Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Applying for Australian conformity assessment body (CAB) determination for medical devices

Guidance to assist Australian corporations seeking to apply for an Australian conformity assessment body (CAB) determination for medical devices (including IVDs) by the TGA.

Published: 1 June 2021

Last updated: 26 June 2024

On this page

Purpose

These guidelines are intended to assist Australian corporations seeking to apply for an Australian conformity assessment body (Australian CAB).

The guideline outlines:

- eligibility information
- requirements for certification-related activities
- requirements for Australian CABs
- how a determination is scoped
- application and determination process
- determination decision
- what to expect once a determination is made.

These guidelines describe the processes associated with applying to become an Australian conformity assessment body. Separate guidelines describe post-determination monitoring activities.

Legislation

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices) Regulations 2002

Corporations Act 2001

About

An Australian CAB determination allows an Australian corporation to operate under the Australian medical devices regulatory framework.

This is broadly outlined under:

- Chapter 4 of the *Therapeutic Goods Act 1989* (the Act) and
- the Therapeutic Goods (Medical Devices) Regulations 2002 (the MD Regulations).

An Australian CAB may issue Australian conformity assessment body certificates to manufacturers of medical devices, and those certificates can be used by an Australian sponsor to support an application for inclusion in the Australian Register of Therapeutic Goods (ARTG).

> Only Australian corporations (as defined by the *Australian Corporations Act 2001*) are eligible to apply for a determination.

As an Australian CAB, your company will be:

- able to issue Australian conformity assessment body certificates to both Australian and overseas manufacturers of medical devices, within the scope of the conformity assessment determination
- responsible for monitoring those manufacturers for their ongoing compliance with the relevant conformity assessment procedures in Schedule 3 of the MD Regulations, and for taking appropriate actions when necessary, such as varying, suspending or revoking certificates.

Your company will also need to meet all the following requirements:

- continually comply with the requirements of your determination and keep records of your certification-related activities
- notify us if there are significant concerns about the safety of a medical device, or the activities of a medical device manufacturer (your client)
- notify us about certain events such as suspending, revoking or varying Australian conformity assessment body certificates
- provide information (on request) and participate in reviews by the TGA about your compliance with the MD Regulations, the conditions of determination and your certification-related activities.

These guidelines provide an overview of the process and requirements for applying for a conformity assessment body determination. It should be read alongside the legislation to which it relates, principally in Divisions 4A.2 - 4A.7 of, and Schedule 3AA to, the MD Regulations.

Eligibility

To be eligible to apply for an Australian CAB determination, your company must:

- be registered as an Australian corporation with the Australian Securities and Investments Commission (ASIC)
- hold a valid Australian Company Number (ACN).

Application requirements

Applications for a conformity assessment body determination must:

- be in English using the application form on our website
- be accompanied by the application fee for the application
- not contain any information that is false or misleading in any way.

Assessment requirements

The main criteria against which your application for a conformity assessment body determination will be assessed are:

- whether the TGA, is satisfied that you, will be able to comply with the requirements of Schedule 3AA to the MD Regulations
- whether the applicant, or other specified persons has, within the 10 years immediately before the application, fallen into any of the "fit and proper person" categories in paragraph 4A.6(3) of the MD Regulations, e.g., been convicted of an offence against the *Therapeutic Goods Act 1989*,

or been convicted of an offence against a law of the Commonwealth or state or territory involving fraud or dishonesty.

Other matters that may form part of the consideration of the fit and proper person criteria include whether an applicant has provided services to the medical devices sector that may lead to an actual or perceived impartiality or a lack of independence, such as:

- quality management system design, development, or management activities
- medical device product design, development, or manufacturing
- consultancy services for medical devices, including activities relating to manufacturing, product design and development, quality management systems or post-market investigation and reporting
- acting as an agent or sponsor for a medical device in Australia.

Certification-related activities

Australian CABs may perform certification-related activities within Australia and overseas.

Certification-related activities may include:

- development and approval of the Australian CAB's quality management system (QMS) for the audit and certification of a medical device manufacturer's QMS, or the review and certification of medical device product submissions
- review and acceptance of applications or submissions from medical device manufacturers, and the issuance of contracts

- assignment of QMS auditors and/or product review teams
- conduct of the regulatory review process
- review of assessment and audit reports and certification decision making activities
- technical review of audit reports
- competency management activities for technical experts including regulatory reviewers and auditors
- management, monitoring and oversight of the Australian CAB's medical device review, audit and certification program.

Some activities must be carried out by appropriately qualified employees of your company and cannot be outsourced:

- review of the qualifications and monitoring of the performance of external experts
- allocation of work to external experts for specific certification-related activities
- auditing and certification activities where the subcontracting in question is to auditing or certification organisations
- the final review and decision making for the issue of conformity assessment body certificates.

> You must have procedures and a written agreement with each contractor that permits access to their premises and allows us to undertake assessment-related activities.
>
> Home offices are not considered to be critical locations unless they are formally designated as an operating location by your company or a contractor.

Other activities which you sub-contract or refer cannot involve any intermediaries.

You must have a written agreement in place with each contractor or consultant to:

- address confidentiality and conflicts of interest and
- take full responsibility for the tasks performed by these individuals.

An authorised officer of the TGA may enter and inspect company or contractor premises to carry out assessment activities in Australia or overseas.

Requirements for Australian conformity assessment bodies

The requirements to be met by an Australian corporation seeking to become an Australian CAB, and to be maintained once your determination has been issued.

These are set out in Schedule 3AA of the MD Regulations.

As the applicant, your company needs to:

- employ personnel with the necessary technical, scientific and clinical competence
- have facilities and processes that will enable you to carry out assessments for the issue of conformity assessment certificates within the scope of your determination
- undertake post-certification activities, including monitoring and surveillance activities of certified manufacturers throughout the audit cycle

- maintain independence and impartiality
- respond so that there are no actual or perceived conflicts of interest in relation to the manufacturers for whom you will perform certification-related activities
- have adequate general liability insurance
- have an effective quality management system.

You are required to document and disclose the nature and management of any relationships between other legal entities when they are part of a larger organisation, where those relationships may have an impact on actual or perceived independence and impartiality.

The Australian CAB framework aims to align where appropriate with European Union (EU) requirements for notified bodies as defined in Annex VII of the European Medical Devices Regulation 2017/745 (EU MDR) and In Vitro Diagnostic Regulation 2017/746 (EU IVDR) that came into force on 25 May 2017.

The requirements also aim to align with the Medical Device Single Audit Program's (MDSAP) criteria for auditing organisations (AO) and implement recommendations from the International Medical Device Regulators Forum (IMDRF) Good Regulatory Review Practices (GRRP) working group (Requirements for Regulatory Authority recognition of CABs conducting medical device regulatory reviews and supporting documents).

The requirements also aim to align with the Medical Device Single Audit Program's (MDSAP) criteria for auditing organisations (AO) and implement recommendations from the International Medical Device Regulators Forum (IMDRF) Good Regulatory Review Practices (GRRP) working group (Requirements for Regulatory Authority recognition of CABs conducting medical device regulatory reviews and supporting documents).

The requirements cover:

- organisational and general requirements for the structure of the Australian CAB

- the assignment of responsibilities, independence and impartiality, confidentiality, financial resources, and liability
- quality management system (QMS) requirements
- resource requirements, relating to the competence, availability, authorisation, monitoring and training of personnel and external resources undertaking certification-related activities, outsourcing arrangements, and the related facilities and equipment
- process requirements, for documented processes and procedures for the conduct of certification-related activities.

The requirements directly reference those in Annex VII, with some modifications covering:

- differences in the terminology used in Australia versus Europe
- the incorporation, of references to the Australian regulatory requirements for manufacturers
- the removal of requirements that are not relevant to Australian CABs.

Annex VII makes references to other “best practice” documents that may be relied upon to establish expectations and detail for the interpretation of requirements, for the implementation of processes, and for outputs of the scheme for regulatory purposes.

These may include:

- international standards (e.g., ISO17021-1) or guidance documents published by the EU Medical Devices Coordination Group (MDCG)
- IMDRF
- the MDSAP consortium, or
- legacy documents from the Global Harmonisation Task Force (GHTF).

Scope of a determination

You may apply for an Australian conformity assessment body determination that either allows you to certify the full range of Australian conformity assessment procedures and all types of medical devices (including IVDs), or a limited range of Australian conformity assessment procedures for specified types of medical devices.

The scope of a determination will only include the procedures and device types for which you have demonstrated adequate resources and competence.

> We continue to accept applications for conformity assessments and issue 'conformity assessment certificates' and make decisions about the inclusion of medical devices in the Australian Register of Therapeutic Goods (ARTG) for marketing authorisation.
>
> Australian conformity assessment bodies will issue 'Australian conformity assessment body certificates' to indicate they have performed an assessment and determined that a manufacturer has adequately applied a relevant conformity assessment procedure.

Conformity assessment procedures

Your application may be assessed against all or some conformity assessment procedures for medical devices and IVDs as set out in Schedule 3 of the MD Regulations.

The relevant conformity assessment procedures for medical devices are:

- Part 1 - Full quality assurance procedures including clause 1.6 - examination of design

- Part 1 - Full quality assurance procedures excluding clause 1.6 - examination of design
- Part 2 - Type examination procedures
- Part 3 - Verification procedures
- Part 4 - Production quality assurance procedures
- Part 5 - Product quality assurance procedures.

The relevant conformity assessment procedures for IVDs are:

- Part 1 - Full quality assurance procedures including clause 1.6 - examination of design
- Part 1 - Full quality assurance procedures excluding clause 1.6 - examination of design
- Part 2 - Type examination procedures
- Part 4 - Production quality assurance procedures.

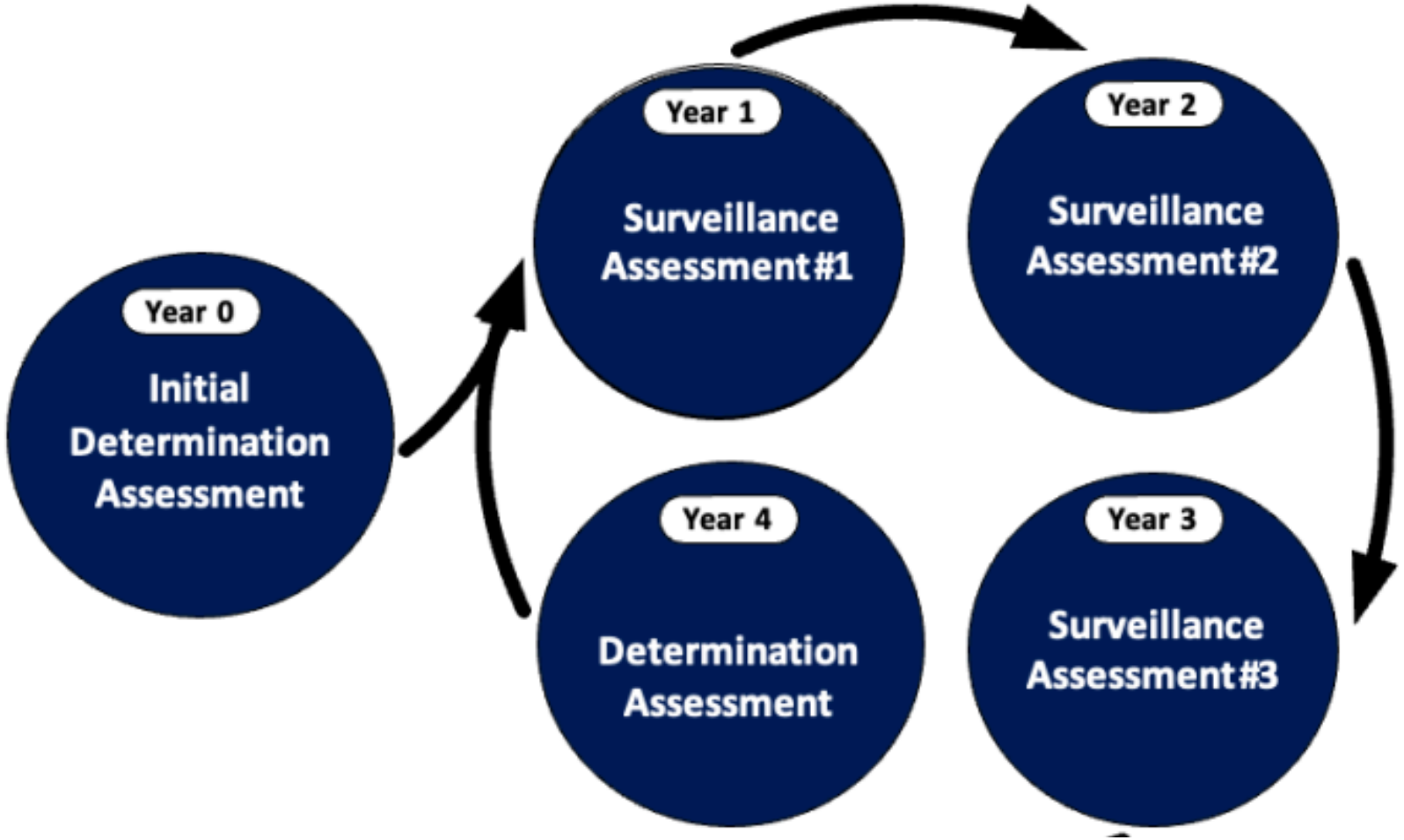
Medical devices

- the scope of medical devices included in a determination will be specified using the list of codes and corresponding types of devices/technologies that are defined in the EU's Commission Implementing Regulation (EU) 2017/2185
- Annex I of EU Regulation 2017/2185 defines the codes and corresponding device types for non-IVD medical devices and Annex II defines the codes and corresponding device types for IVDs.

Application and determination process

Assessment program cycle

Figure 1. 4-year Assessment Program Cycle



Show description of image

The image shows a cyclical process diagram with 5 dark blue circular nodes, each labelled with a year number and assessment type. The nodes are connected by black arrows indicating the flow of the process.

The cycle begins with:

- "Year 0: Initial Determination Assessment"
- "Year 1: Surveillance Assessment #1"
- "Year 2: Surveillance Assessment #2"
- "Year 3: Surveillance Assessment #3"
- "Year 4: Determination Assessment".

After Year 4, the cycle returns to Year 1, creating a continuous loop of assessments over a 4-year period.

This diagram illustrates a recurring assessment process, likely for a surveillance or monitoring program, with an initial determination followed by annual surveillance assessments and a new determination assessment every fourth year.

An initial Australian conformity assessment body determination is valid for 4 years. During this time we monitor performance.

Separate guidelines detail the requirements for Australian CABs once a determination has been made, and for the ongoing monitoring activities undertaken by the TGA.

Refer to Part 4A of the MD Regulations for the requirements related to monitoring.

Pre-application meetings

Before applying, we recommend your company arrange a pre-application meeting to discuss:

- the requirements for a determination
- the assessment process
- the obligations that must be fulfilled by employees of the Australian CAB.

To request a pre-application meeting with us, email AUCAB@health.gov.au.

Apply

Listed below are instructions on how to complete and submit the online application form, and how to pay the fees.

Before commencing an application, you will need a TGA Client ID

Complete an Organisation details form to get a Client ID.

Make sure you select 'Agent' as the organisation role and explicitly identify your organisation as a potential Australian CAB at the time of submission.

Filling in the application form

You must use the online application form.

Use Microsoft Edge or Google Chrome as the web browser to complete this form. Other browsers may not fully support the functionality of the form.

The form is to be completed and signed electronically by a person, who has the relevant authority within the Australian corporation.

You will not be able to save an unsubmitted form as draft. The application form must be started, completed, and submitted at once. Partially completed contents will be lost. Before you start filling out the application form, read the instructions below.

The application form consists of 7 sections:

1. **Introduction:** Section 1 provides an introduction to the application form and definitions for key terms.

2. **Applicant details and current activities:** Section 2 collects information about the applicant, including the applicant's TGA Client ID; information required to support eligibility assessment; the location, primary contacts detail and certification-related activities of head office; as well as the location and certification-related activities of satellite sites within Australia.
3. **Organisation structure and current activities:** Section 3 collects information on applicant's organisational structure and detail of any larger/parent organisation, sibling/sister organisation, and child/subsidiary entity the applicant corporation has business relationship with, who also provide services to medical device sector and undertake certification-related activities.
4. **Proposed scope of conformity assessment determination:** Section 4 requires the applicant to indicate the proposed scope of conformity assessment procedures and medical devices (include IVDs) for determination.
5. **Supporting information:** Section 5 requires submission of supporting information.
6. **Declaration and signature:** Section 6 requires the applicant to make a declaration before submission.
7. **Complete:** Upon successful submission, a confirmation message will display in Section 7 and a notification email will be sent to the primary contact indicated in Section 2 with a copy of application.

Supporting information

The following documents are to be provided at the time of submitting the form:

- evidence of the legal status of the Australian corporation and the date obtained
- for the legal entities identified in Section 3, evidence of the legal status of the entities, and date obtained

- proof of adequate (commercial) general liability insurance for the Australian corporation
- a brief history of your Australian company
- a function and operational unit chart
- evidence of recognition of being an MDSAP AO, as applicable, for the Applicant in Section 2 or any entity identified in Section 3
- where relevant, the Designation Authority's designation report under EU 2017/745 and/or EU 2017/746 for any entity identified in Section 3 of the application form.

> Prepare the required supporting documentation and make sure it's in the right format before you start. Applications need to be submitted with documents.

You can upload as many documents as you want in your online application form, up to 20Mb.

Each upload field will support up to 10MB of attachments in PDF, DOC and DOCX formats. Preface each filename with your corporation's name and TGA client ID.

If you have other file formats, or larger files, select 'Yes' to "Do you have any additional supporting information?". This is at the bottom of Section 5.

Your company is required to have a number of additional documents and records available to demonstrate compliance with Annex VII of the European Directives, as modified by Schedule 3AA.

You do not need to provide these at the time of submitting the initial application form.

Declaration and signature

In making the declaration, you are indicating that you have considered the Australian requirements and agree to comply with those requirements should a determination be made and issued to you.

Your determination will come with some standard conditions. (Refer Division 4A.3 of the Regulations.)

Signing the declaration means you accept we might impose additional non-standard conditions after consulting with you.

After submission

Following a successful submission, the notification email provides you with an application ID number and important information on the next steps.

If you do not receive this notification email after submission, contact us at AUCAB@health.gov.au, or on 1800 141 144.

The application fee must be paid before it's effective.

Once we get your application, we'll send you an invoice for payment.

Don't pay the application fee before getting the invoice. Fee payments must reference the 'application reference code' on the invoice.

> The review of your application will not commence until the application form, the required supporting information has been submitted, and the relevant application fee has been receipted by us.

Fees and charges

Your application and assessment fees depend on the scope of your request.

The preferred method of payment is credit card. You can also pay with an electronic funds transfer (EFT).

> Until you get an invoice from the TGA, don't pay any application or assessment fees.

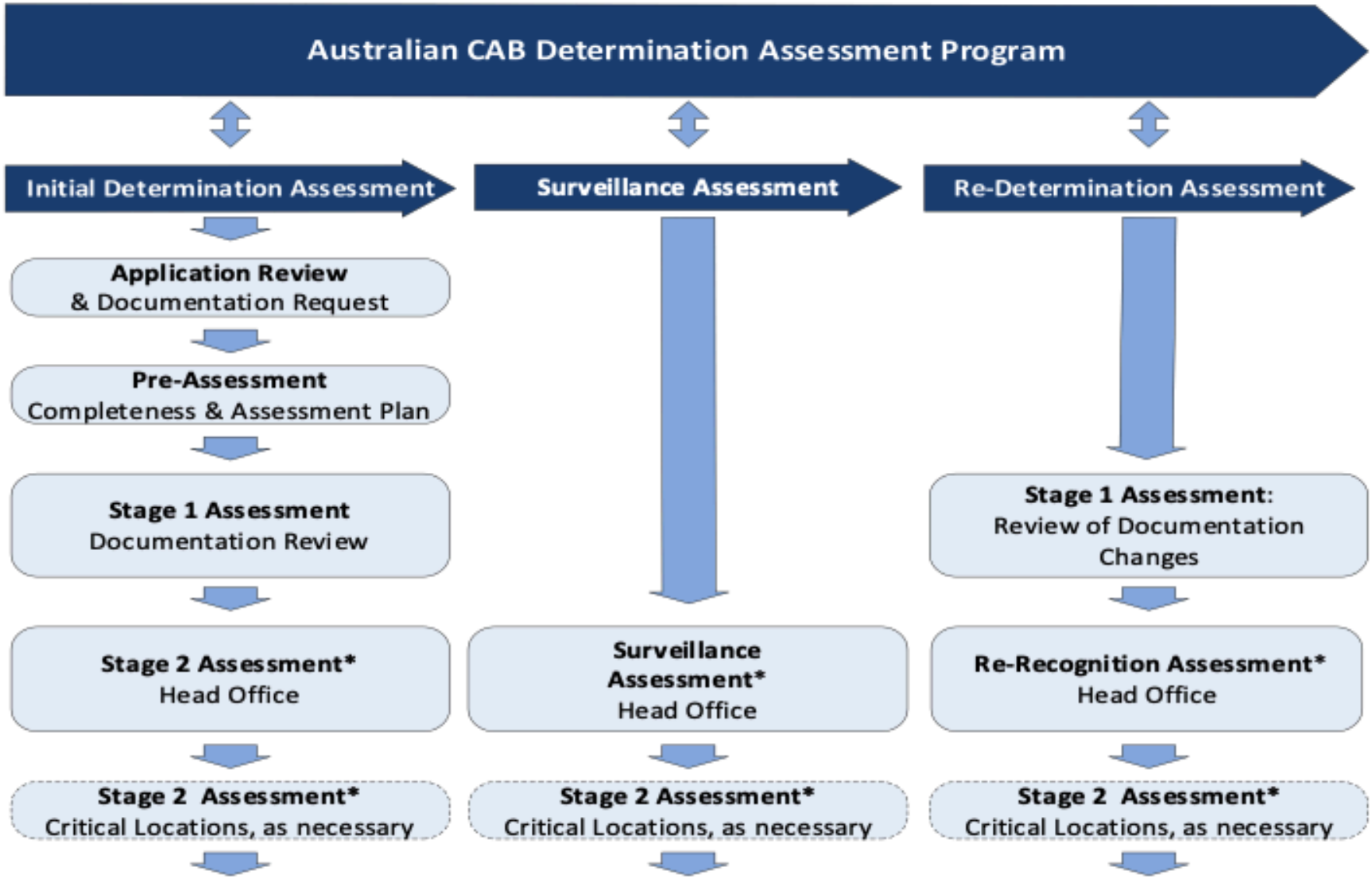
There are three levels of application and assessment fees. See Fees and charges summary - Medical Devices.

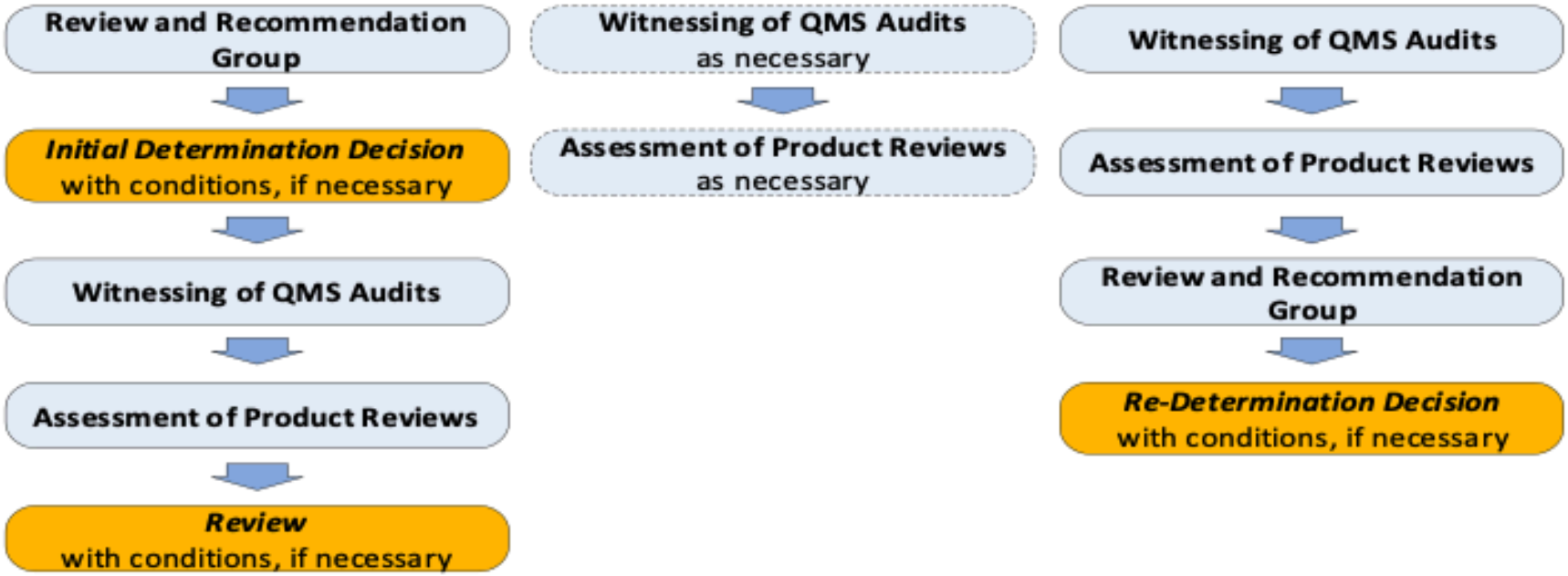
Assessment process

Australian CAB determinations are made and renewed every 4 years.

We base our assessment program on the processes agreed by Regulatory Authorities who are participating in MDSAP and in the development of MDSRP.

Australian CAB determination assessment program





* assessment may be undertaken using an on-site, remote, or desktop assessment, or a combination of any of these

Show description of image

The image shows a flowchart titled "Australian CAB Determination Assessment Program" with three main columns representing different assessment phases:

1. Initial Determination Assessment:
    - Application Review & Documentation Request
    - Pre-Assessment Completeness & Assessment Plan
    - Stage 1 Assessment: Documentation Review
    - Stage 2 Assessment: Head Office

- Stage 2 Assessment: Critical Locations, as necessary
- Review and Recommendation Group
- Initial Determination Decision (with conditions, if necessary)
- Witnessing of QMS Audits
- Assessment of Product Reviews
- Review (with conditions, if necessary)

2. Surveillance Assessment:
    - Surveillance Assessment: Head Office
    - Stage 2 Assessment: Critical Locations, as necessary
    - Witnessing of QMS Audits as necessary
    - Assessment of Product Reviews as necessary
3. Re-Determination Assessment:
    - Stage 1 Assessment: Review of Documentation Changes
    - Re-Recognition Assessment: Head Office
    - Stage 2 Assessment: Critical Locations, as necessary
    - Witnessing of QMS Audits
    - Assessment of Product Reviews
    - Review and Recommendation Group
    - Re-Determination Decision (with conditions, if necessary).

The flowchart illustrates the progression from initial determination through surveillance to re-determination, with various

assessment stages and decision points along the way.

Initial application review

The application review will determine:

- the requested scope for a determination, i.e., the conformity assessment procedures and types of medical devices and the relevant technologies
- whether the supporting information is complete, or whether further application information or documents are required
- the applicant's eligibility to apply.

Request for additional information

We will provide a supporting information checklist.

This will identify, by referencing specific documents and records, the evidence which shows how you will be able to fulfil the requirements for an Australian CAB determination including:

- Regulation 4A.6(3). See Declaration for subregulation 4A.6(3)
- statutory conditions that apply to every determination
- each of the requirements of Annex VII of the European Medical Devices Regulation 2017/745 (EU MDR) and In Vitro Diagnostic Regulation 2017/746 (EU IVDR) as modified by Schedule 3AA of the MD Regulations.

Before the assessment, we'll ask for any additional information. We'll do this in writing.

Assessment

After receiving all the requested paperwork and paying the assessment fee, we will assess at least:

- procedures and records to verify that you will be able to comply with the requirements (determination criteria) for Australian CABs and conditions that apply to the determination
- the implementation of the procedures by your personnel and effectiveness of your QMS.

The assessment activities may include offsite, onsite, or remote, including head office locations.

> In addition to the Australian CABs registered business address (Head Office), critical locations are sites or facilities where critical functions are carried out by, or on behalf of, the Australian CAB.

Witnessing of audits or design examinations

The TGA may witness you performing QMS audits or a design examination.

You are required to have written agreements with the manufacturing facility that allows the TGA to observe the audit and/or have the manufacturer’s permission to use any audit or technical documentation for regulatory purposes, or to share the information with other Regulators.

Assessment fees include the TGA's costs for witnessing these activities.

Determination decision

If all these conditions are met, the Secretary's delegate will make a decision.

These conditions include:

- An assessment of the applicant’s evidence of compliance with the requirements of Annex VII as amended by S3AA is completed satisfactorily.
- Any nonconformity identified during the assessment has been adequately addressed.
- The declaration for paragraph 4A.6(3) of the MD Regulations is done.
- Assessment fee paid in full.

You will need to self-assess whether you, or certain other persons associated with you, meet the criteria set out in sub-regulation 4A.6(3) of the MD Regulations.

Using our downloadable forms template, certify the outcome of your assessment by submitting a signed statutory declaration.

The signatory must:

- hold a senior position in the Australian corporation and
- be authorised to make the certification on behalf of the corporation.

TGA will publish the determination on the Register of Australian CABs.

Next steps

Australian CAB and subcontractors will be monitored annually.

This confirms they continues to:

- meet the regulatory requirements and
- fulfil the obligations that are set out in the medical device regulations.

Australian CABs are subject to re-determination assessment every four years.

Contact us

You can contact the Australian CAB Program Manager for more information.

- Phone: Medical Devices Information Line - 1800 141 144
- Email: AUCAB@health.gov.au.

Topics: Legislation Medical devices safety In Vitro Diagnostic medical devices (IVDs)

Page history

26 June 2024

Updates to 'How to fill in the application form' section to reflect the changes in the application form process.

---

1 June 2021

Original publication.