Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Medical device application audits

Case management process

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Contents

About

This guidance document is for sponsors of medical device applications selected for audit and describes how the TGA will case manage the audit process. It details the process, timeframes, and the role of the TGA case manager. Please note there are some differences in the processes for in vitro diagnostic (IVD) medical device application audits.

Application audit process

All medical device applications are subject to a preliminary assessment. The preliminary assessment process is described in detail on our website.

Potential outcomes from the preliminary assessment are that the application will be:

- refused,
- approved, or
- selected for audit.

If your application is selected for audit, we may:

- revisit the matters reviewed during preliminary assessment in more detail
- ask for evidence of compliance with specific legislative and regulatory requirements including the essential principles
- review details you certified in your application.

The outcome of the audit will determine the outcome of your application in the audit decision.

Mandatory application audits

Regulation 5.3 requires some applications to be selected for audit. This process is referred to as a "mandatory audit". If your application is required to undergo a mandatory audit, you will be required to pay a fee for this process.

The following applications will be selected for mandatory audit:

- Class III medical device applications supported by European Union (EU) Medical Devices Directive (MDD) certificates
- System Or Procedure Packs (SOPP) supported by a Declaration of Conformity (DOC) made under clause 7.5
- Class 4 IVD, Class 3 IVD, point-of-care IVD and self-test IVD applications supported by:
  - EU IVD Directive certificates
  - ISO 13485 certificates along with EU Declaration of Conformity
  - Medical Device Single Audit Program (MDSAP) certificates and without comparable overseas regulator approval for the device.

Non-mandatory application audits

Any application for a medical device, including an IVD medical device, may be selected for non-mandatory audit. Selection is based on our published audit selection criteria (link to be added). You do not need to pay a fee if your application is selected for non-mandatory audit.

Audit selection and s41FH notice

Section 41FH of the Medical Device Regulations specifies the process we will undertake to notify you when your application has been selected for audit. You will receive a s41FH Notice that:

- in the case of a mandatory audit, sets out the legal basis of selecting your application for audit
- in the case of a non-mandatory audit, explains why the delegate decided an audit was appropriate
- specifies the information and documents you are required to provide, which may include information or documents clarifying aspects of information already submitted with your initial application.

Case management

If your medical device application is selected for audit, you will be allocated a TGA case manager and notified about who they are so you can contact them. You will also be notified if the assigned case manager changes during the audit.

Your TGA case manager will:

- Communicate and act as the contact point for you during the audit
- Facilitate meetings with you and the manufacturer where required
- Coordinate assessments by relevant expert teams within the TGA or external experts
- Consolidate and document any deficiencies and information requests from assessment areas
- Engage with you to discuss issues
- Monitor, track and communicate the progress of the audit against timelines
- Coordinate with the Advisory Committee on Medical Devices (ACMD) when necessary for advice about aspects of the application
- Initiate relevant assessments with the TGA's specialist assessment teams.

Table 1 details the case management process for an application audit and explains how and when your case manager will communicate with you.

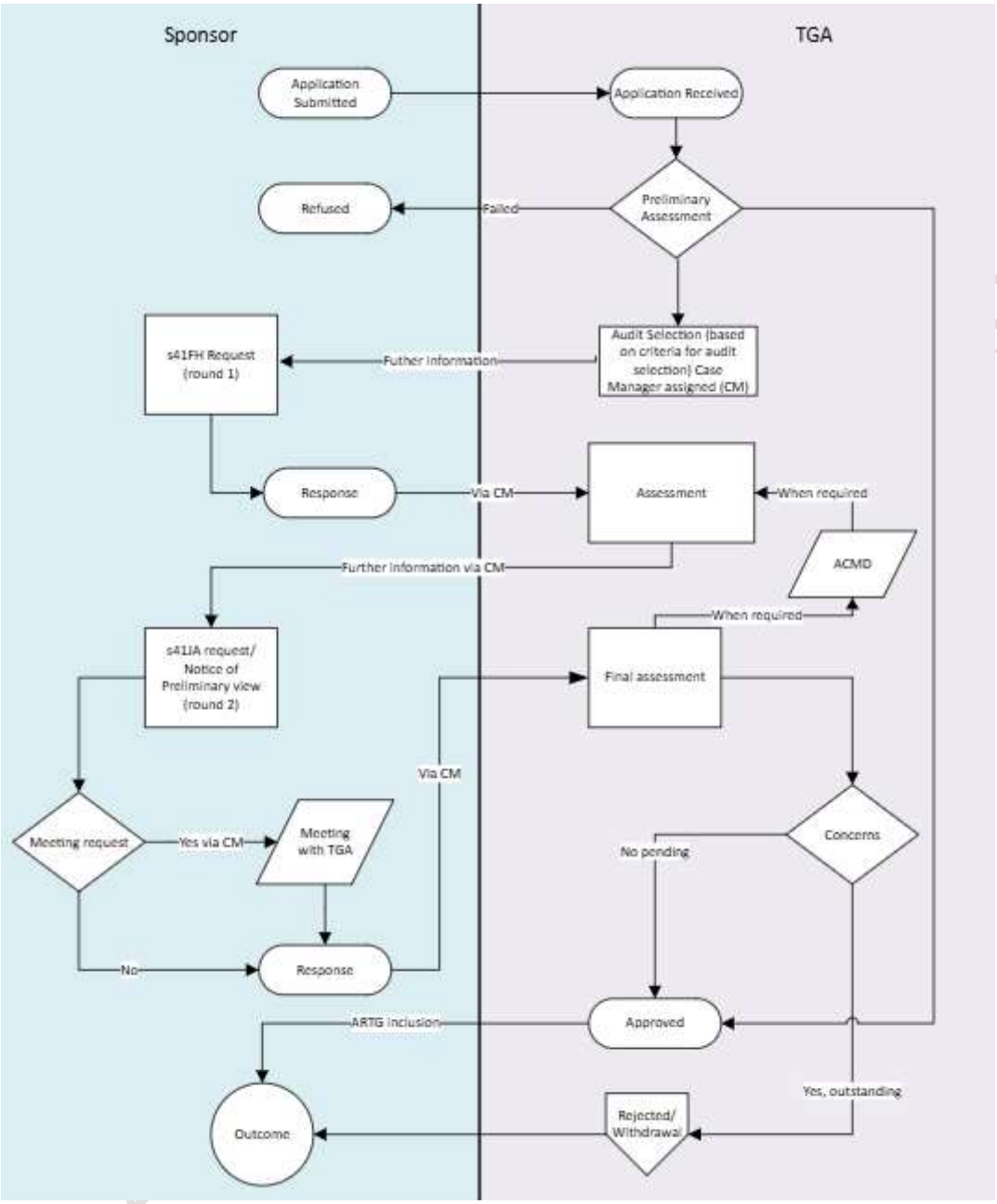
Figure 1 illustrates the case management process in more detail.

Case managers are not assigned for IVD medical device application audits. If your IVD medical device application is selected for audit, the IVD email inbox will be your primary point of contact (IVDs@tga.gov.au). The case manager tasks will be managed by the assessor within the IVD section.

Table 1: Case management communication

Step	You should	We will
Audit Selection	Contact the TGA case manager or IVD inbox	Tell you why we selected the application for audit. Appoint a case manager and a backup contact.
Timeframes & Updates	Understand and raise any concerns	Tell you the expected timeframes for each assessment round and notify you if they change (e.g. we need more information and await your response, we seek ACMD advice, our assessment queue is delayed).
Request for Information	Provide requested information	Ask for any information needed for the audit or clarify if no further information is needed (e.g. we already have the IFU and clinical evaluation reports or clinical and analytical performance reports).
Notice of preliminary view – proposal to refuse application	Provide a tailored response to address the issues raised in the notice or withdraw the application	Tailored response provided by the sponsor: Review the response and a decision will be made. Withdrawal of application. We will perform administrative processes for application withdrawal.
Initial Outcome	Respond to any identified deficiencies	Inform you of the initial audit outcome, including any deficiencies, and give you an opportunity to respond. If the application could be resolved by limiting the intended purpose or by imposing a condition, we will let you know.
Meetings	Request a meeting with the TGA, if required, to clarify information requested, or issues raised by the TGA. You should try to include the manufacturer in the meeting.	Arrange meetings to discuss deficiencies or response plans, if requested.
Response Assessment	Provide a response to any remaining deficiencies	Assess your response and decide the outcome of the application. If a straightforward or minor deficiency remains, we will contact you to resolve it quickly before making a decision.
Audit Completion		If we refuse the application, we will provide detailed reasons and explain how to seek a review of the decision. If no deficiencies remain, we will complete the audit, approve the application, and inform you.

Figure 1: Case management process



Audit level and target timeframes

There are two levels of application audit that can apply to both mandatory and non-mandatory audits:

- Level 1
- Level 2.

Level 1 audits do not require assessment from a specialist evaluation team, and therefore have a target time frame of 30 TGA working days for completion. Level 1 audits may aim to verify compliance with requirements relating to matters including:

- Patient Implant Cards (PIC) and Patient Information Leaflets (PIL)
- Labelling and instructions for use

- Classification and conformity assessment document requirements.

Level 2 audits are more complex and therefore have a target of 180 TGA working days for completion. Level 2 audits often involve assessment by a specialist evaluation team such as the clinical, IVD, software, engineering, biomaterials, or microbiology teams. IVD medical device applications are only subject to level 2 audits.

Audit deficiencies

If no deficiencies are found in the first round of assessment, your case manager will ask the TGA delegate to make an audit decision.

If the audit identifies deficiencies your case manager will issue you with a notice of intention to refuse the application. The notice will explain the reason for intention to refuse and include explicit identification of any deficiencies.

After receiving the notice, you have an opportunity to address the deficiencies in writing. Depending on the nature of the deficiencies you will be given between 20-40 business days to respond. If the deficiencies are complex or substantial you can ask for additional time to respond and it is at the discretion of the delegate to approve the request.

If clarification is needed, or you wish to discuss the application or any issues identified in the Notice, your case manager can meet with you to help progress the application.

Once you respond to the notice we will consider and assess the information you provide to see whether the deficiencies have been addressed. You may be asked to provide additional information, and given a further 20-40 business days to respond. Your case manager will continue to be available to discuss the audit or to arrange a follow-up meeting as necessary during this time. When you provide a final response, your case manager will then ask the delegate to make a decision.

Application clock

We monitor the processing time for each application using an “application clock” that starts once the application has been submitted via the TGA Business Services Portal. The clock starts counting from day zero as soon as the application fee has been paid.

The clock is based on business days, excluding ACT public holidays and weekends.

We stop the application clock in the following circumstances:

- until payment of assessment fees for mandatory audits is received
- when we have provided you with a request for additional information or a notice and we are waiting for your response.

The clock restarts when we receive your payment or your response with ALL the required information.

We may also stop the clock in mutually agreed extenuating circumstances, such as a natural disaster or the death or serious illness of critical personnel responsible for obtaining information.

Advisory Committee on Medical Devices (ACMD)

We may seek advice from the ACMD on any application where specific expertise could inform our decision. Members of the ACMD are chosen for their academic and clinical specialist expertise and appointed by our Minister.

We may consult the ACMD at any stage of the application process about higher-risk devices, applications involving complex issues or where our staff have limited expertise. We may also seek advice from external evaluators as required.

You will be notified as early as possible if we plan to seek advice from the ACMD or an external evaluator about your application. You will be provided with a copy of any questions we ask about your application and the ensuing advice received.

Audit decision

Your case manager will review the assessments from any specialist assessment teams and present the outcomes to the TGA delegate to support them with making a decision about whether to issue an ARTG certificate.

If the delegate refuses to grant you an ARTG certificate, a statement of reasons will be included in the written notice of the decision. We will also explain how you can seek a review of the decision.

If an application is refused, we cannot refund the application or assessment fees.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Devices Review Management Section and Devices In Vitro Diagnostics Section	December 2024

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