Reduction of assessment fees for medical devices
Guidelines for reducing assessment fees for application audits and conformity assessments of medical devices (other than IVDs)
Version 1.1, November 2011
About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- TGA administers the Therapeutic Goods Act 1989 (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website.
## Version history

<table>
<thead>
<tr>
<th>Version</th>
<th>Description of change</th>
<th>Author</th>
<th>Effective date</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1.0</td>
<td>First version of this document. Combined elements of previous internal TGA business rules.</td>
<td>Office of Devices Authorisation</td>
<td>6 October 2011</td>
</tr>
<tr>
<td>V1.1</td>
<td>Minor amendments for consistency, including clarification that the document does not relate to IVD medical devices.</td>
<td>Office of Devices Authorisation</td>
<td>21 November 2011</td>
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Overview

The TGA is fully cost-recovered and collects its revenue primarily through annual charges, application fees, and assessment fees.

The *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations) prescribes certain circumstances where assessment fees for medical devices may be reduced, including:

- reduction in assessment fees where supply of a medical device is in the interests of public health, and it would not be commercially viable if the full amount of the fee were paid (regulation 9.6); and
- reduction in assessment fees where information allows the assessment to be abridged (regulation 9.7).

Information about the fees and charges for medical devices can be found in Section 2 of the Australian Regulatory Guidelines for Medical Devices (ARGMD) available on the TGA website <http://www.tga.gov.au>.

This guideline provides additional information about the eligibility requirements and procedures used by the TGA in order to determine whether assessment fees can be reduced for application audits and conformity assessment applications involving medical devices (other than IVDs).

This document does not cover applications for IVD medical devices, as this is the subject of a separate TGA guidance document: <http://www.tga.gov.au/industry/ivd-fees.htm>.

Scheduled fees

Schedule 5 of the medical devices Regulations specifies the various fees that apply to medical devices, including; application fees, notification fees, and assessment (or evaluation) fees.

Fees prescribed in Schedule 5 of the Regulations are subject to annual adjustment. The level of any reduced assessment fees shall also be adjusted annually in line with changes in the scheduled fees.

The fees and charges currently applicable to medical devices are available on the TGA website <http://www.tga.gov.au>.

Please Note:

- An application fee is payable in order for an application to become effective, and allow the TGA to perform an assessment (if required).
- If the TGA is required to undertake an assessment of the application, further assessment fees will apply in addition to the application fee.

Application fees

A summary of the relevant scheduled application fees for conformity assessment applications, and applications to include medical devices in the Australian Register of Therapeutic Goods (ARTG), are provided in the table below.
### Legislative references for medical device application fees

<table>
<thead>
<tr>
<th>Type of Application</th>
<th>Scheduled Fee Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application to include medical device in the ARTG</td>
<td>Schedule 5, Part 1, Item 1.5</td>
</tr>
<tr>
<td>Different application fees apply to different classes of medical devices.</td>
<td></td>
</tr>
<tr>
<td>Application for conformity assessment certificate</td>
<td>Schedule 5, Part 1, Item 1.1</td>
</tr>
<tr>
<td>Applicable to applications for new certificates, changes to certificates, or re-certification applications.</td>
<td></td>
</tr>
</tbody>
</table>

### Assessment fees

A summary of the relevant scheduled assessment fees for application audits and conformity assessments are provided in the table below.

### Legislative references for medical device assessment fees

<table>
<thead>
<tr>
<th>Type of Assessment</th>
<th>Scheduled Fee Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application audit – Level 1 assessment</td>
<td>Schedule 5, Part 1, Item 1.13</td>
</tr>
<tr>
<td>Application audit – Level 2 assessment</td>
<td>Schedule 5, Part 1, Item 1.14</td>
</tr>
<tr>
<td>Conformity assessment – initial assessment</td>
<td>Schedule 5, Part 1, Item 1.9</td>
</tr>
<tr>
<td>Applicable to applications for new manufacturers, new medical devices (requiring design or type examination), or where previous conformity assessment certificates have since expired.</td>
<td></td>
</tr>
<tr>
<td>Conformity assessment – assessment of changes</td>
<td>Schedule 5, Part 1, Item 1.10</td>
</tr>
<tr>
<td>Applicable to current conformity assessment certificates where a change to the device or QMS is required to be assessed.</td>
<td></td>
</tr>
<tr>
<td>Conformity assessment – Review of QMS certificate</td>
<td>Schedule 5, Part 1, Item 1.2</td>
</tr>
<tr>
<td>Applicable to surveillance audits, and recertification applications, for current Schedule 3, Part 1, 4 or 5 certificates.</td>
<td></td>
</tr>
<tr>
<td>Conformity assessment – Review of product certificate</td>
<td>Schedule 5, Part 1, Item 1.3</td>
</tr>
<tr>
<td>Applicable to a review of current Design Exam (Schedule 3, clause 1.6) or Type Exam (Schedule 3, Part 2) certificates, including recertification applications.</td>
<td></td>
</tr>
</tbody>
</table>
Reduction of assessment fees

Assessment fees for medical devices may be reduced by the Secretary (or their Delegate) under certain circumstances, as provided for under regulation 9.6 and 9.7 of the Regulations.

Regulation 9.6 of the medical devices Regulations states that:

9.6 Reduction of assessment fees

The Secretary may reduce by 70% the amount of an assessment fee specified in Schedule 5 in relation to a medical device if the supply of the medical device:

a. is in the interest of public health; and

b. would not be commercially viable for the manufacturer or sponsor of the medical device if the full amount of the fee were paid.

In order for this regulation to apply, the applicant must be able to clearly demonstrate that the supply of the medical device is in the interests of public health (as opposed to an individual’s health, or the commercial interests of the company). If other similar devices are already available on the Australian market, it is unlikely that assessment fees would be reduced under this Regulation.

In order to consider the commercial viability of supplying the device, the applicant would be required to provide details of likely sales figures and profit margins. This regulatory requirement is only likely to be met for devices of low value and limited sales potential.

The level of fee reduction under Regulation 9.6 is fixed at 70%, and applies only to assessment fees.

Regulation 9.7 of the medical devices Regulations states that:

9.7 Reduction of assessment fees - abridged assessment

1) This regulation applies to an assessment fee specified in Part 1 of Schedule 5 in relation to any of the following:

   a) items 1.2 and 1.3 (review of conformity assessment certificate);

   b) item 1.9 (initial assessment under conformity assessment procedures);

   c) item 1.10 (assessment consequent on a change to:

      i) a medical device; or

      ii) the quality management system applying to a medical device);

   d) items 1.13 and 1.14 (application subject to audit assessment);

   e) item 1.16 (intermediate stage assessment or verification procedures).

2) The Secretary may reduce the amount of the assessment fee if the Secretary has information that allows the assessment to be abridged, being information about:

   a) the medical device to which the fee relates; or

   b) some or all aspects of whether the conformity assessment procedures have been applied to the medical device.
Regulation 9.7 of the medical device Regulations includes provisions for reduction of assessment fees for application audits and conformity assessments, where information is available that allows the assessment to be abridged.

The type of information that can be considered must relate either to the medical device, or to aspects of the conformity assessment procedures that have been applied to the medical device.

It may be possible for the TGA to lower the assessment fee according to the degree of regulatory assessment already undertaken, either by the TGA, or by a recognised conformity assessment body (e.g. European Notified Body).

The amount of any fee reduction under regulation 9.7 will be commensurate with the level of assessment required to ensure regulatory compliance, and applies only to assessment fees.

**Important notes**

- There is no provision in the legislation to consider reduction of application fees, or other assessment fees such as:
  - Supplementary assessment fees under Schedule 5, Part 2.1 for travel costs and preparation time associated with on-site audits,
  - Supplementary assessment fees under Schedule 5, Part 2.2 for the cost of testing devices, for example as part of a Part 2 Type Examination assessment,
  - Assessment fees under Schedule 5, Part 1, Item 1.11 for an assessment of the data relating to a medicinal component of the device.

- The Delegate to the Secretary under regulation 9.6 or regulation 9.7 is responsible for determining whether to reduce an assessment fee, and if so, the amount of the reduction.

- The Delegate to the Secretary is not obliged to reduce an assessment fee.

- Applicants cannot assume that assessment fees will be reduced for a particular application, and should be prepared to pay the full scheduled assessment fee if required.

- In considering whether to reduce an assessment fee, the Delegate to the Secretary is not making an ‘initial decision’ under the Act. As such, applicants cannot ‘appeal’ the amount of the reduction, or the fact that an assessment fee has not been reduced.

- Any fees under $10,000 are rounded to the nearest $10 value, and any fees over $10,000 are rounded to the nearest $100 value.
Application audits

An assessment fee is payable for each application that is required by the Regulations to be selected for auditing under regulation 5.3 (compulsory audits). Fees are not payable for other application audits that the TGA decides to conduct (non-compulsory audits).

There are different fees for Level 1 and Level 2 application audits. Details of the fees currently applicable are available on the TGA website at <http://www.tga.gov.au>.

Application audit assessment fees can be reduced where a sponsor has more than one medical device application able to be grouped with other similar device applications (within the TGA called a ‘submission’).

The procedure below must be followed by applicants to enable the reduction of fees to be considered. If these rules are not followed, the TGA will undertake a full assessment of an application at the scheduled fee.

Applications selected for an application audit will be eligible to be considered for a reduced assessment fee if:

- All the effective applications for inclusion are received on the same day (that is, the application fees are paid on the same day)
- All the applications are for the same medical device classification (that is, all Class III or all Class AIMD)
- A written request from the sponsor for reduced fees is electronically attached to each of the applications by the applicant. In particular, the written request must include:
  - A reference to each of the relevant application ID numbers to be considered for abridged assessment fees.
  - A statement from the sponsor that the standard supporting information package normally required for application audits is entirely common for all of the applications, and will allow an abridged assessment to be performed (except for labelling, instructions for use, or promotional material).
- The Manufacturer’s Evidence used to support each of the device applications must be the same (that is, the devices in each application must be covered by the same certification).
- Applications are selected for a mandatory pre-market application audit as per section 41FH of the Act, and regulation 5.3 of the medical devices Regulations.

If all of the above conditions have been met, then:

- A full scheduled application audit assessment fee will apply to the first application in the group.
- A reduced assessment fee equivalent to 28% of the scheduled application audit assessment fee will be recommended to the Secretary for each of the other applications in the same group.
- Based on the information in each of the applications, and the written request for reduced fees from the sponsor, the delegate of the Secretary under regulation 9.7 will make a decision whether to reduce the amount of the assessment fees.
• The sponsor will be notified of the outcome of this decision at the time the supporting information is requested for the application audit. A statement of reasons shall be provided where the decision is not to reduce the assessment fees.

• An invoice for the total assessment fees to be paid shall be issued to the sponsor under separate cover.

Please Note:

• Application audit assessment fees will not be reduced on the basis of similarity to effective applications received on a different day, or medical devices already included on the ARTG.

• The amount of the reduced application audit assessment fee is fixed and is not negotiable.
Conformity assessments

By default, the TGA will undertake assessment of an application at the full scheduled assessment fee. When submitting a conformity assessment application the applicant may request the TGA to consider an abridged assessment in order to reduce the assessment fees. In doing so, the applicant is required to provide sufficient additional information which could allow the TGA to abridge the assessment.

Where a request for abridgement of the assessment is made because the manufacturer and/or the device has been reviewed by another appropriate assessment body under equivalent regulatory requirements (e.g. a EU Notified Body under the MDD 93/42/EEC), information submitted in support of the application must include the applicable audit reports and/or product assessment reports issued by that assessment body.

Should the information provided not support an abridged assessment, a full assessment will be conducted and the scheduled fee will apply.

Where a Quality Management System (QMS) certificate has been issued by a recognised Canadian CMDCAS Registrar, abridgement of the QMS component (but not the product assessment) may be possible.

Process for requesting an abridged assessment

Written requests for abridgement and reduction of assessment fees must be made before the TGA issues an invoice for the assessment fees. For conformity assessments the requests may be included as part of the supporting information submitted to the TGA in response to the initial request for information.

The written request should include:

- a reference to the relevant submission ID number to be considered for reduced fees;
- the basis on which abridgement is being sought; and
- a statement that evidence to justify the request has been included in the supporting information.

Requests should be addressed to:

Head, Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

When submitting information to support the application, the applicant must provide sufficient documentary evidence to support the request for an abridged assessment.

For example, if the manufacturer already holds full quality assurance and design examination certification from a European Notified Body under the MDD 93/42/EEC, then the applicant will need to submit copies of the certificates, as well as the Notified Body’s supporting audit/assessment reports.

If sufficient documentary evidence is not submitted by the applicant, the assessment will not be able to be abridged, and the Delegate will not be able to apply a reduced assessment fee under regulation 9.7.
TGA process
The process of considering an abridged assessment, and the invoicing of assessment fees, is summarised below:

1. Applicant submits electronic application via TGA eBusiness Services website (may attach written request for an abridged assessment).
2. TGA requests initial supporting information from applicant.
3. Applicant submits requested supporting information, including a copy of the written request for an abridged assessment, and sufficient documentary evidence in support of that request.
4. TGA conducts a 'pre-assessment' of the application, and agrees on an assessment plan for the application. The assessment plan will include consideration of any request for an abridged assessment.
5. If an abridged assessment can be accommodated, a memo recommending a reduction of fees is prepared and sent to the Delegate to the Secretary for consideration.
6. If the Delegate to the Secretary agrees that the TGA has sufficient information to allow an abridged assessment, they will make a determination on an appropriate reduced assessment fee using this document as a guide. If the Delegate to the Secretary does not agree to a request for an abridged assessment, the applicant will be notified.
7. The TGA sends a notification letter to the applicant informing them of the proposed level of assessment and associated fees, and arranges for an invoice to be sent to the applicant for either the full assessment fee, or the reduced assessment fee as determined by the Delegate to the Secretary (if applicable).

Please note:
- Any reduction of assessment fees remains at the discretion of the Delegate to the Secretary for the purposes of regulation 9.7.
- The amount of any reduced assessment fees is not negotiable.
- Once the assessment fees have been invoiced, the fees are due and payable according to the instructions on the invoice.
- The TGA cannot consider abridged assessments, or reduction of assessment fees, for Schedule 3, Part 3 Verification conformity assessment certification.
- Additional assessment fees may be incurred if supplementary assessment work is required during the application that was not initially forecast.
Eligibility for abridged assessments

Quality system certificates
The scenarios relating to a manufacturer’s QMS that may allow an abridged assessment to be conducted by the TGA are described below.

1. The manufacturer plans to implement a substantial change to the quality management system under a Schedule 3, Part 1, 4 or 5 conformity assessment certificate;
   and
   The incorporation of the change in the respective conformity assessment certificate does not require a full assessment by the TGA.

2. The manufacturer holds current EC certification issued by a Notified Body under an EU Medical Devices Directive (93/42/EEC or 90/385/EEC), or ISO13485 certification issued under CMDCAS by a Health Canada recognised registrar;
   and
   The assessment undertaken by the assessment body incorporated the same elements of an assessment required for a Schedule 3, Part 1, 4 or 5 conformity assessment certificate;
   and
   An initial assessment or surveillance audit has been undertaken within the previous 12 months.

3. The manufacturer has been selected for a surveillance audit of a Schedule 3, Part 1, 4 or 5 conformity assessment certificate by the TGA;
   and
   The manufacturer holds current EC certification issued by a Notified Body under an EU Medical Devices Directive (93/42/EEC or 90/385/EEC), or ISO13485 certification issued under CMDCAS by a Health Canada recognised registrar;
   and
   An assessment has been undertaken by the assessment body within the previous 12 months;
   and
   That assessment incorporated the same elements as a TGA surveillance audit.

4. The manufacturer holds current EC certification issued by a Notified Body under an EU Medical Devices Directive (93/42/EEC or 90/385/EEC), or ISO13485 certification issued under CMDCAS by a Health Canada recognised registrar;
   and
   The manufacturer plans to implement a substantial change to the quality management system under a Schedule 3, Part 1, 4 or 5 conformity assessment certificate;
   and
   The change has been satisfactorily assessed by the assessment body.

5. The manufacturer holds conformity assessment certification under Schedule 3 Part 1, clause 1.6, Part 4, or Part 5 of the Regulations;
   and
   The manufacturer applies for changes to the content of a certificate that require little or no assessment by the TGA (e.g. change to name of manufacturer only).
6. The manufacturer holds a QMS certificate issued under the Australia-Canada MoU by a participating Canadian Registrar.
   The MoU QMS certificate will be recognised by the TGA, and taken into consideration as part of an application for a Schedule 3, Part 1, 4 or 5 conformity assessment certificate.
   An initial on-site audit of the manufacturer’s QMS will not be undertaken by the TGA where a Canadian MoU certificate has been issued.

In each of these circumstances the TGA may be able to abridge the assessment of the manufacturer’s QMS to allow:

- a reduced review of the technical files for each kind of medical device, or
- a desk audit of the QMS documentation (instead of an on-site audit).

The level that a QMS assessment is able to be abridged is dependent on many factors, including:

- the existence, and content, of audit reports from other assessment bodies, and
- whether an on-site audit has been undertaken recently.

Scenarios other than those described above may also allow an abridged assessment of the manufacturer’s QMS to be conducted, however this will be reviewed on a case-by-case basis and will need to be supported by a detailed justification from the manufacturer.

Please note:

- Approvals by an assessment body not significantly aligned with the Australian regulatory requirements cannot be used as the basis for an abridged assessment.
  For example, approvals by the US FDA under the 510(k) process, or QMS certification to ISO9001, are not considered appropriate to allow an abridged assessment.
# Product certificates

The scenarios relating to a medical device covered by a Design Exam or Type Exam certificate that may allow an abridged assessment to be conducted by the TGA are described below.

<p>| | |</p>
<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
</table>
| 1. | The manufacturer holds current EC certification issued by a Notified Body under an EU Medical Devices Directive (93/42/EEC or 90/385/EEC), or a Canadian product licence issued by Health Canada;  
   and  
   The assessment undertaken incorporated the same elements of an assessment required for a conformity assessment certificate under clause 1.6 (Design Exam) or Part 2 (Type Exam) respectively. |
| 2. | The manufacturer plans to implement a substantial change to the design of the device under a Schedule 3, clause 1.6 or Part 2 conformity assessment certificate;  
   and  
   The incorporation of the design change does not require a full assessment by the TGA. |
| 3. | The manufacturer applies for a Part 2 (Type Exam) certificate and holds a relevant Type Test certificate;  
   and  
   The Type testing has been performed against a recognised Medical Device Standard;  
   and  
   Testing has been performed by a testing laboratory with accreditation by NATA or other IAF member. |
| 4. | The manufacturer submits an initial application for Schedule 3, clause 1.6 (Design Exam) certificates for different kinds of Class III/AIMD medical devices;  
   and  
   One kind of device in the application is subject to full design examination;  
   and  
   The other devices in the application are similar enough for a concurrent assessment to be conducted. |
| 5. | The manufacturer submits an initial application for a Schedule 3, clause 1.6 (Design Exam) certificate;  
   and  
   The kind of medical devices in the application are similar enough to a device previously subject to full design examination by the TGA. |
| 6. | The manufacturer holds conformity assessment certification under Schedule 3, clause 1.6 (Design Exam) or Part 2 (Type Exam);  
   and  
   The manufacturer applies for changes to the content of a certificate that require little or no assessment by the TGA (e.g. change to name of products only). |

In each of these circumstances the TGA may be able to abridge the assessment of the design of the kind of medical device to allow:
- a reduced examination of the design dossier for each kind of medical device (Design Exam), or
• a reduction in the type testing required, or the assessment of the type testing reports (Type Examination).

The level that a product assessment is able to be abridged is dependent on many factors, including:

• the existence, and quality, of technical assessment reports from the assessment body,
• the complexity of the technology involved, and
• the similarity of the device with previously TGA assessed devices.

Scenarios other than those described above may also allow an abridged assessment of the medical devices to be conducted, however this will be reviewed on a case-by-case basis and will need to be supported by a detailed justification from the manufacturer.

Please note:

• In relation to Design Exam (clause 1.6) or Type Exam (Part 2) certificates, an assessment fee will apply for each ‘kind of medical device’. This means that a separate assessment fee will apply to each Unique Product Identifier (UPI) covered by the certificate or application.

• Type Exam certification under the EU Medical Devices Directives cannot be used to abridge an assessment for Schedule 3, clause 1.6 (Design Exam) conformity assessment certification.

• Design Exam certification under the EU Medical Devices Directives cannot be used to abridge an assessment for Schedule 3, Part 2 (Type Exam) conformity assessment certification.
Possible level of reduced assessment fees

The tables below indicate the minimum assessment fee level that may be considered for different conformity assessment certificate applications, in cases where an abridged assessment is considered appropriate.

Minimum assessment fee levels for Schedule 3, Part 1, 4 or 5 certificates (initial or change applications)

<table>
<thead>
<tr>
<th>Level of Technical File Review</th>
<th>Level of QMS Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>No audit (desk or on-site)</td>
<td>No audit (desk or on-site)</td>
</tr>
<tr>
<td>Desk audit or on-site audit</td>
<td>Desk audit or on-site audit</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>None</th>
<th>No assessment fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor</td>
<td>One third (1/3) the value of the scheduled fee</td>
</tr>
<tr>
<td>Major</td>
<td>Two thirds (2/3) the value of the scheduled fee</td>
</tr>
<tr>
<td></td>
<td>Full scheduled fee applies</td>
</tr>
</tbody>
</table>

**Example:** For an application for an initial Schedule 3, Part 1 certificate, where the technical file review is abridged to a minor level, and an on-site QMS audit is undertaken, an assessment fee equal to two thirds of the full Schedule 3, Part 1 assessment fee may be applied.

Minimum assessment fee levels for Schedule 3, clause 1.6 (Design Exam) or Part 2 (Type Exam) certificates (initial, change or recertification applications)

<table>
<thead>
<tr>
<th>Level of Review of Product Design</th>
<th>Level of Review of Product Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>No assessment fee</td>
</tr>
<tr>
<td>Low</td>
<td>One third (1/3) the value of the scheduled fee</td>
</tr>
<tr>
<td>Medium</td>
<td>Two thirds (2/3) the value of the scheduled fee</td>
</tr>
<tr>
<td>High</td>
<td>Full scheduled fee applies</td>
</tr>
</tbody>
</table>

**Example:** For an application for a change to a Schedule 3, clause 1.6 (Design Examination) certificate, where the level of the design review is abridged to a low level, an assessment fee equal to one third of the full Schedule 3, clause 1.6 assessment fee may be applied.