are operationalised in clinical settings. For more information see Using PICM for quality improvement and assessment preparation.

Assessors will spend at least 75% of the assessment time in clinical areas talking to members of the workforce who are available on the day. They will also talk to patients, their carers and consumer representatives.

Being observed in the workplace can understandably cause anxiety. It is important to remember that the assessors are there to observe how the safety and quality systems implemented by the governing body are supporting safe patient care, not an individual's performance.

The assessors will interview a variety of members of the workforce; the questions will vary depending on the actions the assessors are reviewing. The workforce is not expected to know information outside of their safety and quality roles and responsibilities.

Consumer involvement

The Imaging Standards include requirements for imaging providers to partner with consumers. The partnering with consumers actions recognise the importance of involving patients in their own care and providing clear communication to patients to support shared decision making. Partnering with consumers involves treating consumers with dignity and respect, sharing information, and encouraging participation and collaboration.

Assessors will make every effort to minimise the impact on the usual delivery of care and services provided by the imaging provider. However, assessors will expect to speak to consumers and/or consumer representatives during an assessment.

Imaging services implement systems to notify consumers that an assessment is occurring and that with their consent, assessors may observe and/or interview them about the care they receive.

Consumers and consumer representatives are provided with opportunities to provide input into the assessment process in writing, in person, via telephone or electronically, including in confidence or anonymously.

Organisations will have a variety of ways to meet the actions of the Partnering with Consumers Standard, and the availability of consumer representatives will vary. If consumer representatives are not available during the assessment (either in person or via telephone), there are an additional five days post assessment for assessors to gather information, including interviewing consumers who were not available during the assessment.

Assessors are required to sign a confidentiality agreement and have the same obligations as the workforce regarding patient privacy and confidentiality.

What happens after the assessment?

The lead assessor will convene an exit meeting to provide a summary of the assessment outcomes. This is an opportunity to identify what is working well and opportunities for improvement. A final report will be made available to the imaging provider within 20 business days of the final assessment.

Appendix 3 - Rating scale

During an accreditation, each action will be rated using the scale below.

Rating	Application	Reporting and follow up requirements
Met	All requirements of the action are fully met.	**Reporting** Accrediting agencies provide the imaging provider with a written report within 20 business days. **Follow up** None required.
Met with recommendations	**Initial assessment** The requirements of an action are largely met with the exception of a minor part of the action or location in the organisation, where additional implementation is required. **Final assessment** All actions rated met with recommendations are reassessed at final assessment. If the action is not fully met at the final assessment, imaging providers can retain a met with recommendations and be reassessed at the next assessment. **Mandatory reassessment** Where a mandatory reassessment is required, actions rated met with recommendations at the initial assessment are reassessed. If the action is not fully met at the mandatory reassessment it can retain met with recommendations and be reassessed during the next accreditation cycle. **Next accreditation cycle** An imaging provider cannot be awarded met with recommendations for the same action for **two consecutive**	**Reporting** **Initial assessment** For all actions rated met with recommendations, assessors provide a clear and concise explanation of the: • minor part of the actions that have not been fully met • specific part of the actions or locations in the practice where the rating applies • requirements for the action to be rated as met. Met with recommendations may be awarded at each assessment within the same accreditation cycle. **Follow up** Imaging providers are to address the actions rated with recommendations before the final assessment, mandatory assessment (where required) and the initial assessment in the next accreditation cycle.

	accreditation cycles. Where this occurs, the action is rated as **not met**.	
Not met	**Initial assessment** Part or all the action's requirements have not been met. **Mandatory reassessment** Where a mandatory reassessment is required, actions rated not met at the initial assessment are reassessed. At the mandatory reassessment, these actions may be rated met, met with recommendations, or not met. If the action is not fully met at the mandatory reassessment it is recorded as met with recommendations and will be reassessed during the next accreditation cycle. **Final assessment** All actions rated not met are reassessed at final assessment. At the final assessment, not met actions may be rated met, met with recommendations, or not met.	**Reporting** **Initial assessment** At the summation meeting following an initial assessment, assessors specify the actions rated not met and provide an explanation for the rating. A summary report on the initial assessment includes a list of not met actions and is provided to the imaging provider within **five** business days. This report includes a written explanation for all not met ratings. Imaging providers are given a remediation period of **60 business days.** **Final assessment** All actions rated not met from the initial assessment are reassessed at final assessment. If any of the actions remain not met, the imaging provider's accreditation will be withdrawn, and Services Australia and the regulator will be informed. **Mandatory reassessment** Where a mandatory reassessment is required, actions rated not met at the initial assessment are reassessed. If any of the actions remain not met, the imaging provider's accreditation will be withdrawn, and Services Australia and the regulator will be informed.
Not applicable	Actions are rated not applicable when the action is not relevant to the imaging services provided by the imaging provider.	**Reporting** Accrediting agencies provide an initial determination of the imaging provider's submission before the assessment.

	Imaging providers need to apply to their approved accrediting agency well in advance of an assessment for an action to be rated as non-applicable. At assessment, assessors verify the initial determination and award these actions not applicable status if it is justified.	
Not assessed	Actions that are not part of the assessment and not reviewed.	