Business rules for reduced assessment fees for in vitro diagnostic medical devices (IVDs)

Version 1.1, July 2012
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 <www.tga.gov.au>.
## Version history

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<th>Author</th>
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<tr>
<td>V1.0</td>
<td>Update of fees, formatting of document into new template</td>
<td>IVD section</td>
<td>29/08/2011</td>
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<tr>
<td>V1.1</td>
<td>Update to show reduced fees as a percentage of the full fees.</td>
<td>IVD team</td>
<td>25/07/2012</td>
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Business rules for reduced assessment fees for in vitro diagnostic medical devices (IVDs)

Overview

The TGA is fully cost-recovered and collects its revenue primarily through annual charges, application, audit and assessment fees. The fees and charges currently applicable to IVD medical devices are available at <http://www.tga.gov.au/about/fees-current.htm>.

The Therapeutic Goods (Medical Devices) Regulations 2010 (the Regulations) prescribes certain circumstances where fees may be reduced, including:

- reduction in assessment fees payable where supply of an IVD is in the interests of public health and it would not be commercially viable if the full amount of the fee were paid;
- reduction in assessment fees where information allows the assessment to be abridged;
- annual charges of $0 during the transition period until 30 June 2014; and
- exemptions from annual charges for low value turnover products (to apply from 1 July 2014).

Information about the fees and charges for IVDs and the options for fee reductions can be found in the guideline Fees and charges for IVD medical devices at <http://www.tga.gov.au/industry/ivd-fees.htm>.

This guideline provides additional information about the business rules that apply to the reduction in assessment fees where information allows the assessment to be abridged. These business rules apply to application audit assessment fees and conformity assessment fees.

Abridged assessments

Regulation 9.7 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations) includes provisions for reduced fees for application audits and conformity assessments where information is available that allows the assessment to be abridged. These provisions apply to IVDs under the new regulatory framework and are relevant to assessment fees for applications that require a mandatory application audit (technical file review) or applications for conformity assessment by the TGA. The type of information that can be considered must relate either to the medical device itself or to one or more aspects of the conformity assessment procedures that have been applied to the medical device. It may be possible for the TGA to proportionally lower the assessment fee according to the degree of regulatory oversight already undertaken, either by the TGA, for example during the registration process for Human Immunodeficiency Virus (HIV) or Hepatitis C virus (HCV) assays under the previous framework, or by a recognised conformity assessment body.

The level of 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. There is no provision within the legislation to reduce application fees, and annual charges can only be reduced under the “low volume turnover” provisions as described above.

Appendix 1 explains the business rules that will make fee reductions possible under Regulation 9.7 and summarises the conditions that may result in abridged assessments.

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1 See the Business Rules in Appendix 1 for details of when certification from overseas conformity assessment bodies will be recognised.
Registered IVDs currently supplied in Australia

Registered IVDs for HIV and HCV that are Class 4 IVDs under the new framework have undergone detailed evaluation prior to entry in the Australian Register of Therapeutic Goods (ARTG). Therefore they will be eligible for abridgement of fees associated with design examination. Similarly, registered IVDs that are Class 3 IVDs under the new framework (e.g. HIV or HCV viral load assays) will also be eligible for abridgement of fees associated with a mandatory technical file review (TFR).

Other IVDs that have been evaluated by the TGA

Some IVDs, e.g. Faecal Occult Blood Tests (FOBTs) for home use, may have undergone a detailed safety evaluation by the TGA prior to listing in the ARTG under the previous framework. These IVDs may be eligible for abridgement of fees for a mandatory TFR as part of an application for inclusion in the ARTG under the new framework.

Decisions regarding abridgement

By default, the TGA will undertake assessment of an application at the full prescribed fee. On making an application for conformity assessment by the TGA, or an application for inclusion in the ARTG for an IVD that requires a mandatory technical file review, the applicant may request abridgement and provide additional information which allows the TGA to reduce the level of assessment and the applicable assessment fees.

Written requests for abridgement and fee reduction must be made before the TGA issues any invoices for the assessments. For applications for inclusion in the ARTG that are subject to a mandatory application audit (TFR), the request must be electronically attached to each of the relevant applications at the time of lodgement. For conformity assessments by the TGA the requests may be submitted either as attachments to the applications, or as part of the dossier submitted to the TGA in response to an initial request for information under section 41JA.

The written requests must include:

- a reference to each of the relevant application ID numbers to be considered for reduced fees;
- the basis on which abridgement is being sought; and
- where the request is attached to an eBS application, a statement that evidence to support the request will be included in the submission documentation.

Requests should be addressed to:

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

Where a request for abridgement of the assessment for a Conformity Assessment Certificate issued by the TGA is made because the regulatory requirements have been reviewed by a Notified Body recognised for the purposes of 98/79/EC IVDD or by Health Canada under the Canadian Medical Devices Regulations, supporting information to be provided in the submission documentation must include the applicable audit reports and/or design examination reports issued by that Notified Body or by Health Canada. Should the information provided not support the requested abridgement, a full assessment will be required and the full prescribed fee will be charged.

Where a Quality Management System (QMS) Certificate has been issued by a CMDCA Registrar and a Conformity Assessment Certificate issued by the TGA is required, abridgement of the QMS component (but not the product-based component of the assessment) may be possible.

Any reduction of assessment fees remains at the discretion of the Head, Office of Devices Authorisation. The amount of the reduced assessment fee is not negotiable. If it becomes apparent during the assessment that additional work is required due to unexpected complexities, then additional fees may be imposed.
Determination of reduced fees

Fees prescribed in the Regulations are subject to annual adjustment. Reduced fees as set out in these business rules are shown as a percentage of the full fee as prescribed in the Regulations.

An applicant may submit a request for reduced fees on grounds other than those set out in Appendix 1 but, as noted above, any reduction in assessment fees remains at the discretion of the Head, Office of Devices Authorisation.
## Appendix 1 – Business rules for reduced fees

### Application Audits (Technical File Reviews)

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<td><strong>Business rule 1(a):</strong></td>
<td>A manufacturer produces a single STED for a group of related IVDs. If two or more applications for inclusion in the ARTG are submitted for products requiring a mandatory TFR, and the STED is shared between these products, then a reduced fee can be considered if the applications are:</td>
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<td>If more than one application includes IVDs that are required to undergo a mandatory TFR and the contents of the STED are applicable to IVD(s) from each application, then the fees may be reduced. The full prescribed fee will apply to one application, and reduced fees applied to any subsequent application(s).</td>
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<td>Effective applications for inclusion in the ARTG must be received by the TGA on the same day; the IVDs must have the same sponsor and manufacturer; and be similar in nature.</td>
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<td>Examples: An application for a point of care testing analyser is submitted at the same time as a separate application for a number of Class 2 chemistry test strips for use on the analyser. Both applications must be selected for audit (TFR) under Regulation 5.3. The first TFR will attract the full fee but the fee for additional TFRs can be reduced.</td>
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<tr>
<td>Applicable Fee: Full prescribed fee for one IVD requiring a mandatory TFR</td>
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<td>Each additional IVD sharing the common technical file and requiring basic administrative review only – 12% of the full fee;</td>
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<td>Where individual IVDs covered by the common technical file require more than basic review due to differences across the information supplied for the IVDs – 35% of the full fee.</td>
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<td>The standard information package (STED) normally required for a TFR must essentially be the same for each of the IVDs covered, except for labelling, instructions for use, and any other information specific to the individual IVDs.</td>
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<td>The level of reduced fee will be determined on a case-by-case basis. The amount of assessment required will inform this decision.</td>
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### Application Audits (Technical File Review)

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<td>If a single application includes more than one IVD that is subject to a mandatory TFR, then the TGA will select one or more products from the range of IVDs covered by that application to undergo detailed review. One TFR fee will apply per application.</td>
<td>This rule applies to a single application for inclusion in the ARTG covering multiple IVDs some or all of which may be subject to a mandatory TFR. The IVDs do not necessarily need to share the same STED. The TGA will select one or more of the IVDs to undergo review.</td>
<td>A group of Chlamydia IVDs incorporating several different methodologies, e.g. tests utilising a nucleic acid technology and an immunoassay-based technology, may be selected for review due to the significant differences between products.</td>
<td>Full prescribed fee for first IVD requiring a mandatory TFR. Where additional IVDs from the same application are selected – no additional fee.</td>
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<td>If an application includes an IVD that is required to undergo a mandatory TFR; and the IVD is currently registered in the ARTG (i.e. has an AUST R); then the fees may be reduced. Note: this rule does not apply to IVDs that are currently listed in the ARTG (i.e. have an AUST L) unless they have also undergone a safety evaluation by the TGA.</td>
<td>Reduction of fees for TFRs applicable for HIV and HCV assays currently registered in the ARTG where they are intended to monitor patients with active infections. These include HIV or HCV quantitative nucleic acid tests for performing viral loads or genotyping assays. The IVD for inclusion in the ARTG must be the same IVD that is currently registered, and must not include any changes that will require detailed assessment as part of the TFR.</td>
<td>An HIV or HCV quantitative nucleic acid test (viral load assay) or an HIV or HCV genotyping assay that is currently registered in the ARTG.</td>
<td>Reduced fee for mandatory TFR requiring basic administrative review only – 12% of the full fee.</td>
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### Application for Conformity Assessment (Full QMS or Production QA)

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<td><strong>Business rule 2(a):</strong> If an Australian or overseas manufacturer is:</td>
<td>This rule applies when a manufacturer applying for a TGA conformity assessment certificate (Full QMS or Production QA) already holds a relevant Manufacturing licence. Although the QMS will have already been reviewed, aspects such as compliance with the Essential Principles, risk analysis and performance data will not have been reviewed previously by the TGA. These and other aspects essential for issuing a TGA conformity assessment certificate may require further assessment, the extent of which will be determined as part of the pre-assessment process. Fees set will be consistent with the assessment activity required to be performed. In general, the full fee will be required if an on-site audit is performed, although reduced fees will apply if the licensing audit is done in conjunction with the conformity assessment audit.</td>
<td>An Australian manufacturer who holds a current TGA-issued Manufacturing licence for production of IVDs containing material of human origin.</td>
<td>Reduced fee for conformity assessment under Schedule 3, Part 1 or Part 4 – 30% of the full fee</td>
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<tr>
<td>• applying for Full QMS or Production QA certification; and</td>
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<td>• holds a current unconditional Manufacturing licence issued under Part 3-3 of the Therapeutic Goods Act 1989; and</td>
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<td>• the scope of the Manufacturing licence includes the IVD(s) that is to be assessed; and</td>
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<td>• the assessment for the Manufacturing licence incorporated the same quality management system elements as required for an assessment for TGA conformity assessment certification; then the fees may be reduced.</td>
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<tr>
<td><strong>Business rule 2(b):</strong> If an Australian or overseas manufacturer:</td>
<td>This rule applies when a manufacturer already holds a relevant Australian Manufacturing licence and a TGA conformity assessment certificate. If a surveillance audit for the conformity assessment certificate is due but the manufacturer has undergone a licensing audit within the previous 12–18 months which resulted in an unconditional continuation of that Manufacturing licence, then a reduction of fees may be possible.</td>
<td></td>
<td>Reduced fee for conformity assessment surveillance audit under Schedule 3, Part 1 or Part 4 – 5% of the full fee</td>
</tr>
<tr>
<td>• holds a current unconditional Manufacturing licence issued under Part 3-3 of the Therapeutic Goods Act 1989 and a TGA conformity assessment certificate issued under Part 4-4 of the Therapeutic Goods Act 1989; and</td>
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<td>• the manufacturer has been selected for a surveillance audit for the purpose of maintaining the conformity assessment certificate;</td>
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</table>
### Manufacturers holding a TGA-issued Manufacturing licence

**Further Detail**
- an audit has been performed for the Manufacturing license within the previous 12–18 months; and
- the scope of the Manufacturing licence audit included the quality management system under which the IVDs are manufactured, as defined in the initial conformity assessment certification; and
- the outcome of the audit resulted in an unconditional continuation of the Australian Manufacturing licence;

then the assessment may be abridged and the fees reduced.

### Australian manufacturers holding EC certification

**Business rule 3:**

If an Australian manufacturer:

- holds current EC certification issued by a European Notified Body under Annex IV or Annex VII of the in-vitro diagnostic medical devices Directive 98/79/EC (IVDD); and
- the assessment undertaken by the Notified Body incorporated the same elements of an assessment as required for a Full QMS or Production QA conformity assessment certificate issued by the TGA; and
- an initial assessment or surveillance audit has been undertaken by the Notified Body within the previous 12–18 months;

then the TGA conformity assessment may be abridged and fees reduced accordingly.

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<td>If an Australian manufacturer:</td>
<td>This applies when an Australian manufacturer already holds an EC certificate to Annex IV or VII of the IVDD and an associated audit was conducted within the previous 12–18 months.</td>
<td>An Australian manufacturer produces an IVD for screening for phenylketonuria. The IVD is included in List B, Annex II of the IVDD and accordingly the manufacturer has EC Annex IV IVDD certification.</td>
<td>Reduced fee for conformity assessment under Schedule 3, Part 1 or Part 4 – 30% of the full fee</td>
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<tr>
<td>holds current EC certification issued by a European Notified Body under Annex IV or Annex VII of the in-vitro diagnostic medical devices Directive 98/79/EC (IVDD); and</td>
<td>It is expected that manufacturers who may be eligible under this rule will be subject to a shortened audit if an audit is applicable.</td>
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<td>the assessment undertaken by the Notified Body incorporated the same elements of an assessment as required for a Full QMS or Production QA conformity assessment certificate issued by the TGA; and</td>
<td>Once a TGA conformity assessment certificate for quality systems has been issued to an Australian manufacturer, all future surveillance audits or the assessment of a change to a quality management system or, if required, a change to an IVD will be performed by the TGA.</td>
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<td>an initial assessment or surveillance audit has been undertaken by the Notified Body within the previous 12–18 months;</td>
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<tr>
<td><strong>Business rule 4(a):</strong>&lt;br&gt;If an overseas manufacturer:&lt;br&gt;• holds current EC certification issued by a European Notified Body under Annex IV or Annex VII of the in-vitro diagnostic medical devices Directive 98/79/EC (IVDD); and&lt;br&gt;• the assessment undertaken by the Notified Body incorporated the same elements of an assessment as required for a Full QMS or Production QA conformity assessment certificate issued by the TGA; &lt;br&gt;then the assessment may be abridged and fees reduced accordingly.</td>
<td>This rule applies to manufacturers who hold an EC Certificate to Part 3 of either Annex IV or Annex VII of the IVDD. The TGA will review the audit reports and other relevant manufacturer’s documentation. &lt;br&gt;This rule will only apply where the TGA has experience with both the manufacturer and the manufacturer’s technology – new manufacturers or current manufacturers undertaking manufacture of a device using technology that is new to the manufacturer will normally be audited by the TGA.&lt;br&gt;As the legislation requires that the TGA issues a conformity assessment certificate for Class 4 IVDs, the TGA will apply this rule on a case-by-case basis, depending on the IVD involved, the manufacturer’s experience and the TGA’s knowledge of the manufacturer.</td>
<td>An European IVD manufacturer of an HBsAg enzyme immunoassay (which is included on List A of Annex II of the IVDD) holds relevant EC Certification but requires a TGA issued conformity assessment certificate.</td>
<td>Reduced fee for conformity assessment under Schedule 3, Part 1 or Part 4 – 30% of the full fee</td>
</tr>
<tr>
<td><strong>Business rule 4(b):</strong>&lt;br&gt;If an overseas manufacturer:&lt;br&gt;• holds both a current TGA conformity assessment certificate and current EC certification issued by a European Notified Body under Annex IV or Annex VII of the in-vitro diagnostic medical devices Directive 98/79/EC (IVDD); and&lt;br&gt;• the manufacturer has been selected for a review of the conformity assessment certificate (surveillance audit) by the TGA; and&lt;br&gt;• the assessment undertaken by the Notified Body incorporated the same elements required to be</td>
<td>This rule applies when a manufacturer holds both a current TGA conformity assessment certificate and EC certification. If a surveillance audit was recently performed by a Notified Body to maintain the EC certificate, then abridgement may be possible for the TGA conformity assessment certificate surveillance audit which is now required.&lt;br&gt;If the relevant Notified Body has not audited the overseas manufacturer within the preceding 12–18 months, then the TGA would normally conduct an on-site surveillance audit at full fees. It is therefore beneficial for a manufacturer to ensure that surveillance audits are conducted within the required period.</td>
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<td>Reduced fee for conformity assessment surveillance audit under Schedule 3, Part 1 or Part 4 – 10% of the full fee</td>
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## Overseas manufacturers holding EC certification

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<tr>
<td>reviewed for a conformity assessment certificate (surveillance audit) and the surveillance audit has been undertaken within the previous 12–18 months; then the assessment may be abridged and fees reduced accordingly.</td>
<td>An overseas manufacturer holding both an EC certificate and a TGA issued conformity assessment certificate intends to move manufacturing sites. The Notified Body responsible for the EC certification has already assessed and approved this change.</td>
<td>Reduced fee for review of conformity assessment under Schedule 3, Part 1 or Part 4 – 25% of the full fee</td>
</tr>
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</table>

**Business rule 4(c):**

If an overseas manufacturer:

- holds both a TGA conformity assessment certificate and current EC certification issued by a European Notified Body under Annex IV or Annex VII of the in-vitro diagnostic medical devices Directive 98/79/EC; and
- the manufacturer plans to implement a significant change to the quality management system; and
- the change has been satisfactorily addressed and approved by the Notified Body;

then the assessment may be abridged and fees reduced accordingly.
### Overseas manufacturers holding an ISO 13485 certification issued by a CMDCAS Registrar

#### Further Detail
- QMS certificates issued by a participating Registrar who has undergone a mutual confidence building exercise with the TGA will allow for abridgment of the QMS component of an application for a TGA issued conformity assessment certificate.
- Product assessment appropriate to the type of IVD(s) covered by the application is required.

#### Example
- Further information on the operation of the reciprocal arrangement between the TGA and Health Canada can be found on the TGA website [http://www.tga.gov.au/about/international-links.htm](http://www.tga.gov.au/about/international-links.htm)

#### Applicable Reduced Fee
- Reduced fee for conformity assessment under Schedule 3, Part 1 or Part 4 – 30% of the full fee

#### Business rule 5(a):
If a Canadian manufacturer who is applying for a conformity assessment certificate issued by the TGA:
- holds ISO 13485 certification that is issued by a CMDCAS Registrar recognised by the TGA under the MoU with Health Canada;
then the assessment will be abridged and fees reduced accordingly.

#### Business rule 5(b):
If an overseas manufacturer who is applying for a conformity assessment certificate issued by the TGA:
- holds ISO 13485 certification that is issued by a CMDCAS Registrar who is NOT recognised by the TGA under the MoU with Health Canada;
then the assessment may be abridged and fees reduced accordingly.
## Application for Conformity Assessment (Design Examination or Type Examination)

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<td><strong>Business rule 6(a):</strong></td>
<td>• This rule applies to manufacturers of HIV assays and HCV assays that are registered in the ARTG.</td>
<td>An application for Design Examination for a HCV or HIV assay with a current AUST R number.</td>
<td>Reduced fee for conformity assessment (Design Examination) under Schedule 3, Clause 1.6 – as prescribed in Schedule 5, Item 1.9A (d) of the Regulations</td>
</tr>
<tr>
<td><strong>Business rule 6(a):</strong></td>
<td>• If an Australian or overseas manufacturer of an IVD that is currently registered in the ARTG submits an initial application for a conformity assessment certificate including examination of design; and</td>
<td>• An application for Design Examination for a HCV or HIV assay with a current AUST R number.</td>
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<td>• the evaluation of the IVD conducted as part of the Registration process incorporated the same elements of an assessment as required for Design Examination certification; then the reduced assessment fee for abridged Design Examination, as prescribed in Schedule 5, may apply.</td>
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<tr>
<td><strong>Business rule 6(b):</strong></td>
<td>• This rule applies to a manufacturer applying for a Design Examination certificate for an IVD that has been in use for a number of years.</td>
<td>An HTLV assay that has been in use in Australia over many years. The assay is used in blood donor screening and requires a TGA issued Design Examination certificate as a Class 4 IVD. Data held by the manufacturer can be used to support the assay’s performance claims</td>
<td>Conformity assessment (Design Examination) under Schedule 3, Clause 1.6</td>
</tr>
<tr>
<td><strong>Business rule 6(b):</strong></td>
<td>• If an Australian or overseas manufacturer of an IVD that is currently listed or exempt under Chapter 3 of the Therapeutic Goods Act 1989 submits an initial application for a conformity assessment certificate including examination of design; and</td>
<td>• An application for Design Examination for a HCV or HIV assay with a current AUST R number.</td>
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<td>• local data exists in a format acceptable to the TGA that will result in a reduced assessment of performance data; then the assessment may be abridged and fees reduced.</td>
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**Further Detail**

**Examples**

- An HTLV assay that has been in use in Australia over many years. The assay is used in blood donor screening and requires a TGA issued Design Examination certificate as a Class 4 IVD. Data held by the manufacturer can be used to support the assay’s performance claims.

**Applicable Reduced Fee**

- Reduced fee for conformity assessment (Design Examination) under Schedule 3, Clause 1.6 – as prescribed in Schedule 5, Item 1.9A (d) of the Regulations.
### Manufacturers of IVDs previously supplied in Australia

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<td>- The extent of abridgement of performance testing and the fee reduction depends upon the extent of information available and will be determined on a case-by-case basis.</td>
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### Overseas manufacturers holding EC or Canadian Certification

#### Business rule 7(a):
If an overseas manufacturer:
- holds current EC certification issued by a European Notified Body under Annex V of the in-vitro diagnostic medical devices Directive 98/79/EC (IVDD) or a Class III or IV Medical Device Active Licence Listing (MDALL) for an IVD that is issued by Health Canada under the Canadian Medical Devices Regulations; and
- the assessment undertaken by the Notified Body or Health Canada incorporated the same elements of an assessment as required for a Type Examination certification;
then the assessment may be abridged and fees reduced.

<table>
<thead>
<tr>
<th>Further Detail</th>
<th>Examples</th>
<th>Applicable Reduced Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>- If an IVD manufactured overseas has an EC Certificate to Annex V of the IVDD, or a Canadian product licence issued by Health Canada, it may be possible to reduce fees for the assessment of an application for a TGA-issued Type Examination certificate.</td>
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<tr>
<td></td>
<td><strong>Reduced fee for conformity assessment (Type Examination) under Schedule 3, Part 2 – 20% of the full fee</strong></td>
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</tbody>
</table>

#### Business rule 7(b):
If an overseas manufacturer:
- holds current EC certification issued by a European Notified Body under Annex IV part 4 of the in-vitro diagnostic medical devices Directive or
- holds current EC Design Examination certificate (Annex IV, part 4) or a Canadian product licence issued by Health Canada, and the assessment reports are available to the TGA for review, then provided it is not also
- an overseas manufacturer of a Class 4 IVD not currently registered in the ARTG holds a current EC Design Examination certificate (Annex IV, part 4) or a Canadian product licence issued by Health Canada, and the assessment reports are available to the TGA for review, then provided it is not also
- an overseas manufacturer of a Hepatitis B surface antigen enzyme immunoassay (included on List A of Annex II of
| | | |

#### Examples

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<thead>
<tr>
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<tbody>
<tr>
<td><strong>Reduced fee for conformity assessment (Design Examination) under Schedule 3,</strong></td>
</tr>
</tbody>
</table>

| **Historical document** | | |
### Further Detail

- The assessment undertaken by the Notified Body or Health Canada for the issue of a product licence incorporated the same elements of an assessment as required for Design Examination certification; then the assessment may be abridged and fees reduced.

**Note:** This rule does not apply to immunohaematology reagent (IHR) IVDs for which a reduced fee for Design Examination certification is prescribed in Schedule 5 of the Regulations.

### Applicable Reduced Fee

- The fee will be reduced by 25% of the full fee.

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### Overseas manufacturers holding EC or Canadian Certification

<table>
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<tr>
<th>(98/79/EC) or a Class IV Medical Device Active Licence Listing (MDALL) for an IVD that is issued by Health Canada under the Canadian Medical Devices Regulations; and</th>
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<tr>
<td>- the assessment undertaken by the Notified Body or Health Canada for the issue of a product licence incorporated the same elements of an assessment as required for Design Examination certification; then the assessment may be abridged and fees reduced.</td>
</tr>
</tbody>
</table>

### Manufacturers of IVDs previously supplied in Australia

#### Business rule 8:

- If an Australian or overseas manufacturer:
  - submits an initial application for Design Examination certification; and
  - the kind of IVDs under this activity which would require individual conformity assessment are similar enough for the assessment to be concurrently conducted; and
  - one of the devices in the application is subject to full conformity assessment, then the assessment may be abridged and fees reduced.

#### Further Detail

- This rule applies to a single manufacturer applying for TGA Design Examination certificates for a number of related IVDs which are sufficiently similar for the assessments to be conducted simultaneously. The first IVD is subject to full evaluation fees for the Design Examination certificate, but the evaluation fees for each subsequent related application that is submitted at the same time may be reduced.

- Suitability for reduced assessment fees on the basis of similarity will be determined on a case-by-case basis and is dependent on the submission of appropriate information to substantiate the request.

#### Examples

- A manufacturer with a range of HIV assays which incorporate antibody testing and antigen/antibody combination testing using the same technology.

#### Applicable Reduced Fee

- Reduced fee for conformity assessment (design examination) under Schedule 3, Clause 1.6 – 10% of the full fee.
Abbreviations used in table:
ARTG – Australian Register of Therapeutic Goods
CMDCAS – Canadian Medical Devices Conformity Assessment System
Manufacturing Licence – Licence of Good Manufacturing Practice, issued under Part 3-3 of the Therapeutic Goods Act, 1989
Full QMS – Full Quality Assurance procedures under Schedule 3 Part 1 of the Therapeutic Goods (Medical Devices) Regulations, 2002
Production QA – Production Quality Assurance under Schedule 3 Part 4 of the Therapeutic Goods (Medical Devices) Regulations, 2002
QMS – quality management system
STED – Summary Technical Documentation
TFR – Technical File Review
TGA-HC MOU – Memorandum of Understanding between Health Canada and the TGA