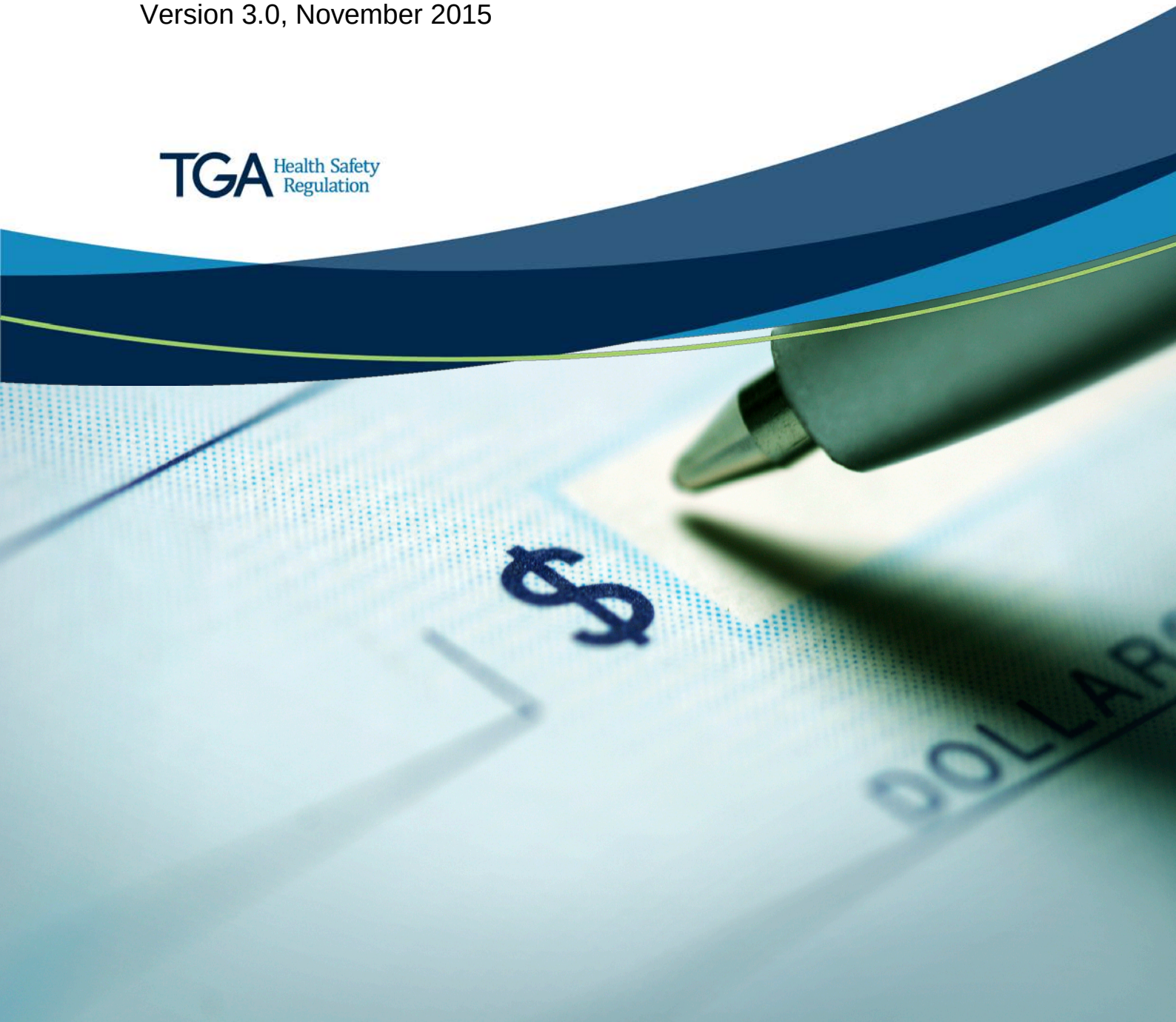
Australian Government
Department of Health
Therapeutic Goods Administration

Reduction of assessment fees for medical devices

Guidelines for reducing assessment fees for ARTG application audits and conformity assessments of medical devices (including IVDs)

Version 3.0, November 2015

TGA Health Safety Regulation



About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The 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 <https://www.tga.gov.au>.

Version history

Version	Description of change	Author	Effective date
V1.0	First version of this document. Combined elements of previous internal TGA business rules.	Office of Devices Authorisation	06/10/2011
V1.1	Minor amendments for consistency, including clarification that the document does not relate to IVD medical devices.	Office of Devices Authorisation	21/11/2011
V2.0	References to Department of Health and Ageing updated to Department of Health References to Office of Devices Authorisation updated to Devices Authorisation Branch Various edits to improve clarity including addition of document numbering, addition of information box in Section 3.1.1 and other textual edits. Correction to Table 1.2 to remove "recertification" and to add "where new certificates are required for previous conformity assessment certificates that are expiring" under Item 1.9. Fractional fees updated to percentages in Section 3.3	Devices Authorisation Branch	22/04/2015
V3.0	Updated to include IVD medical devices References to Devices Authorisation Branch updated to Medical Devices Branch Reference to Monitoring and Compliance Branch in Section 1 removed	Medical Devices Branch	24/11/2015

Contents

1. 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 the Secretary has information about the medical device, or the conformity assessment procedures that have been applied to the medical device, that 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 <https://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd>.

This guideline provides additional information about the eligibility requirements and procedures used by the TGA in order to determine whether assessment fees administered by the Medical Devices Branch can be reduced for application audit assessments and conformity assessments involving medical devices (including IVDs).

This document has been updated to cover IVD medical devices and replaces the previously published guideline entitled *Business rules for reduced assessment fees for IVDs*.

1.1 Scheduled fees

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

By default, the full scheduled fee applies to all applications, notifications and assessments for medical devices and the applicant should always be prepared to pay the full amount. There is no legislated obligation for the Secretary to reduce any fees; however, the Secretary does have the discretion to reduce fees in some circumstances.

The fees prescribed in Schedule 5 of the Regulations are subject to annual adjustment.

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

1.1.1 Application fees

A summary of the legislative references for 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.

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 in relation to the application, further assessment fees will apply in addition to the application fee.
- There is no legislative provision for the reduction of application fees.

Table 1.1 Legislative references for medical device application fees

Type of Application	Scheduled Fee Reference
Application to include medical device in the ARTG Different application fees apply to different classes of medical devices.	**Schedule 5, Part 1, Item 1.5**
Application for conformity assessment certificate Applicable to applications for new certificates or changes to certificates.	**Schedule 5, Part 1, Item 1.1**

1.1.2 Assessment fees

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

Table 1.2 Legislative references for medical device assessment fees

Type of Assessment	Scheduled Fee Reference
Application audit assessment - Level 1	**Schedule 5, Part 1, Item 1.13**
Application audit assessment - Level 2	**Schedule 5, Part 1, Item 1.14**
Application audit assessment for Class 1, Class 2 and Class 3 IVD medical devices	**Schedule 5, Part 1, Item 1.14A**
Conformity assessment - initial assessment Applicable to applications for new QMS certificates or new design or type examination certificates, including where new certificates are required for previous conformity assessment certificates that are expiring or have expired.	**Schedule 5, Part 1, Item 1.9** (non-IVD medical devices) **Schedule 5, Part 1, Item 1.9A** (IVD medical devices)

Type of Assessment	Scheduled Fee Reference
Conformity assessment – assessment of changes Applicable to current conformity assessment certificates where a change to the device or QMS is required to be assessed.	**Schedule 5, Part 1, Item 1.10** (non-IVD medical devices) **Schedule 5, Part 1, Item 1.10A** (IVD medical devices)
Conformity assessment – Review of QMS certificate Applicable to surveillance inspections, or any other review to determine whether the conformity assessment procedures have been applied to the kinds of devices covered by the certificate, for current Schedule 3, Part 1, 4 or 5 certificates.	**Schedule 5, Part 1, Item 1.2**
Conformity assessment – Review of product certificate Applicable to a review of current Design Exam (Schedule 3, clause 1.6) or Type Exam (Schedule 3, Part 2) certificates, in relation to certification of compliance with the essential principles.	**Schedule 5, Part 1, Item 1.3** (non-IVD medical devices) **Schedule 5, Part 1, Item 1.3A** (IVD medical devices)

1.2 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 regulation 9.6 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 for the Secretary 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.

Note that both conditions, a. **and** b., must be met in order for Regulation 9.6 to apply.

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. 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, 1.3 and 1.3A (review of conformity assessment certificate);
    b. items 1.9 and 1.9A (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. item 1.10A (assessment consequent on a change to:
        i. an IVD medical device; or
        ii. the quality management system applying to an IVD medical device);
    e. items 1.13, 1.14 and 1.14A (application subject to audit assessment);
    f. 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 audit assessments 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), if sufficient evidence is available that allows the TGA to abridge the assessment.

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.

1.3 Important notes

9.7 Reduction of assessment fees – abridged assessment

- 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 of 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 of 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, the amount of the reduction, or the fact that an assessment fee has not been reduced, is not subject to review under section 60 of the Act.
- Any reduced fees under $10,000 are rounded to the nearest $10 value, and any reduced fees over $10,000 are rounded to the nearest $100 value.

2. ARTG application audits

The Act and the Regulations (under paragraph 41FH(1)(a) and regulation 5.3 respectively) specify that certain applications to include devices in the ARTG must be selected for audit (compulsory audits). An audit assessment fee is payable for each application that the legislation requires to be selected for auditing. The TGA may also decide to select certain applications for audit (non-compulsory audits). Assessment fees are not payable for application audits where the TGA has decided to select an application for audit.

Depending on the application and the kind of device, the level of audit assessment will be determined. There are different fees for Level 1 and Level 2 application audits and IVD application audits, as specified under Items 1.13, 1.14 and 1.14A of Schedule 5 of the Regulations. The specified audit fees can be reduced under Regulation 9.7 where assessment can be abridged; for example, when a sponsor submits more than one application for inclusion of similar devices that can be grouped together for the purposes of assessment.

The following scenario is an example showing how fees may be reduced for application audit assessments:

- A sponsor submits multiple effective applications for device ARTG inclusion.
- All the effective applications for inclusion are received on the same day (that is, the application fees are paid on the same day);
- The applications are subject to compulsory audit as per paragraph 41FH(1)(a) of the Act and regulation 5.3 of the Regulations;
- All the applications are for the same medical device classification and are covered under the scope of the same Full Quality Assurance certificate (same Manufacturer's Evidence);
- A written request from the sponsor for reduced fees is electronically attached to each of the applications and includes:
  - A reference to each of the relevant application ID numbers to be considered for abridged assessment fees; and
  - An explanation on why and how the assessment can be abridged (i.e. information required for the audit assessment is sufficiently common for all applications to allow an abridgment of the assessment).

The delegate of the Secretary for the purposes of regulation 9.7 considers the request for fee reduction along with the other submitted information. If the delegate decides that there is sufficient information to allow abridgment of some of the assessment, then the audit assessment fees can be reduced, and in this case:

- A full scheduled audit assessment fee will be charged for the audit of one of the applications; and
- A reduced audit assessment fee (generally equivalent to 28% of the scheduled fee) will be charged for each of the other applications in the same group.
- An invoice will be issued by the TGA for the amount of the audit assessment fees approved by the delegate.

There may be other scenarios where the delegate would determine that adequate information was available to allow an application audit assessment to be abridged, and the corresponding fees to be reduced. Requests for such fee reductions are considered on a case by case basis.

Please note:

- Any reduction of assessment fees remains at the discretion of the Delegate of 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 decision to reduce the audit assessment fees is not subject to review under section 60 of the Act.

3. 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. an EU Notified Body under the MDD 93/42/EEC or IVDD 98/79/EC), detailed evidence of such third party assessment must be provided. The information submitted in support of the application must include the applicable audit reports and/or product assessment reports issued by that assessment body; the quality of such evidence will determine whether fee reduction is possible on this basis.

Should the TGA determine that the information provided does not support an abridged assessment, a full assessment will be conducted and the scheduled fees 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.

3.1 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, Devices Authorisation Branch
    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 or IVDD 98/79/EC, 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, or does not contain adequate detail, 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.

3.1.1 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.
2. Applicant submits supporting information, including the written request for an abridged assessment, and sufficient documentary evidence in support of that request.

Please note:

- Applications for new certificates to recertify a device or manufacturer, where a previous TGA certificate is expiring, do not require a request for an abridged assessment.
- The Secretary will already have information, from the assessment conducted for the previous certification period, which should allow the assessment to be abridged and the corresponding fees to be reduced.
- A fee reduction will automatically be considered for these recertification applications.

3. 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.
4. If an abridged assessment can be accommodated, a memo recommending a reduction of fees is prepared and sent to the Delegate of the Secretary for consideration.
5. If the Delegate of 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 of the Secretary does not agree to a request for an abridged assessment, the applicant will be notified as per the following step.
6. 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 of 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.

3.2 Eligibility for abridged assessments

3.2.1 Quality system certificates

The application scenarios relating to a manufacturer's QMS that may allow an abridged assessment to be conducted by the TGA are described below in Table 3.1.

Table 3.1

No.	Scenario
1.	An application is made for certification of a manufacturer's QMS under the Schedule 3 Part 1, Part 4 or Part 5 conformity assessment procedures; **and** The manufacturer holds current EC certification issued by a Notified Body under the relevant Annex of an EU Medical Devices Directive (e.g. 93/42/EEC or 90/385/EEC), EU IVD Directive 98/79/EC or ISO13485 certification issued under CMDCAS by a Health Canada recognised registrar; **and** The scope of the EU or HC certification incorporates the same manufacturing sites and device categories relevant to the assessment required for the Schedule 3, Part 1, 4 or 5 conformity assessment certificate; **and** An onsite audit has been undertaken by the assessment body within the previous 12 months; **and** A sufficiently detailed report of the most recent audit (and a sufficiently detailed report of the most recent certification or recertification audit if the most recent audit was surveillance only) has been provided to the TGA.

No.	Scenario
2.	A currently certified manufacturer plans to implement a substantial change to the quality management system under a Schedule 3 Part 1, Part 4 or Part 5 conformity assessment certificate; **and** An application for assessment of this change is made; **and** The manufacturer holds current and relevant EC certification issued by a Notified Body under an EU Medical Devices Directive (e.g. 93/42/EEC or 90/385/EEC), EU IVD Directive 98/79/EC or ISO13485 certification issued under CMDCAS by a Health Canada recognised registrar; **and** The change has been satisfactorily assessed by the assessment body; **and** A sufficiently detailed report of this assessment has been provided to the TGA.
3.	A currently certified manufacturer plans to implement a substantial change to the quality management system under a Schedule 3 Part 1, Part 4 or Part 5 conformity assessment certificate; **and** An application for assessment of this change is made; **and** The change requires minimal assessment by the TGA (e.g. change to name of manufacturer only).

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, and/or
- a desk assessment of the QMS documentation (instead of an on-site inspection).

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 and evidence 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).
- Fees for assessing changes, as specified in Items 1.10 and 1.10A of Schedule 5, already reflect a reduction from full initial fees. When an application is submitted for assessment consequent on change, it may or may not be possible to further reduce these change fees.

3.2.2 Product certificates

The application 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 in Table 3.2.

Table 3.2

No.	Scenario
1.	An application is made for conformity assessment certification of a new Class III, AIMD, or Class 4 IVD medical device; **and** The manufacturer holds current and relevant EC certification issued by a Notified Body under an EU Medical Devices Directive (e.g. 93/42/EEC or 90/385/EEC) or EU IVD Directive 98/79/EC or holds a Canadian product licence issued by Health Canada, for the same device; **and** The assessment undertaken for the EC or HC certification incorporated the same elements of an assessment that are required for a TGA conformity assessment certificate under Schedule 3 Part 1 clause 1.6 (Design Exam) or Part 2 (Type Exam) **and** A sufficiently detailed report of this assessment has been provided to the TGA.

No.	Scenario
2.	The manufacturer plans to implement a substantial change to the design of a device currently certified under Schedule 3 Part 1 clause 1.6 or Part 2; **and** An application for assessment of this change is made; **and** The manufacturer holds current and relevant EC certification issued by a Notified Body under an EU Medical Devices Directive (e.g. 93/42/EEC, 90/385/EEC), EU IVD Directive 98/79/EC or a Canadian product licence issued by Health Canada, for the same device; **and** An assessment of the change has been undertaken for the EC or HC certification **and** A sufficiently detailed report of this assessment has been provided to the TGA.
3.	An application is made for a Schedule 3 Part 2 (Type Exam) certificate for a new device and the manufacturer 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; **and** A sufficiently detailed report of this assessment has been provided to the TGA.
4.	An application is made for Schedule 3, clause 1.6 (Design Exam) certificates for a range of new kinds of either Class III or AIMD or Class 4 IVD medical devices; **and** One application is subject to full design examination; **and** The other applications are similar enough for a concurrent assessment to be conducted.
5.	An application is made for a Schedule 3, clause 1.6 (Design Exam) certificate for a new device; **and** The kind of medical device in the application is similar enough to a device previously subject to full design examination by the TGA.

No.	Scenario
6.	The manufacturer plans to implement a substantial change to the design of a device currently certified under Schedule 3 Part 1 clause 1.6 or Part 2; **and** An application for assessment of this change is made; **and** The change to the design requires minimal 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, which may include:

- 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.

3.3 Possible level of reduced assessment fees

The tables below indicate some examples of assessment fee levels that may be considered for different conformity assessment certificate applications, in cases where an abridged assessment is considered appropriate. The TGA delegate may decide that a different percentage of the scheduled fee is more appropriate for a particular application, depending on the level of effort required to conduct the assessment.

3.3.1 Quality system certificates

Table 3.3 Examples of assessment fee levels for Schedule 3, Part 1, Part 4 or Part 5 certificates. Note: these are examples only; each application requires individual consideration due to varying QMS complexity.

Level of Assessment	Possible Fee for Schedule 3, Part 1, Part 4 or Part 5 certificates
Issue of a new QMS certificate requiring on-site inspection of manufacturer's facilities including review of QMS documentation and technical files.	Full scheduled fee under Item 1.9 or 1.9A applies
Issue of a new QMS certificate where desk assessment of manufacturer's QMS documentation including inspection reports from a Notified Body is possible.	65% of the scheduled fee under Item 1.9 or 1.9A
Assessment of change relevant to a current QMS certificate involving assessment of Notified Body reports and QMS documentation.	65% of the scheduled fee under Item 1.10 or 1.10A
Assessment of a minor change relevant to a current QMS certificate.	30% of the scheduled fee under Item 1.10 or 1.10A
Issue of a new certificate for recertification of a manufacturer's QMS with an expiring TGA certificate where there are no significant changes in the manufacturer's QMS or technical files.	15% of the scheduled fee under Item 1.9 or 1.9A

3.3.2 Product certificates

Product assessments for Schedule 3 Part 1 clause 1.6 (Design Examination) or Schedule 3 Part 2 (Type Examination) vary widely between different kinds of medical devices depending on the component assessments required. For example, a non-IVD medical device may require some or all of the following component assessments:

- Clinical
- Engineering
- Biocompatibility
- Microbiology (sterility)

- Biological Science
- Toxicology
- More rarely, other components like Pharmaceutical Chemistry

IVD medical devices generally require assessment of multiple components such as analytical and clinical performance, product and specimen stability, risk analysis and management, undertaken in a single IVD assessment.

The TGA assessment plan will consider the number of components requiring assessment and the degree to which those components can be abridged to arrive at an estimate of the total assessment effort required. This will determine whether a reduced fee is possible; or whether supplementary fees may be required.

Table 3.4 Examples of assessment fee levels for Schedule 3, clause 1.6 (Design Exam) or Part 2 (Type Exam) certificates - Note: these are examples only, each application requires individual consideration due to varying device complexity.

Example Levels of Assessment	Possible Fee Level for Schedule 3 Part 1 Clause 1.6 or Schedule 3 Part 2 certificates
Design examination certificate for a new kind of device requiring multiple component assessments. Notified Body technical report supplied but contains summaries only.	Full scheduled fee under Item 1.9 or 1.9A applies
Assessment of a design change to a currently TGA certified device. All component assessments are not required, Notified Body report supplied and provides sufficient detail to allow abridgement.	65% of the scheduled fee under Item 1.10 or 1.10A
New design examination certificate for a kind of device based on a minor design change to an existing TGA certified device. Abridged assessment possible based on prior TGA assessment.	30% of the scheduled fee under Item 1.9 or 1.9A
New design examination certificate for recertification of a device with an expiring TGA certificate. Abridged assessment possible based on post-market data.	15% of the scheduled fee under Item 1.9 or 1.9A
New design examination of a kind of device which is a system comprising two Class III devices. Multiple component assessments required for each component device.	Full scheduled fee under Item 1.9 applies, plus a fee for supplementary assessment under Item 1.12

Example Levels of Assessment	Possible Fee Level for Schedule 3 Part 1 Clause 1.6 or Schedule 3 Part 2 certificates
Design examination certificate for a new kind of IVD medical device. Detailed Notified Body technical report supplied and provides sufficient detail to allow assessment to be abridged.	30% of the scheduled fee under Item 1.9A *Note: fee reduction does not apply to immunohaematology reagent IVDs for which a reduced fee is specified in Schedule 5*

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Reference/Publication #