Australian Government
Department of Health
Therapeutic Goods Administration

Determinations for Australian conformity assessment bodies

Medical devices and IVDs

Guidelines for applicants

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TGA Health Safety Regulation

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Contents

About these guidelines

These guidelines are intended to assist Australian corporations seeking to apply for an Australian conformity assessment body (Australian CAB) determination for medical devices (including IVDs) by the Therapeutic Goods Administration (TGA). The guidelines outline:

- the eligibility information
- the requirements for certification-related activities
- the requirements for Australian CABs
- how a determination is scoped
- the application and determination process
- the 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.

An Australian CAB determination allows an Australian corporation to operate under the Australian medical devices regulatory framework, which is broadly outlined under Chapter 4 of the *Therapeutic Goods Act, 1989* (the Act) and the Therapeutic Goods (Medical Device) 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 (within the meaning of corporation in 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.

In addition, your company will need to meet all the following requirements:

- continually comply with the requirements of your determination and keep records of your certification-related activities.
- notify the TGA if there are significant concerns about the safety of a medical device, or the activities of a medical device manufacturer (your client).
- notify the TGA 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.

This document provides an overview of the process and requirements for applying for a conformity assessment body determination, and 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 for an Australian CAB determination

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); and
- hold a valid Australian Company Number (ACN).

Application requirements

Applications for a conformity assessment body determination must:

- be made in English using the application form, accessible from the TGA 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; and
- 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 are required to have procedures and a written agreement with each contractor that permits access to their premises and allows the TGA 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 that 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, are set out in Schedule 3AA of the MD Regulations.

As the applicant, your company is required 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 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.

The TGA will 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

The assessment program cycle is shown in Figure 1 below.

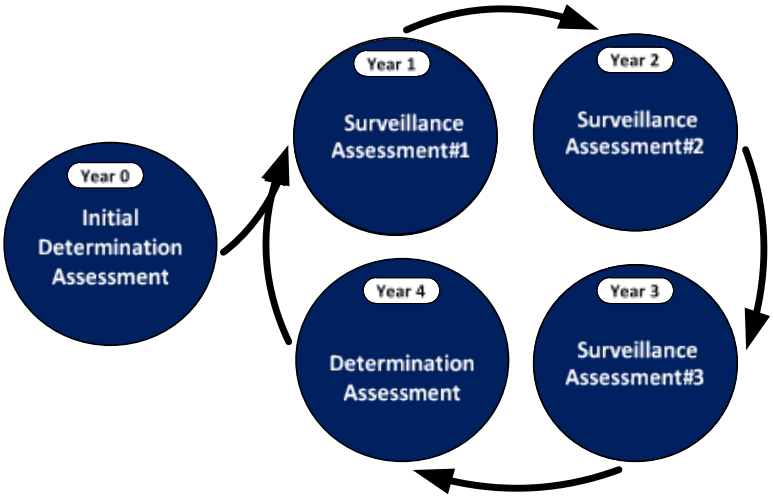


Figure 1 Four year Assessment Program Cycle

An initial Australian conformity assessment body determination will be valid for 4 years, during which the TGA will 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. You should refer to Part 4A of the MD Regulations for the requirements related to monitoring.

Pre-application meetings

Prior to submitting an application, it is recommended that your company arrange a pre-application meeting to discuss the requirements for a determination, the assessment process, and the obligations that must be fulfilled by employees of the Australian CAB.

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

How to apply

Instructions on completing and submitting the on-line application form and supporting documentation, to the TGA, and for the payment of fees, are provided below.

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

Follow the instructions at https://www.tga.gov.au/tga-business-services-getting-started-tga to apply for a Client identification number by completing an Organisation details form. Ensure you select 'Agent' as the organisation role and explicitly identify your organisation as a potential Australian CAB at the time of submission.

How to fill in the application form

You must use the on-line application form. Use Google Chrome as the web browser to complete this form. Other browsers may not 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 to do so.

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 2, 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 1 or any entity identified in Section 2.
- Where relevant, the Designation Authority's designation report under EU 2017/745 and/or EU 2017/746 for any entity identified in Section 2.

Ensure the required supporting documentation is assembled and in the correct format before starting the on-line application. Documents will need to be attached to the form before the application can be submitted.

Your on-line application form will support up to 50Mb of attachments and no more than 20 documents. Any one document must not exceed 20Mb. Preface each filename with the application's reference number. If an attachment consists of more than one file then provide them as a single 'ZIP' file.

If you have other file formats, larger files that need to be submitted, or are having difficulties, please contact the TGA at AUCAB@health.gov.au.

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

Applications are not effective until the application fee has been paid. 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.

A number of standard conditions will be applied to your determination when it is issued. (Refer Division 4A.3 of the Regulations.) In signing the declaration, you acknowledge that the TGA may impose additional non-standard conditions after consulting with you and prior to issuing a determination.

How to submit an application

1. A draft application form may be saved and closed at any time. You will be prompted to enter an email address so that a notification can be provided with instructions on how to access the draft form again.
2. To share the draft application with another user, you will be prompted to enter the email address of the other user.
3. A draft form may be opened using the link provided in the notification email or by selecting "Open Saved Form" on the on-line application introduction page. You will be prompted to enter the application reference code.

Draft application forms must be started, completed and submitted within a 3 month period, or the partially completed contents will be lost.

A Saved Form email notification will advise the date and time that the draft form will be deleted from the system. A reminder notification is not provided.

4. Ensure that electronic copies of the supporting documentation have been uploaded at the time that the application is submitted.

Once the application is completed and the supporting documentation has been uploaded select the "Submit" button on the last page of the application. You will receive a confirmation notification by email to confirm that the application has been received. If there are any concerns or questions about the application, please contact the TGA via email at AUCAB@health.gov.au, or through the Information Line on 1800 141 144.

The TGA will send an invoice for payment of the relevant application fee. The application fee should not be paid before the invoice has been provided, as the unique 'application reference code' must be referenced in the fee payment.

The Assessment Process section below describes how an application will be processed after receipt of the application and payment of the application fee.

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

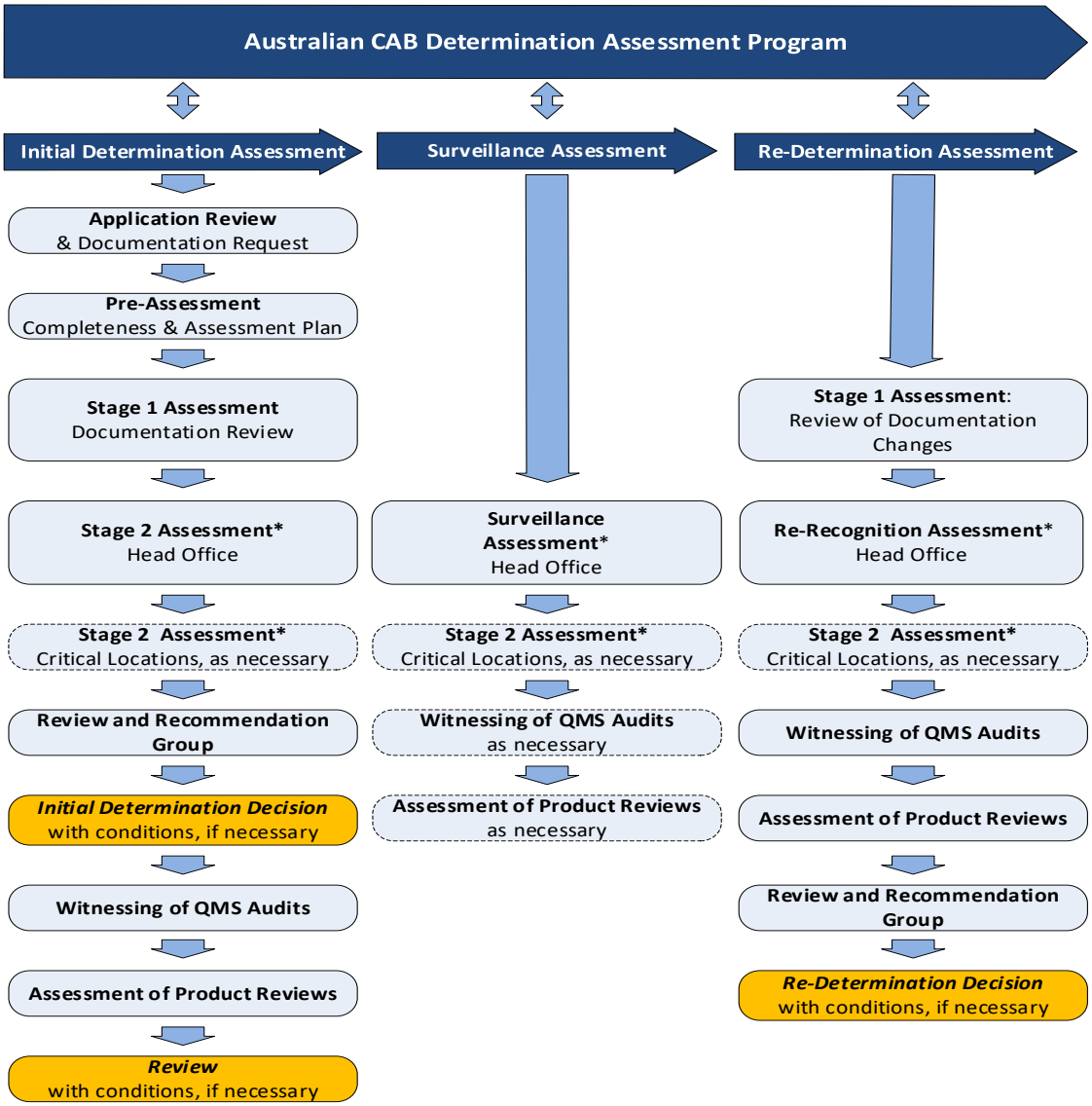
Application and assessment fees are based on the scope of the determination you have applied for. Payment can be made by electronic funds transfer (EFT) or credit card (preferred).

Do not pay any application or assessment fees, until you receive an invoice from the TGA.

There are three levels of application and assessment fees published on the TGA website. See Schedule of fees and charges - Medical Devices.

Assessment process

Australian CAB determinations are made and renewed on a four year cycle. The TGA will base their assessment program on the processes agreed by Regulatory Authorities who are participating in MDSAP and in the development of MDSRP.



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

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

The TGA will provide a supporting information checklist to 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) for further information.
- 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.

The TGA will identify if any additional information required and make a request for it in writing prior to the assessment.

Assessment

Following receipt of all requested documentation and the assessment fee has been paid, the TGA will carry out an assessment of, at least, the following:

- 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.

The TGA's costs for witnessing these activities are included in the relevant assessment fee.

The determination decision

A determination will only be made by the Secretary's delegate once the following conditions are all met:

- 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.
- A declaration for paragraph 4A.6(3) of the MD Regulations is completed.
- The assessment fee is paid in full.

In addition 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.

A template is available to 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. .

The determination will be published on the TGA website in the Register of Australian CABs.

What to expect once an initial determination is made

The Australian CAB, and any subcontractors, will be subject to a cycle of annual surveillance assessments to confirm that the Australian CAB continues to satisfy 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 4 years.

Further information

Applicants are encouraged to contact the Australian CAB Program Manager at the TGA for further information.

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

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Therapeutic Goods Administration

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