Australian Government
Department of Health
Therapeutic Goods Administration

Auditing of medical device, including IVD medical device, applications

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TGA Health Safety Regulation

Contents

Auditing of medical device, including IVD medical device applications

This guidance is for sponsors who have submitted an application for inclusion of a kind of medical device, including IVD medical device, in the Australian Register of Therapeutic Goods (ARTG). It describes when an application audit may be conducted and the audit assessment process.

Application audits are conducted to verify that devices submitted for inclusion in the ARTG meet the relevant legislative requirements.

For some applications, an audit is mandatory under the legislation. Others may be selected for auditing at the discretion of the delegate.

Applications subject to mandatory audit under the legislation incur an audit assessment fee, which is additional to the application fee.

Audit assessment fees are listed in the TGA's schedule of fees and charges.

Some applications may be eligible for a reduction in the audit assessment fees.

Applications selected for audit at the discretion of the delegate, do not incur an audit assessment fee.

A review is underway to determine if changes are necessary to the current audit process and respective fees, with consultation to occur with industry where required on any subsequent proposed changes.

Applications that must be selected for audit

Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations)(link is external), specific device applications are subject to mandatory auditing unless they:

- have a TGA conformity assessment certificate, or
- have EU MDR 2017/745 or EU IVDR 2017/746 certification that has not been suspended or revoked, or
- are included in the ARTG as an export only medical device, including export only IVD medical device.

The kinds of devices which are subject to mandatory audit are specified in regulation 5.3 of the Regulations, and include:

a. a medical device (other than a condom) that is a barrier indicated for contraception or prevention of the transmission of disease in the course of penile penetration during sexual intercourse;
b. a medical device that is an implantable contraceptive device;
c. a medical device that is a spinal fusion implantable device;
Note: Examples of spinal fusion implantable devices include screws, cages, plates, hooks or rods that are intended to be used during spinal fusion surgical procedures.
d. a medical device that is specifically intended by the manufacturer to be used for disinfecting another medical device;
g. a medical device that is an implantable intra ocular lens;
h. a medical device that is an intra ocular visco elastic fluid;

i. a Class III medical device that has not been assessed under the EC Mutual Recognition Agreement or the EFTA Mutual Recognition Agreement;

j. any of the following IVD medical devices:

   i. non assay specific quality control material that is intended for monitoring a Class 4 IVD medical device;

   ii. an IVD medical device that is intended for self testing;

   iii. an IVD medical device that is intended for point of care testing;

   iv. a Class 3 IVD medical device that is intended for detecting the presence of, or exposure to, a sexually transmitted agent;

   v. an IVD medical device for managing or monitoring the treatment of infections diagnosed using a Class 4 IVD medical device (for example, quantitative nucleic acid test (NAT) and genotyping assays for HIV and HCV);

   vi. an IVD medical device that is intended to be supplied for use under the pharmaceutical benefits scheme;

   vii. an IVD medical device that is intended to be supplied for use in a national screening program;

   viii. if the Secretary is not satisfied that a body or authority has the authority and expertise to exercise a power or perform a function of the Secretary mentioned in subregulation 3.5(1) — an IVD medical device that has been manufactured in a location and at a site where that body or authority has exercised such a power or performed such a function in relation to the device;

   viiia. a class 4 IVD medical device

   ix. a Class 4 in house IVD medical device;

   x. an IVD companion diagnostic.

For IVD manufacturers, regulation **5.3(1)(j)(viii)** relates to whether appropriate conformity assessment evidence is held to demonstrate that product assessment has taken place.

For information on what appropriate conformity assessment evidence is, see: Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices (including IVDs)

Sponsors should check regulation 5.3 of the Regulations for the complete list of devices that are subject to mandatory auditing.

Systems and procedure packs

A certificate issued for the sterilisation of a system or procedure pack, under Part 4 of Schedule 3 of the Regulations, by the TGA (where the special conformity assessment procedure under regulation 3.10 and clause 7.5 of Schedule 3 of the Regulations has been applied to the kind of medical device) is not a Conformity Assessment Certificate issued in relation to a kind of medical device.

The issued certificate is in relation to the sterilisation of the system or procedure pack, not the system or procedure pack itself.

Therefore, if a system or procedure pack is of a kind of medical device listed in regulation 5.3, it must be selected for audit.

Applications selected at the discretion of the delegate

Any application for a medical device, including an IVD medical device, may be selected for audit at the discretion of the delegate, to determine or establish if:

- the product is a medical device, including an IVD medical device
- the clinical benefit of the device outweighs any risk associated with its use
- the device is being included for the purpose intended by the manufacturer
- your application contains information that is false or misleading
- the device is correctly classified
- you have:
  - sufficient information available to substantiate compliance with the Essential Principles OR procedures in place, including a written agreement with the manufacturer, to ensure that this information can be obtained within the period required under the Regulations.
  - sufficient information available to substantiate the application of those conformity assessment procedures OR procedures in place, including a written agreement with the manufacturer, to ensure that this information can be obtained within the period required under the Regulations.
- the device does not contain substances that are prohibited imports for the purposes of the *Customs Act 1901*
- the information included in, or with, the application is complete and correct.

Steps in the audit process

This is an outline of the information contained in the following webpages and the associated guidance documents

1. The application audit process
   a. Time frames for providing documentation
   b. Presentation of requested documentation
   c. List of supporting documentation for medical device application audit
2. Fees associated with audit assessments
   a. Current assessment fees
   b. How to pay assessment fees

Guidance on IVD medical device application audits, often referred to as technical file review, is available on the website.

Step 1 – The application audit process

If your application is selected for audit, you will be notified within 20 days of paying your application fee via a notification letter issued under section 41FH of the *Therapeutic Goods Act 1989* (the Act).

The notification letter will outline the;

- information that you are required to provide
- timeframe within which you must provide the required information
- audit assessment fee you are required to pay (where applicable).

Your application will lapse unless you:

- pay the audit assessment fee (where applicable), and
- supply the information requested

within the time frames given in the notification letter.

If you allow your application to lapse, your application fee will not be refunded.

Time frames for providing documentation

You generally have 10-20 working days to provide information that demonstrates compliance with the essential principles and application of conformity assessment procedures appropriate to the kind of medical device (matters certified under section 41FD of the Act).

The date for providing the requested information will be specified in the notification letter.

If you do not provide the requested information and documentation within 10 working days of the date specified in the letter or if you fail to pay the fee associated with the audit assessment (where applicable) your application will lapse.

Once you have supplied the information requested and we have assessed it, you may be required to provide further information under section 41JA of the Act.

Presentation of requested documentation

Provide requested information as a complete stand-alone submission.

Provide all requested information in English. Where material is not originally in English, submit a full translation. The accuracy of the translation is the responsibility of the sponsor.

Any text, pictures and drawings must be legible, and pictures and drawings must be clearly labelled.

Advertisements for medical devices that are directed to consumers are required to comply with:

- Chapter 5 of the Act
- Part 2 of the *Therapeutic Goods Regulations 1990*
- the Therapeutic Goods Advertising Code

If your submission is **less than 15 pages**, you may clearly state the application ID and the applicant name in the subject line and **email** your submission to: devices@tga.gov.au.

If your submission is **longer than 15 pages**, provide the information electronically in the form of a CD or DVD containing all of the relevant material. **Send** your submission to:

Devices Applications Section
Medical Devices Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

List of supporting documentation for medical device application audit

Examples of the documentation you may be required to provide, if your medical device application is selected for audit, are provided in the table below. This list is not definitive and, depending on the nature of your application, you may be required to provide documentation not contained within this list.

Levels of application audit

For medical device (excluding IVD) applications there are two levels of audit assessment:

- Level 1
- Level 2

TGA will determine what level of audit assessment is appropriate for your application. The documents we request you to provide will depend on the level of audit assessment.

For IVD medical device applications there is only one type of audit assessment, sometimes referred to as a technical file review.

Table 1: Example of documentation that may be required for each level of audit

Level	Documentation that may be required
Level 1	Manufacturers Declaration of Conformity(DOC)
	For a system or procedure pack, provide evidence of compliance of the kind of medical device with the requirements under regulation 3.10 of the Regulations and clause 7.5 of Schedule 3 of the Regulations (where the special conformity assessment procedure provided under clause 7.5 of Schedule 3 of the Regulations has been applied to the kind of medical device)
	Information to be provided with, and used to promote the 'kind of medical device' in Australia, including copies of: • labelling • pictorial images of the device • packaging – inner and outer packaging for the device • instructions for use • product manual • other brochures related to the device • advertising material for the medical device including brochures, extracts from web pages, and advertisements • medical device patient cards and leaflets
Level 2	All the documentation listed for a level 1 audit
	Clinical evidence
	Risk management report
	Efficacy and performance data (for medical devices that are intended to be used for disinfecting other medical devices)

Level	Documentation that may be required
Technical file review (IVDs)	See Application audit (technical file review) of IVD medical device applications for information requested for an application audit

Step 2 – Fees associated with audit assessments

There is no audit assessment fee if your application has been selected for audit at the discretion of the delegate.

There is an audit assessment fee for an application that **must be** selected for audit under 5.3 of the Regulations.

You will receive an invoice if you are required to pay an audit assessment fee.

For medical device (excluding IVD) applications, the audit fee is dependent on the level of audit assessment:

- Level 1
- Level 2

The TGA will determine what level of audit assessment is appropriate for your medical device application and the fee you are required to pay, based on the audit assessment level.

For IVD medical device applications, the audit assessment fee is the same regardless of the classification of the device.

Current audit assessment fees

To access the current audit assessment fees go to the Schedule of fees and charges:

- click on 'Medical devices' or 'IVD medical devices'
- the assessment fees are listed under 'Application audit assessment fees'

How to pay the required application audit assessment fee

Refer to the payment options webpage for ways to pay your application audit assessment fee.

If you do not pay the audit assessment fee, your application will lapse under s41FK of the Act.

Reduction of assessment fees

If audit assessment can be abridged, there are certain circumstances where audit assessment fees can be reduced. For further information see Reduction of assessment fees for medical devices under the heading 'Application Audits'.

Related information and guidance

Therapeutic Goods Regulations 1990 (Schedule 9 - Table of fees).

Step 3 – Time frames for conducting audits

The time taken to conduct the application audit assessment for your device is dependent on a number of factors including:

- the time you take to pay the audit assessment fees (if applicable);
- the time you take to provide requested information; and
- the quality of the information you provide to the TGA.

There are no legislative timeframes for application audits.

Step 4 – Withdrawing or lapsing your application

Withdrawal of your application

You may withdraw your application at any time prior to a decision being made whether or not to include your medical device, including IVD medical device, in the ARTG. You can withdraw your application through TBS.

Any fees you have paid will not be refunded if you withdraw your application.

Once you have paid a fee there are very limited circumstances under which you will be able to obtain a refund. Refer to refunds for further information.

What happens next?

If your application is withdrawn:

- you will receive an email confirming that your application has been withdrawn
- you cannot supply the kind of medical device as it has not been included in the ARTG
- you can resubmit a new application and recommence the process at any time.

Lapsing your application

If you fail to comply with any request made by TGA within the timeframes specified in the notification letter provided to you or fail to pay the associated audit assessment fee, the audit will not continue and your application will lapse.

Examples may include failure to:

- comply with a notice under section 41FH of the Act within 10 working days after the end of the period specified in the notice letter
- comply with a requirement to deliver a reasonable number of samples of the kind of medical device to which the application relates

- comply with a notice under section 41JA of the Act to give information relating to devices of that kind within a further 10 working days from the day specified in the notice letter
- provide information in connection with the application, including information for the purpose of section 41JA of the Act, that is false or misleading in a material particular
- pay an audit assessment fee for the application within 28 days after the day that you were notified of the amount of the fee.

Any fees you have paid will not be refunded if you allow your application to lapse.

Once you have paid a fee there are very limited circumstances under which you will be able to obtain a refund. Refer to refunds for further information.

Lapsing of the application is not a decision of the Secretary, and is not subject to a review under section 60 of the Act.

What happens next

If your application is lapsed:

- you will receive written notification outlining that your application has lapsed and the reasons why your application has lapsed
- you cannot supply the kind of medical device as it has not been included in the ARTG
- you can resubmit a new application and recommence the process at any time.

Step 5 – Application audit outcome

Once your application audit assessment is completed and a decision is made, you will receive notification regarding the outcome of your application audit assessment.

Outcome of the application audit

Provided your application has not been withdrawn or lapsed, your audit assessment will conclude with one of the following outcomes:

- decision to include your kind of device in the ARTG
- decision not to include your kind of device in the ARTG.

Decision to include your kind of device in the ARTG

If the delegate is satisfied as to all aspects considered in the audit assessment, your medical device, including IVD medical device, will be included in the ARTG.

What happens next?

If a decision is made to include the kind of medical device in the ARTG:

- you will receive email notification outlining the decision to include your medical device in the ARTG

- you can print your ARTG certificate of inclusion (Step 8 of the Medical device ARTG inclusion process)
- you have ongoing responsibilities as a sponsor of a medical device, including IVD medical device, included in the ARTG (Step 9 of the Medical device ARTG inclusion process).

Decision not to include your kind of device in the ARTG

If the delegate is not satisfied as to all aspect considered in the audit assessment, your medical device, including IVD medical device, will not be included in the ARTG.

What happens next

If a decision is made not to include your kind of medical device in the ARTG:

- you will receive written notification outlining:
  - the decision not to include the device in the ARTG
  - the reasons for not including the device in the ARTG
  - information about the appeal process under section 60 of the Act.
- you may request a review of this decision under section 60 of the Act. Refer to the TGA internal review guideline for information on the appeal process.
- any fees paid will not be refunded. Refer to refunds for information.
- you cannot supply the kind of medical device as it has not been included in the ARTG
- you can recommence the process to include the kind of medical device in the ARTG at any time.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch	March 2019
V1.1	Updated to include details about which devices are subject to mandatory auditing	Medical Devices Authorisation Branch	September 2020
V1.2	Updated to include that devices that have EU MDR 2017/745 or EU IVDR 2017/746 certification that has not been suspended or revoked are not subject to mandatory auditing.	Medical Devices Authorisation Branch	January 2022
V1.3	Updated list of applications that are subject to mandatory audit to align with Regulation 5.3 as published at 26 November 2021	Medical Devices Authorisation Branch	January 2022

Therapeutic Goods Administration

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Reference/Publication #