



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

What a manufacturer needs to know about conformity assessment and declarations of conformity for IVDs

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TGA Health Safety
Regulation

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.

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Version history

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Conformity Assessment procedures for each class of IVD

The conformity assessment procedures, including Australian declaration of conformity requirements, are detailed in Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations).

Depending on the classification of a device, there are a number of different conformity assessment procedures a manufacturer may use to demonstrate compliance with the Essential Principles. Generally, the conformity assessment procedure is more rigorous the higher the risk class. The table below summarises the conformity assessment procedures most likely to be used for each class of IVD based on TGA experience with equivalent classes of medical devices (other than IVDs). Manufacturers may choose to complete procedures that are more comprehensive than the minimum, but this is not required by the TGA. The table also indicates the relevant clause of Schedule 3 describing which Australian declaration of conformity is appropriate for each option.

Class of IVD	Conformity assessment procedures most likely to be used	Declaration of conformity legislative reference
Class 1 IVD	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary)	Schedule 3, Part 6, clause 6.6
Class 2 IVD	Part 1 (Full Quality Assurance Procedures) excluding clause 1.6 (Examination of Design); or	Schedule 3, Part 1, clause 1.8
	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment by the Secretary) + Part 4 (Production Quality Assurance Procedures)	Schedule 3, Part 6, clause 6.6
Class 3 IVD	Part 1 (Full Quality Assurance Procedures) excluding clause 1.6 (Examination of Design)	Schedule 3, Part 1, clause 1.8
Class 4 IVD & Class 4 in-house IVDs	Part 1 (Full Quality Assurance Procedures) including clause 1.6 (Examination of Design)	Schedule 3, Part 1 clause 1.8
Class 1–3 in-house IVDs	Part 6A (Procedures applying only to certain classes of in-house IVDs)	Not required
Systems or Procedure Packs	Part 7 (Procedures for medical devices used for a special purpose)	Schedule 3, Part 7, clause 7.5

Application of the procedures under Part 2 (Type Examination) is generally more costly for manufacturers, but is an option that can be considered for Class 3 and Class 4 IVDs and Class 4 in-house IVDs, in conjunction with Part 4 (Production Quality Assurance Procedures).

Conformity assessment procedures under Part 3 (Verification) and Part 5 (Product Quality Assurance) cannot be applied to IVD medical devices.

More information on relevant conformity assessment options is provided in the next table.

Summary of Australian conformity assessment procedures

Part	Requirements	Applicable classifications	Considerations for manufacturer
<p>Part 1 – Full quality assurance procedure - encompassing design, production, packaging, labelling and final inspection of an IVD</p>	<p>Manufacturer must implement a full quality management system (i.e. all clauses of ISO 13485 including clauses 7.3 and 7.5.2) and arrange for the quality management system to be audited by an appropriate conformity assessment body.</p> <p>See under heading Manufacturer’s evidence accepted by the TGA in Section <i>What a sponsor needs to know about conformity assessment and manufacturer’s evidence for IVDs</i> for further details.</p>	<p>All except Class 1, 2 and 3 in-house IVDs</p> <p>Please note: for Class 4 IVDs and Class 4 in-house IVDs, Clause 1.6 – Examination of design - must also be applied</p>	<p>Assessment can cover a wide range of devices – not limited to a specific device.</p> <p>If the conformity assessment procedure is applied to all devices manufactured, new devices that are Class 2 or 3 IVDs that fit into the scope of the certificate should not require additional assessment/s by the conformity assessment body.</p> <p>For Class 4 IVDs and Class 4 in-house IVDs, and Australian manufacturers of Class 2 and Class 3 IVDs, assessment by the TGA is required.</p> <p>The quality management system must be maintained.</p> <p>Periodic surveillance audits will be performed by the conformity assessment body.</p>

Part	Requirements	Applicable classifications	Considerations for manufacturer
Part 1, Clause 1.6 – Examination of Design – involves an examination of the design dossier for IVDs to which the manufacturer has applied a Part 1 conformity assessment procedure	The technical documentation for the Class 4 IVD and Class 4 in-house IVD (also referred to as a design dossier) must be submitted for examination by the TGA to assess compliance with the Essential Principles.	Class 4 IVDs and Class 4 in-house IVDs	<p>A separate certificate is required for each kind of medical device that is a Class 4 or Class 4 in-house IVD within the meaning of section 41BE of the <i>Therapeutic Goods Act 1989</i> and Regulation 1.6—see <i>Kinds of IVD medical devices</i> in the Section <i>Including IVD medical devices in the ARTG</i>.</p> <p>This must be done in conjunction with Part 1 assessment of the quality management system by the TGA. If a Part 1 certificate issued by the TGA is current, depending on the scope of the changes required for the new kind of Class 4 IVD, no further assessment of the quality management system may be needed.</p>
Part 2 – Type examination – involves an examination of a representative sample of a kind of IVD (the type).	<p>Testing can be conducted by the TGA or EU Notified Body; OR</p> <p>The TGA or EU Notified Body can conduct tests on the device at the manufacturer’s site and supervise or review the testing; OR</p> <p>The TGA or EU Notified Body will subcontract the testing to an accredited test laboratory (either in Australia or overseas).</p>	<p>Class 3 and 4 IVDs and Class 4 in-house IVDs</p> <p>Please note: Part 4 – Production Quality Assurance – must also be applied</p>	<p>Only applies to a specific IVD (type).</p> <p>If substantial changes are made to the design or intended performance of the IVD, the manufacturer must notify the TGA and arrange for re-examination of the type.</p> <p>Certification of the quality management system for production quality assurance under Part 4 must be maintained.</p> <p>For Class 4 IVDs and Class 4 in-house IVDs, and Australian manufacturers of Class 3 IVDs, assessment by the TGA is required.</p>

Part	Requirements	Applicable classifications	Considerations for manufacturer
Part 4 - Production quality assurance - a quality management system encompassing the production and final inspection of an IVD	<p>Manufacturer must implement a quality management system (i.e. all clauses of ISO 13485 excluding design and development—clause 7.3) and arrange for the quality management system to be audited by an appropriate conformity assessment body.</p> <p>See under heading Manufacturer's evidence accepted by the TGA in Section <i>What a sponsor needs to know about conformity assessment and manufacturer's evidence for IVDs</i> for further details.</p>	<p>Class 2, 3 and 4 IVDs and Class 4 in-house IVDs</p> <p>Please note: Part 2 – Type examination – must also be applied to Class 3 and 4 IVDs and Class 4 in-house IVDs</p>	<p>Assessment can cover a wide range of devices – not limited to a specific device.</p> <p>For Class 2 IVDs this only covers production – the design of each device still requires Part 6 (Declaration of Conformity).</p> <p>For Class 3 and 4 IVDs and Class 4 in-house IVDs medical devices this only covers production – the design of each device still requires conformity assessment under Part 2 (Type Examination).</p> <p>For Class 4 IVDs and Class 4 in-house IVDs assessment by the TGA is required.</p> <p>The quality management system must be maintained.</p> <p>Periodic surveillance audits will be performed by the conformity assessment body.</p>
Part 6 – Declaration of Conformity (not requiring assessment by Secretary) - preparing technical documentation for an IVD and establish a post-market monitoring system	<p>Manufacturer ensures that the devices comply with the Essential Principles and prepares documentation that demonstrates conformity.</p>	<p>Class 1 and Class 2 IVDs</p>	<p>For Class 1 IVDs the evidence (Declaration of Conformity) is not required to be submitted to the TGA but MUST be available upon request.</p> <p>For Class 2 IVDs Part 4 (Production Quality Assurance) is also required.</p>

Part	Requirements	Applicable classifications	Considerations for manufacturer
Part 6A – Procedures applying only to certain classes of in-house IVDs	Laboratories (or laboratory networks) manufacturing in-house IVDs will be required to notify the TGA of the IVDs manufactured in each laboratory for inclusion on a database. Such laboratories must be accredited as medical testing laboratories by NATA or by a conformity assessment body determined by the Secretary, and demonstrate compliance with the National Pathology Accreditation Advisory Committee (NPAAC) performance standard for development and use of in-house IVDs.	Class 1, 2 and 3 in-house IVDs Please note: Part 6A does not apply to Class 4 in-house IVDs	Laboratories must implement a quality management system that is accredited to ISO 15189 – Medical laboratories – Particular requirements for quality and competence. Laboratories must notify the TGA of the in-house IVDs manufactured annually. Class 4 in-house IVDs are subject to the same conformity assessment procedures required for commercial Class 4 IVDs. For more information please see Section <i>In-house IVDs</i>
Part 7 – Conformity Assessment Procedures for devices used for a Special Purpose	Clause 7.5 applies to system or procedure packs	All, except Class 1,2 and 3 in-house IVDs	For systems and procedure packs see Section <i>Systems and Procedure packs</i> .
Part 8 – Clinical Evaluation procedures	The conformity assessment procedures the manufacturer must follow for obtaining and evaluating clinical data.	All	See Section - <i>Essential Principles -14 Clinical Evidence</i>

Please note: Conformity assessment procedures under Part 3 and Part 5 cannot be used for IVDs.

Part 1 Full quality assurance procedures (excluding Clause 1.6)

A manufacturer applies this procedure to Class 2, 3 and 4 IVDs and Class 4 in-house IVDs by implementing a full quality management system that takes into account the regulatory requirements for the:

- design
- production
- packaging
- labelling
- final inspection processes
- implementation of an ongoing monitoring system.

For IVDs assessed under Part 1, the manufacturer produces the technical documentation via the certified quality management system procedures for design and development (ISO 13485 clause 7.3). The production of the device is also performed via the quality management system.

Assessment by the TGA is carried out against the requirements of the Australian legislation. Assessment by overseas certification bodies against the relevant overseas legislation will be reviewed by the TGA for compliance with the Australian legislation.

The TGA will audit the quality management system (all clauses of ISO 13485 or equivalent standard), including an assessment of the manufacturer's technical documentation for the devices, which includes clinical evidence. The technical documentation must be available for review by the TGA who verifies its existence and completeness.

The conformity assessment certification remains valid only if it is subject to periodic and satisfactory surveillance audits.

Changes to the quality system that broaden its scope or substantially alter the approved system, design or production arrangements may require further assessment or approval by the conformity assessment body.

Once a manufacturer has obtained conformity assessment evidence under this Part they must then prepare an Australian Declaration of Conformity in accordance with clause 1.8 of Schedule 3 of the Regulations. For Class 4 IVDs and Class 4 in-house IVDs a clause 1.6 certificate is also required before the Australian declaration of conformity can be prepared.

Application of the procedures under Part 1 is recommended for manufacturers that produce IVDs in a range of classes including Class 2, 3 and 4 IVDs and Class 4 in-house IVDs who, on a regular basis:

- Produce new devices; or
- Improve or modify their devices

However, Part 1 can be an onerous option for manufacturers that only produce Class 2 IVDs as it includes an assessment of design control and exceeds the minimum conformity assessment requirements for Class 2 IVDs.

Please note: Requirements for Full Quality Assurance under Part 1 are similar to the EU IVDD Annex IV requirements.

Part 1, Clause 1.6 Examination of design

This procedure applies to Class 4 IVDs and Class 4 in-house IVDs and requires the TGA to examine the design for each device. For a subsection of Class 4 IVDs and Class 4 in-house IVDs—currently IVDs to detect the presence of or exposure to HIV, HCV or HTLV—the TGA will require performance testing on Australian samples unless:

- In the case of HIV and HCV, the IVD is currently registered in the ARTG and no significant changes have been made to the design since the device was subjected to performance testing for registration in Australia; or
- In the case of HTLV, the manufacturer is able to supply performance data that in the opinion of the TGA is representative of the genotypic variants found in Australian samples.

The assessment is based on the design and development records produced under the manufacturer's quality management system and compiled/summarised into a 'design dossier'.

A separate certificate is required for each kind of medical device that is a Class 4 or Class 4 in-house IVD within the meaning of section 41BE of the *Therapeutic Goods Act 1989* and Regulation 1.6—see *Kinds of IVD medical devices* in the Section ***Including IVD medical devices in the ARTG***.

Changes to the design or production of Class 4 IVDs and Class 4 in-house IVDs may also require further assessment or approval.

Re-examination of the design, which will be based on postmarket surveillance data, changes to relevant standards and any other changes that may affect compliance with the Essential Principles, will be required after 5 years.

Once a manufacturer has obtained conformity assessment evidence under this Part they must prepare an Australian Declaration of Conformity in accordance with clause 1.8 of Schedule 3 of the Regulations.

Please note: Requirements for Design Examination under Clause 1.6 are similar to the EU IVDD Annex IV.4 requirements.

Part 2 Type examination procedures

The options available for Class 3 and 4 IVDs and Class 4 in-house IVDs with this conformity assessment procedure are:

- the TGA or EU Notified Body (for overseas manufacturers) will conduct tests on the device at the manufacturer's site and will supervise or commission the testing
- the testing can be conducted within the TGA or an EU Notified Body's own laboratory
- the TGA or EU Notified Body may subcontract the testing to an accredited testing laboratory (either in Australia or overseas).

The manufacturer must make an application for the TGA or an EU Notified Body, to examine a representative sample of the type of device (the 'type'). The type must:

- have been designed and produced according to the Australian Essential Principles
- be a finished device
- be constructed of the same materials and manufactured in the same way as intended for general production.

The TGA will determine if the design of the type satisfies the Essential Principles. This will be done through examination of the supporting documentation and testing for compliance to a safety and performance standard, or standards applicable to the device. Testing or the supervision of the testing may occur on the manufacturer's premises subject to the agreement of the manufacturer and the TGA or EU Notified Body.

The manufacturer must also seek further certification against Australian Part 4 – Production Quality Assurance Procedures.

Application of the procedures under Part 2 is recommended for manufacturers of Class 3 and 4 IVDs and Class 4 in-house IVDs who:

- Do not currently have a design control system and do not wish to implement one in the future
- Do not have a Design Dossier for their Class 4 IVD or Class 4 in-house IVD.

However, since any modification to the device would require an additional type examination this option is usually only feasible for manufacturers who do not intend to produce new versions or improve or modify their devices.

Please note: Requirements for Type Examination under Part 2 are similar to the EU IVDD Annex V requirements.

Part 3 Verification procedures

This procedure cannot be used for IVDs.

Part 4 Production quality assurance procedures

In this conformity assessment procedure, the manufacturer must implement a quality management system for the production and final inspection of Class 2, 3 and 4 IVDs and Class 4 in-house IVDs that specifically includes regulatory requirements and an ongoing monitoring system.

Assessment by the TGA is carried out against the requirements of the Australian legislation. Assessments by overseas certification bodies against the relevant overseas legislation will be reviewed by the TGA for compliance with the Australian legislation. The TGA will audit the quality management system (all clauses of ISO 13485 excluding design and development – clause 7.3, or equivalent standard), including an assessment of the manufacturer's technical documentation for the devices.

Manufacturers of Class 3 and 4 IVDs and Class 4 in-house IVDs that have undergone a type examination under Part 2 must also apply the Part 4 conformity assessment procedures. When a Part 2 has been completed together with this part, manufacturers may then prepare an Australian *Declaration of Conformity* in accordance with clause 4.7 of Schedule 3 of the Regulations.

Manufacturers of Class 2 IVDs that have followed the procedure described in Part 6 may also use this procedure. For Class 2 IVDs a Declaration of Conformity is made under Part 6 with reference to the certification issued under Part 4, in accordance with clause 6.6 of Schedule 3 of the Regulations.

The certification only remains valid if it is subject to periodic surveillance.

Changes to the quality system that add additional kinds of products to the range covered, or that alter the approved system, may require further assessment or approval.

Combined with Part 6, assessment under this Part is recommended for manufacturers of Class 2 IVDs who produce new models of their devices, or improve or modify their devices on a regular basis and do not produce other devices of a higher class.

Please note: Requirements for Production Quality Assurance under Part 4 are similar to the EU IVDD Annex VII requirements.

Part 5 Product quality assurance procedures

This procedure cannot be used for IVDs.

Part 6 Declaration of conformity (not requiring assessment by Secretary)

This part can be used for Class 1 and Class 2 IVDs.

In this conformity assessment procedure, the manufacturer of the device ensures that the device(s) comply with the Essential Principles and prepares documentation that allows the conformity to be self-assessed by the manufacturer.

The manufacturer is also required to implement an ongoing monitoring system.

For Class 2 IVDs the manufacturer must seek further certification against Part 4.

When a manufacturer has correctly applied this Part they should then prepare an Australian Declaration of Conformity in accordance with clause 6.6 of Schedule 3 of the Regulations.

Application of the procedures under this Part is recommended for manufacturers of Class 1 IVDs and (when combined with Part 4) manufacturers of Class 2 IVDs that do not produce other devices of a higher class.

Please note: Requirements for self-assessment and making a declaration under Part 6 are similar to the EU IVDD Annex III requirements.

Part 6A Procedures applying only to certain classes of in-house IVDs

This procedure applies to manufacturers of Class 1, 2 and 3 in-house IVDs.

To meet the requirements of this procedure the manufacturer (laboratory or laboratory network) must:

- notify the TGA on a day no later than 1 July 2014 and then update on a day no later than each anniversary of the initial notification:
 - the contact details of the laboratory; and
 - the name and Class of all the in-house IVDs manufactured
- meet the National Pathology Accreditation Advisory Council (NPAAC) performance standard *Requirements for the Development and Use of In-house In Vitro Diagnostic Devices*

- be accredited as a medical testing laboratory by the National Association of Testing Authorities (NATA) or assessed by a conformity assessment body determined suitable by the TGA
- meet the standard ISO 15189 Medical laboratories - Particular requirements for quality and competence.

The laboratory is required to hold information in relation to the quality management system, the design and manufacture of the in-house IVD and other documentation specified in the NPAAC standard, and to provide such documentation to the TGA if requested. This information will generally be reviewed as part of a laboratory's regular accreditation inspection by NATA.

The manufacturer is also required to implement a post-marketing system for the ongoing monitoring of the performance of the in-house IVD and to notify the TGA of any adverse events.

For more information please see Section – *In-house IVDs*

Part 7 Medical devices used for a special purpose

This procedure must be applied to systems and procedure packs.

To meet the requirements of this procedure the manufacturer must have documentary evidence to demonstrate that each of the medical device components, including each IVD, has:

- met the Essential Principles
- had the relevant conformity assessment procedures applied to it
- make an Australian Declaration of Conformity in accordance with clause 7.5 of Schedule 3 of the Regulations
- establish and maintain a post-market monitoring system

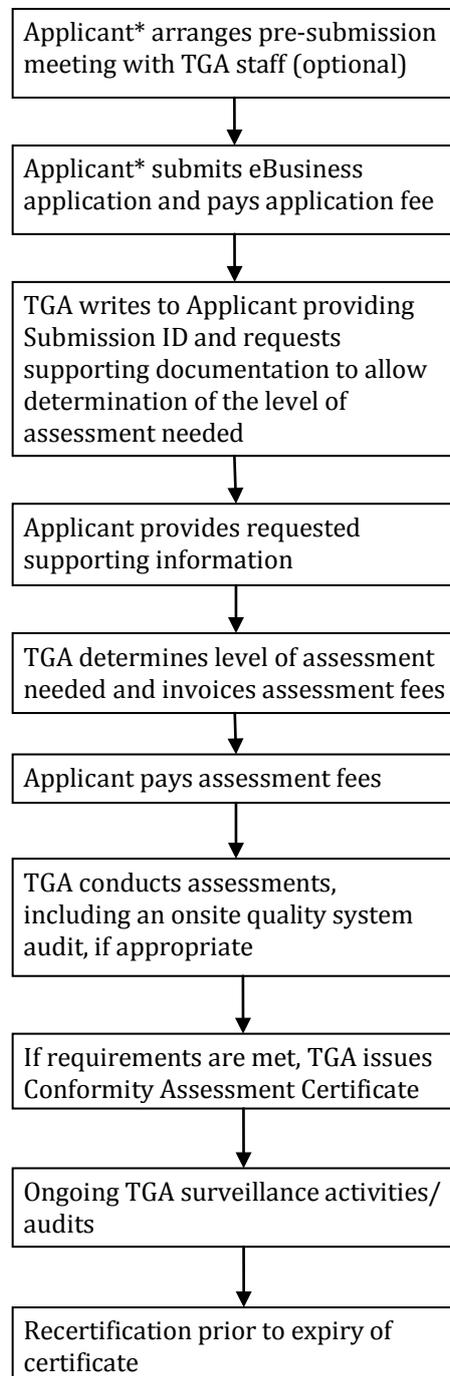
For more information please see Section – *Systems and procedure packs*

Part 8 Clinical Evaluation procedures

Every medical device requires clinical evidence, appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the Essential Principles. For more information please see Section - *Essential Principles -14 Clinical Evidence*

TGA Conformity Assessment Certificates

Application process flowchart



*Applicant may be a manufacturer or their agent or representative.

Pre-submission meetings

Manufacturers are invited and encouraged to meet with the TGA prior to submitting their application for a TGA Conformity Assessment Certificate. A meeting will assist to:

- ensure that the applicant understands the conformity assessment process
- introduce the devices to the TGA so that issues are considered before the application is lodged and documentation can be provided with the application to address any concerns.

Pre-submission meetings may be face-to-face or via teleconference.

Meetings provide a valuable opportunity to discuss any anticipated difficulties, which should assist in a timely completion of the assessment. However, please be aware that at the time of the meeting, the TGA cannot guarantee the acceptability of the application or anticipate the outcome of the assessment. To arrange a meeting an email can be sent to devices@tga.gov.au.

Applicants requesting a pre-submission meeting should be prepared to provide:

- a presentation on a novel, or newly developed device, its use and design, or a list of the devices to be covered by the application
- a summary of the testing done and evidence held, including clinical evidence
- an outline of the dossier(s) to be presented (for a Class 4 IVD or Class 4 in-house IVD) or the technical files for lower classification devices
- proposed conformity assessment route(s)
- a summary of readiness for quality management system audit of the manufacturer and/or description of other regulatory QMS certification for the manufacturer
- an expected date of submission of an application.

There are no fees for a pre-submission meeting.

Documentation for applications – Quality Management System documentation

Manufacturers who apply for a TGA Conformity Assessment Certificate will be requested to complete a supporting data form and provide documents that detail specific parts of their quality management system. As a guide, documentation that is generally requested includes:

- Copy of the latest version of the Quality Manual (as required under ISO 13485:2003, clause 4.2.2)
- Organisational chart (if not part of QM)
- Product requirements (specifications) for the products included in the scope of the certificate
- A list of critical suppliers and a description of how purchasing requirements are fulfilled (ISO 13485:2003, clause 7.4.1)
- Plans of the manufacturing facility or facilities
- List of critical processes and the status of their validation (ISO 13485:2003, clause 7.5.2.1). If the product is supplied sterile, a copy of sterilisation validation reports

- Procedure for a feedback system (ISO 13485:2003, clause 8.2.1, Regulations for post market requirements)
- Procedure for the issue and implementation of advisory notices and notification of adverse events (ISO 13485:2003, clause 8.5.1, Uniform recall procedure for therapeutic goods).
- Documents providing the basis for any reduction in assessment fees applied for by the applicant.

Documentation for applications – Summary Technical Documentation (STED)

Manufacturers who apply for a TGA Conformity Assessment Certificate are required to hold technical documentation to demonstrate that each device complies with the Essential Principles.

The Global Harmonisation Taskforce (GHTF) has released the Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices (STED), which provides guidance on the technical documentation that should be assembled and submitted to demonstrate conformity to the Essential Principles. While it is not mandatory for manufacturers to adhere to all the recommendations outlined in the GHTF STED document, it provides useful guidance on the documentation which may be requested and examined by the TGA (at on-site audit or by submission) for the product assessment component of a conformity assessment. The GHTF STED guidance can be accessed at <http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n063-2011-summary-technical-documentation-ivd-safety-conformity-110317.pdf>.

Where an application for conformity assessment covers a number of IVDs, the TGA will review the technical documentation for a sample of the IVDs. The technical documentation to be assessed, and the level of detail required, will vary on a case by case basis depending on:

- classification of the IVD
- complexity of the IVD
- period that it has been on the market
- whether the IVD has the following characteristics:
 - it incorporates a novel technology
 - it is an already marketed IVD type that is now being offered for an intended purpose different from the original one
 - it incorporates novel or potentially hazardous materials
 - the IVD type raises specific public health concerns.

Components of the STED or design dossier

Device Description

A detailed description of the IVD must be provided, including information addressing each of the following points:

- Intended purpose;
- Intended user;

- Risk class according to Australian regulations;
- Acceptable specimen types;
- Description of principle of the assay and methodology used; and
- Description of individual components included in the IVD.

Where applicable, the following should also be provided:

- A description of the specimen collection and/or transport materials required or recommended to be used;
- A description of the accessories, other IVDs and other products that are not medical devices which are intended to be used in combination with the IVD;
- For assays requiring instrumentation, a description of the relevant instrumentation characteristics or details of dedicated instrumentation to be used;
- A description of any software to be used; and
- A complete list of any configurations or variants of the IVD, other than kit size, that will be made available.

Where applicable, a review of platforms/instrumentation and other materials, including dedicated specimen receptacles, that are required (or recommended) to be used in combination with an IVD will occur as part of the conformity assessment.

Device History

A summary of the product history in the Australian market and any other jurisdiction(s) in which the IVD is supplied will be requested to allow the TGA to make an assessment of the safety and efficacy of the IVD in the post-market environment. Details should include a list of countries or regulatory jurisdictions, approximate numbers of IVDs and/or period of time supplied, summary of any adverse events, recalls, corrective/preventive actions or refusal to approve for supply.

The inclusion of information clearly identifying products either as new to the Australian market, or as previously supplied in the Australian market and transitioning to the requirements of the new IVD regulatory framework, will assist the TGA in prioritising the assessment of new products, so as to reduce as much as possible any delay to the market caused by a backlog of IVDs transitioning to the requirements of the new regulations.

Essential Principles Checklist

A copy of the Essential Principles checklist that summarises conformity to each applicable Essential Principle by reference to appropriately applied standards, or other appropriate means will be requested. Evidence of compliance must refer to documents, reports, internal procedures, etc and should include a cross-reference to the location of the documents listed within the checklist. In order to establish that an IVD complies with the relevant provisions of the Essential Principles, the TGA may request further information in relation to any of the documents referenced or expected to be held as part of the product technical file.

The TGA will accept a European Essential Requirements checklist to IVDD requirements provided it is also accompanied by a short statement to provide assurance from the manufacturer “that the Australian Essential Principles, as described in Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002, have been met”.

A template Essential Principles checklist is available from the TGA website at www.tga.gov.au.

Risk Analysis and Control Summary

For Class 1-3 IVDs, a summary of the risk management activities performed by the manufacturer of the device must be provided. The summary should include as a minimum:

- a list of possible hazards arising from false positive or false negative results;
- indirect risks which may result from IVD-associated hazards e.g. instability of test components, integrity of packaging, selection of specimens;
- the user/operator hazards such as any risks arising from reagents and specimens containing infectious agents; and
- the risk mitigation strategies that have been implemented to reduce unacceptable risks.

Taking into account risk mitigating activities, the results of the risk analysis should provide a conclusion that the remaining risks are acceptable when compared to the benefits. The risk analysis and control summary may be submitted either in a summary (text) format or as a reduced table. An example of such a summary is the Risk Management Report required by Clause 8 of ISO14971:2007.

For Class 4 IVDs or Class 4 in-house IVDs, detailed information about the risk management plan including risk analysis, risk evaluation and risk control, must be provided.

Design and Manufacturing information

A summary of the design and manufacturing processes at a level of detail appropriate to the risk class of the device should be provided. The summary should include a review of the design features that make the IVD suitable for its intended purpose, an overview of manufacturing processes and controls, manufacturing sites, a description of critical assay ingredients, a description of the major systems or critical processes, and details of any decision pathways or algorithms used, as appropriate.

Clinical Evidence Report

Every medical device requires clinical evidence, and for IVDs this represents the information that supports the clinical utility and the performance of the IVD as intended by the manufacturer. A clinical evidence evaluation report that demonstrates conformity with the applicable provisions of the Essential Principles (as specified in EP14) must be available for all IVDs, other than those that are exempt from inclusion in the ARTG. The Clinical Evaluation Procedures described in Clause 8, Schedule 3 of the Regulations set out the requirements, and focus on the manufacturer obtaining clinical investigation data through conducting performance evaluations and/or carrying out a literature review of published and unpublished scientific literature.

It is important to note that evidence to support the clinical competence of the author (e.g. short curriculum vitae) must accompany the submitted clinical evidence report to provide assurance that the clinical evidence has been evaluated by a competent clinical expert.

Clinical utility

The clinical utility of a parameter is the demonstration of its potential or established usefulness for patient management decision making, and provides the means for making decisions about effective treatment or preventive strategies.

For many common IVDs with a broad history spanning many years of use, clinical utility has long been established and there are well recognised associations with a particular disease or condition. For these IVDs it is not expected that extensive information be further documented simply for the purpose of submission for premarket approval. For more recently developed IVDs which involve the use of a new technology, a new application, a new biomarker, pharmacogenomics, etc, evidence of clinical utility may be required. Where confirmation of an IVD's clinical utility is required to be

documented, the process for generating appropriate evidence should commence at the research phase and often involves ongoing collaborative development over time. Evidence of clinical utility is typically established using a summary of literature searches and expert opinions, and is supplemented with appropriate clinical or research data as it becomes available.

If a manufacturer considers that evidence of an IVD's clinical utility is not required to be compiled and submitted for review due to its recognised association with a particular disease or condition, this decision is required to be documented and clearly justified as part of the clinical evidence report.

Performance evaluation

Performance evaluation studies incorporate both the clinical and analytical performance characteristics of an IVD. The analytical performance aspects of an IVD's performance evaluation are addressed under the following section – ***Product validation and verification***

The clinical performance of an IVD is demonstrated by correlating the use of an IVD with a specific clinical condition, in accordance with the target population and intended user. Clinical performance is a measure of an IVD's ability to correctly identify patients as either having or not having a particular disease or condition, based on their true clinical status. Clinical performance characteristics include diagnostic sensitivity and diagnostic specificity, which may vary depending on the choice of a cut-off value for the assay, and the negative and positive predictive values which depend on the prevalence of the disease or condition within the population of interest.

For many IVDs, providing data that has been drawn from a clinical performance study or generated within a target population may not always be an essential component of the clinical evidence. For well established and standardised analytes, demonstration of the IVD's analytical performance characteristics may be sufficient to support the use of the IVD as intended by the manufacturer, particularly when the clinical utility for a type of IVD has been long accepted. Where it is available in a suitable form, published literature or experience gained by routine diagnostic testing which includes post market surveillance data, a summary of adverse events, and details of any field safety corrective actions (recalls, notifications, hazard alerts) may provide sufficient evidence to support the clinical performance of an IVD. The manufacturer must justify the grounds on which they are circumventing either fully or in part, the requirement to provide clinical performance data wherever this occurs.

For IVDs that are intended to be used by lay persons or at the point of care, it is expected that clinical performance studies take into consideration the level of knowledge, understanding and skills for such users by providing evidence to demonstrate appropriate performance within that target population.

Product Validation and Verification

Evidence to demonstrate the analytical performance characteristics of the IVD is a requirement under Essential Principle 15 and forms a critical part of the manufacturer's performance evaluation studies, as required for clinical evidence.

The information presented for each study should provide sufficient detail for the assessor to understand how the study was conducted, the characterisation of specimens/samples used, acceptance criteria, explanations for anomalous results, and the outcomes/conclusions drawn. It is acceptable to combine two or more aspects of analytical performance into fewer separate studies provided each of the studies is well designed and all relevant variables and test characteristics are effectively demonstrated. The following analytical performance characteristics should be specifically addressed, as appropriate to the type of IVD.

Specimen type

A list of all appropriate specimen type(s) suitable for use with the IVD must be provided, including anticoagulants, matrices or any special instructions or conditions associated with specimen collection. Information should also address specimen stability, appropriate storage conditions and

where applicable, transport conditions. Storage includes elements such as duration, temperature limits, number of freeze/thaw cycles.

Analytical performance study reports should include information about the nature of the specimen types tested (e.g. spiked, wild type etc) and the geographic location where specimens were obtained, as appropriate.

Accuracy

The term accuracy refers to both trueness and precision (reproducibility and repeatability).

Demonstration of trueness requires utilisation of an acceptable reference method or comparison with reference material of a higher order.

Reproducibility should include information about studies to estimate total variability and as appropriate, between-day, between-run, between-sites, between-lots, between-operators and between-instrument variability.

Repeatability should include information about studies to estimate total variability and as appropriate, within-run variability.

The results of testing should include samples that represent the full range of expected analyte concentrations within the target population, and for Class 3 and Class 4 IVDs, and Class 4 in-house IVDs, detailed information is required.

Analytical sensitivity

Demonstration of analytical sensitivity should provide as part of the study design, the analyte tested, how the levels were established, specimen characterisation and number of replicates tested at each concentration. Calculations used to determine the assay sensitivity should be included.

For Class 3 and Class 4 IVDs, and Class 4 in-house IVDs, detailed information is required.

Analytical specificity

Information relating to any studies conducted to determine the effect caused by potentially interfering or cross-reacting substances or agents on test results should be provided. Consideration should be given to both exogenous and endogenous factors expected to be encountered.

For Class 3 and Class 4 IVDs, and Class 4 in-house IVDs, detailed information is required.

Measuring range of assay

A summary of the studies conducted to define the assay measuring range should be included for both linear and non-linear systems. Information provided should describe the lower limit of detection and how this was determined (e.g. preparation of dilutions, standards, number of replicates) and include an investigation into any potential effects of prozone or high-dose hook effect, if applicable.

Traceability of calibrator and controls

Information summarising the traceability of calibrators and trueness control materials should be provided, if applicable. Methods used to determine traceability to reference material of a higher order, acceptance criteria, and the assignment and validation of values should be included.

Determination of assay cut-off

Where applicable, a summary of the process used to establish the assay cut-off should be provided. Information provided should be based on the population studied, method(s) used to establish the true status and any statistical methods used to generate results e.g. Receiver Operator characteristic (ROC) curve.

Verification and validation of instrumentation/software

For verification and validation of instrumentation and/or software IVDs, the study report should include a summary of performance testing undertaken conducted in a valid end-user environment.

Stability

Stability studies to support the claimed shelf-life under closed, in-use and transport conditions must be provided. For Class 3 and Class 4 IVDs, and Class 4 in-house IVDs, a copy of the study protocol, a detailed study report showing the results of testing, any calculations performed and conclusions drawn should be included. For Class 2 IVDs a summary report detailing the nature of the stability study conducted, any anomalous results/investigations, and a conclusion which supports the proposed shelf life and storage conditions is considered acceptable.

For closed shelf life studies, data must be generated by testing at appropriate storage time intervals using a minimum of 3 separate production batches of IVDs. Temperature ranges assigned for testing should encompass both the upper and lower storage temperatures claimed. Real time data which extends beyond the proposed shelf life should be provided for at least 1 batch of product. Accelerated data generated using product stored under exaggerated conditions (including elevated temperature, high humidity, increased light and vibration, as appropriate) will be accepted for subsequent batches of product as an interim measure until such time as real time studies can be completed. Ongoing real time studies for those products where the shelf-life has been assigned on the basis of partially-accelerated data should be monitored closely, and the manufacturer should reduce the shelf-life in line with the real-time data as appropriate.

For newly released products only, where insufficient time has passed to allow at least one production batch of product to undergo appropriate real time stability testing since the time of release, the TGA may give consideration to the assignment of a nominal (reduced) shelf life on the basis of accelerated stability studies, provided they have been conducted under exaggerated conditions that include elevated temperature, high humidity, increased light and vibration, as appropriate. Ongoing real time studies are required to be monitored closely.

In-use (open vial) stability and transport simulation studies should be conducted using at least one batch of product, with a study design which includes conditions appropriate to the intended use and expected conditions likely to be encountered for the product.

For further information refer to CLSI standard EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents.

Information to be Supplied with the IVD

The sponsor is required to provide clear, legible copies of representative information that is to accompany the kind of IVD medical device when supplied in Australia, including:

- Labelling;
- Instructions For Use; and
- Advertising material (e.g. brochures, web-pages, published advertisements, etc.), where available.

Labelling and instructions for use are not necessarily required for every model or variation, unless there are significant differences in content. However, the copies provided are required to be representative of what will be supplied in Australia.

The sponsor's name and address must be provided with the IVD in such a way that the user can readily identify the sponsor. Labelling requirements are prescribed in Regulation 10.2 and Essential Principle 13.2 in Schedule 1.

All representative information must be provided in English.

Depth of Information to be provided

The following table summarises the depth of detail required to be contained in the STED for a product undergoing conformity assessment by the TGA. References to Class 4 IVDs in this table indicate the level of detail expected in the design dossier for products undergoing a design examination.

Section	Class 1	Class 2	Class 3	Class 4
Device description including variants				
Device description	Address each point – all classes			
Reference to previous device generation – not yet available on any market	SUMMARY	SUMMARY	SUMMARY	SUMMARY
Device history – already available on the market in another jurisdiction	SUMMARY	SUMMARY	SUMMARY	SUMMARY
Risk analysis and control	SUMMARY / REDUCED TABLE			DETAILED
Design and manufacturing information				
Device design	SUMMARY	SUMMARY	SUMMARY	DETAILED
Clinical evidence	SUMMARY	SUMMARY	DETAILED	ELABORATE
Manufacturing processes	-	-	-	SUMMARY
Design and manufacturing sites	SUMMARY	SUMMARY	SUMMARY	SUMMARY
Product validation and verification				
Specimen type	SUMMARY	SUMMARY	SUMMARY	DETAILED
Accuracy – Trueness	SUMMARY	SUMMARY	DETAILED	DETAILED
Precision – Reproducibility and Repeatability	SUMMARY	SUMMARY	DETAILED	DETAILED
Traceability of control and control materials	SUMMARY	SUMMARY	SUMMARY	DETAILED
Analytical sensitivity	SUMMARY	SUMMARY	DETAILED	DETAILED
Analytical specificity	SUMMARY	SUMMARY	DETAILED	DETAILED
Measuring range of the assay	SUMMARY	SUMMARY	DETAILED	DETAILED
Validation of assay cut-off	SUMMARY	SUMMARY	DETAILED	DETAILED
Software	SUMMARY	SUMMARY	SUMMARY	DETAILED

Section	Class 1	Class 2	Class 3	Class 4
Stability				
Claimed shelf life	SUMMARY	SUMMARY	DETAILED	DETAILED
In use stability	SUMMARY	SUMMARY	DETAILED	DETAILED
Shipping stability	SUMMARY	SUMMARY	DETAILED	DETAILED

The following information elaborates on the terms used in the table to describe the depth of detail:

Summary information

- Brief description of protocol
- Study results
- Study Conclusion

Detailed information

- Study protocol
- Method of data analysis
- Study report (summary of external reports)
- Study Conclusion

Elaborated information

- Study protocol
- Method of data analysis
- Study report (all external reports)
- Study Conclusion
- Raw/line data

The following table shows the terms used for the various devices classes in the GHTF document and their equivalents for IVDs under the Australian regulations.

GHTF IVD Class	Australian IVD Class
Class A	Class 1 IVD
Class B	Class 2 IVD
Class C	Class 3 IVD
Class D	Class 4 IVD

The STED should demonstrate the compliance of the IVD with the Australian legislative requirements. An EP Checklist for the Australian Essential Principles is available on the TGA website at <http://www.tga.gov.au/industry/devices-forms-essential-principles-checklist.htm>.

Applications for certificates

A manufacturer should only lodge an application for a TGA Conformity Assessment Certificate when they are satisfied that their quality management system and associated technical documentation satisfies the requirements of the Therapeutic Goods (Medical Devices) Regulations 2002.

All manufacturers can lodge an application for a Conformity Assessment Certificate directly with the TGA. An overseas manufacturer may choose to engage an Australian agent to lodge the application on their behalf; however this is not a TGA requirement. Applications can also be lodged on behalf of the manufacturer by another party. The certificate is issued to the manufacturer, not the agent.

An application fee is payable for lodging the application – details of the current fees are available at <http://www.tga.gov.au/about/fees-current.htm>. Further fees are payable for any assessments that are required and these fees vary, depending on the conformity assessment procedure the manufacturer has chosen to use. For more information on fees please see Section – **Fees and charges**.

If a manufacturer has not previously obtained certification from the TGA or an EU Notified Body (or other equivalent certification) it is essential that they contact the TGA so they can obtain advice on their options for obtaining conformity assessment evidence, via:

- email to devices@tga.gov.au
- the Medical Devices Information Line on 1800 141 144

How to lodge an application

Creating an e-business account

Before making an application, the manufacturer or an authorised person acting on behalf of the manufacturer must be a client of the TGA. This is achieved by establishing an eBusiness Services (eBS) account which is used to make electronic applications for medical devices including IVDs. The forms and instructions are at <http://www.ebs.tga.gov.au>.

Lodging an electronic application for a TGA Conformity Assessment Certificate

Once the applicant has access to eBS, they must lodge an electronic application for a TGA Conformity Assessment Certificate. No electronic attachments should be attached to this form as the supporting information will be requested separately.

An invoice will be generated and the applicant must pay the application fee to the TGA. If a manufacturer does not pay the application fee the application will be terminated. No further fees are required at this stage. Any assessment fees applicable to the conformity assessment are calculated once the TGA determines the assessment needed and are invoiced separately to the applicant.

Submitting supporting documentation and declaration forms

Once the electronic application is lodged with the TGA and the application fee is processed, the applicant will receive a letter from the TGA with the Submission ID. The letter will include an initial request to provide supporting information that meets the following criteria:

- Two hard copies of the supporting documentation are required. An additional copy in electronic format (on CD or DVD) is highly desirable and may assist the TGA with the assessment.
- The supporting information must be supplied in loose-leaf binders. Plastic sleeves or stapled material are not acceptable.

- The information should be sectioned for ease of reference, and a table of contents provided which details the content of the binder(s).
- There should be appropriately named tab identifiers. For example, the Labelling information should be separated from the other documents by a tab identifier named *Labelling Information*.
- Each page should be sequentially numbered.
- Standard A4 paper should be used for all submissions wherever practicable. Text and tables should be prepared using margins that allow the document to be printed on A4 paper, or A3 paper where a larger format is necessary. The left hand margin should be sufficiently large that information is not obscured through binding.
- Font sizes for text and tables should be of a style and size that are large enough to be easily legible, even after photocopying or when provided electronically.
- Information supporting an application must be in English and legible. Where material is not originally in English a full translation must be submitted, the accuracy of which is the responsibility of the applicant.

All documentation (whether electronic or hard copies) submitted in support of the application should include the Submission ID number.

Where to deliver the information

The supporting documentation should be sent to:

By Post:

IVD Assessment Section
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606 AUSTRALIA

Or

By Courier:

IVD Assessment Section
Office of Devices Authorisation
Therapeutic Goods Administration
136 Narrabundah Lane
SYMONSTON ACT 2609 AUSTRALIA

TGA processing of applications

Once the application and supporting information is received by the TGA, a pre-assessment of the application will be conducted. If the TGA finds that the manufacturer or the documentation is not ready for assessment the application may be terminated. If this happens the TGA will contact the manufacturer to discuss the options available. If the application is terminated the application fee will not be refunded.

Further information may be necessary to process the application. The TGA may send a formal request (under Section 41JA of the Act) for more information.

Please note: Each request for information will be accompanied with a specified timeframe for response. If the manufacturer is not able to provide the requested information within this timeframe (plus a further 10 working days) the application will lapse. If the application has lapsed, the manufacturer will need to reapply to obtain a TGA Conformity Assessment Certificate.

If the application has the necessary supporting information the manufacturer will be sent a formal acceptance letter advising that the application is suitable to proceed, and the relevant assessment fees will be invoiced.

The TGA may invoice reduced assessment fees if a request for abridgement is submitted in writing, either at the same time as the application, or as part of the dossier submitted to the TGA in response to the initial request for information. A reduction in assessment fees will only occur where there are grounds for an abridged assessment. Examples of when this might occur are:

- where the manufacturer holds a TGA manufacturing licence and only a 'top-up' QMS assessment is required
- where a device was a therapeutic good for in vitro diagnostic use that was Registered in the ARTG under Chapter 3 of the *Therapeutic Goods Act 1989*
- the applicant provides EU Notified Body reports of similar assessment performed under a relevant EU Directive. However, the TGA reserves the right to conduct a full assessment, with full fees, if the reports provide insufficient evidence of a thorough and comprehensive assessment.

For further information on reduction of assessment fees see Section – ***Business rules for reduced assessment fees for in vitro diagnostic medical devices (IVDs)***.

The TGA may refer the application to the Advisory Committee on Medical Devices (ACMD) for advice at anytime during the assessment process. Sponsors should be aware that the decision to refer an application to ACMD is at the TGA's discretion. If the application is referred, sponsors will be advised and invited to make further submissions to the TGA on the basis of the interim outcome of the Design Examination. Both the interim assessment by the TGA and the manufacturer's response to the interim assessment will be considered by ACMD. An additional 60 TGA working days will be added to the target evaluation time frame for applications sent for review by ACMD.

On-site audits

On-site audits are an important element of the assessment process for manufacturers who have applied for a TGA Conformity Assessment Certificate. The TGA will conduct a risk assessment on the device and the manufacturer to determine if an initial on-site audit is required to be conducted prior to the Conformity Assessment Certificate being issued. The risk assessment will take into account audits that have been conducted by EU Notified Bodies and Health Canada-recognised Registrars. The TGA will focus on the assessment of the critical production processes in the audit report, as well as any other issues that have been identified.

Mandatory conditions are imposed on all manufacturers holding a TGA Conformity Assessment Certificate and include the requirement to undergo regular reviews of their QMS. Surveillance audits will be scheduled regularly—generally at least 18 months apart and no more than five years apart. Audits may be conducted more frequently if issues arise. Fees are payable to the TGA for on-site audits.

The applicant will be notified in the formal acceptance letter if an on-site audit is required before a certificate is issued and the TGA will contact the applicant to arrange a suitable audit time.

Fit and proper persons

All applicants for a Conformity Assessment Certificate are required to self-assess whether they or certain other persons associated with the applicant meet the criteria set out in paragraph 41EC(3)(a) of the Act, and to certify the outcome by submitting this Certificate to the TGA. In deciding whether to issue a Conformity Assessment Certificate the TGA must consider whether an applicant or specified persons associated with an application has in the preceding 10 years failed to meet one or more of the specified criteria - for example, whether they have been convicted of an offence against the Act or a corresponding State law, or convicted of an offence involving fraud or

dishonesty. More information about the requirements is available on the TGA website www.tga.gov.au.

Issue of certificates

Certificates will be issued to the manufacturer once:

- the assessment of the device's compliance to the Essential Principles is satisfactorily completed
- the quality system audit (if conducted) is closed out – all non-conformities are resolved
- all clearances (including the Fit and Proper Person certification) are completed
- all fees (assessment, additional audit fees) are paid in full.

The applicant will be given an explanation and statement of reasons for any refusal to issue, or restriction on, the TGA Conformity Assessment Certificate. The decision is also appealable, subject to the legislative appeal provisions.

Next steps

Once the TGA Conformity Assessment Certificate is issued to the manufacturer, the Australian sponsor of the device will be required to register the certificate as conformity assessment evidence (manufacturer's evidence) with the TGA through the e-Business system. For more information please see Section – [***What a sponsor needs to know about conformity assessment and manufacturer's evidence for IVDs.***](#)

Once the certificates are accepted, the Australian sponsor can proceed with an application to include the medical device in the ARTG. The device cannot be legally supplied to the market in Australia unless the application for inclusion is approved, as a valid ARTG entry must exist prior to supply.

No further assessment will be conducted by the TGA for IVDs that are covered by a TGA Conformity Assessment Certificate.

Changes to current certificates

If any of the details on a TGA Conformity Assessment Certificate are no longer correct, the manufacturer must notify the TGA. Changes include:

- changes to details on the certificate (e.g. name and/or address details)
- adding new devices
- changing details on the Schedule of Suppliers
- substantial modifications to the design of, or production processes for, an existing device.

The manufacturer needs to submit an application to the TGA. Applications for changing an existing TGA Conformity Assessment Certificate should be lodged electronically using the eBusiness system. The application should indicate the existing certificate number that needs to be changed and the change required on the certificate.

Details of the fees payable for changing a TGA Conformity Assessment Certificate are available at <http://www.tga.gov.au/about/fees-current.htm>.

The TGA will need to conduct an assessment of the documentation submitted with each application for a change and further evidence to support the change may be required before a new certificate is issued.

Conditions on certificates

Under the *Therapeutic Goods Act 1989*, three types of conditions may be imposed when a TGA Conformity Assessment Certificate is issued. They are:

- automatic conditions imposed under section 41EJ
- conditions imposed at the time the certificate is issued under section 41EK
- conditions imposed after the certificate has been issued under section 41EL.

Automatic conditions on a TGA Conformity Assessment Certificate

Under section 41EJ of the Act, there are four types of conditions that will be imposed automatically when a TGA Conformity Assessment Certificate is issued:

1. Entry and inspection powers

The manufacturer will allow an authorised person to:

- enter premises, including premises outside Australia, at which the manufacturer, or any other person deals with the medical devices covered by the certificate
- inspect those premises and the medical devices, and to take samples of the devices
- carry out tests or require tests to be carried out on the devices, on the premises
- to see and copy any requested documents relating to the medical device or the manufacturer's quality management system.

2. Review requirements

The manufacturer will cooperate with any review by the TGA of matters relating to the certificate, including:

- the application of quality management systems
- compliance with the Essential Principles
- any other conformity assessment procedures specified in the regulations.

3. Notification of substantial changes

The manufacturer of a medical device will notify the TGA, in writing, of any plan for substantial changes to the:

- quality management systems
- product range
- product design.

4. Payment of fees

Any prescribed fees for a review of a TGA Conformity Assessment Certificate will be paid when they are due.

Conditions imposed when a certificate is issued

When a TGA Conformity Assessment Certificate is issued, in addition to the automatic conditions outlined above, other conditions may be imposed under section 41EK of the Act. They are conditions on:

- one or more of the devices covered by the certificate
- the manufacturer's quality management system.

Conditions imposed after the certificate has been issued

After a TGA Conformity Assessment Certificate is issued, the TGA may vary, remove or impose new conditions on the certificate under section 41EL of the Act. This action can result from an initiative of the TGA or at the request of the applicant for the certificate. The TGA will provide written notice of the proposed change to the manufacturer.

The new conditions may relate to:

- one or more of the devices covered by the certificate
- the manufacturer's quality management system
- varying or removing existing conditions.

The new conditions will take effect immediately if action is required to prevent the imminent risk of death or serious injury. In all other cases, they will take effect 20 working days after the notice has been provided.

A decision by the Secretary or a delegate to impose a condition on a TGA Conformity Assessment Certificate after the certificate has been issued is an appealable decision as it would be an 'initial decision' under section 60(1)(e) of the Act.

Suspension and revocation of certificates

If false statements are made in connection with an application for a TGA Conformity Assessment Certificate, fines up to a maximum of \$6600 can be imposed (section 41EI).

Please note: Financial penalties are specified in the Act as penalty units. The value for each penalty unit is currently \$110, in accordance with section 4AA of the Crimes Act 1914. This amount may change in the future.

Grounds also exist for revoking the certificate by written notice to the person who has been issued with the certificate under section 41ET of the Act if the TGA is satisfied that:

- the conformity assessment procedures have not been applied to IVDs covered by the certificate

- the manufacturer of the IVD covered by the certificate, refuses or fails to comply with a condition on the certificate
- the manufacturer mentioned on the certificate no longer manufactures any of the kinds of IVDs covered by the certificate
- the manufacturer mentioned on the certificate is not a fit and proper person
- a person who is managing the affairs of the manufacturer mentioned on the certificate is not a fit and proper person
- a person who has effective control over the manufacturer mentioned on the certificate is not a fit and proper person to have that control
- a person fails to provide information or documents within 10 working days of a request from the TGA about:
 - a kind of IVD
 - a quality management system to which the certificate applies.

However, if it is likely that the grounds for revocation do exist, a TGA Conformity Assessment Certificate may be suspended prior to any revocation proceedings being put in place (section 41EM).

Suspension of a TGA Conformity Assessment Certificate leads to the suspension from the ARTG of the IVDs covered by the certificate. Supply of those devices in Australia is then suspended.

If a TGA Conformity Assessment Certificate is revoked, it will lead to the entry in the ARTG for the IVDs covered by that certificate being cancelled. Supply of those devices in Australia is then illegal.

Details of these procedures can be found in Divisions 3 and 4 of the Act, including the:

- notices of proposed suspensions
- duration of suspensions
- revocation of suspensions
- automatic revocation
- immediate revocation
- revocation
- limiting revocation
- publication of revocations
- dates of effect of revocations.

Surveillance

TGA Conformity Assessment Certificates are subject to ongoing surveillance of the manufacturer and its products by the TGA.

Normally the initial onsite audit of a manufacturer is a full audit covering all applicable aspects of the manufacturer's quality management system.

Surveillance audits normally occur approximately every 18 months after certification, but may occur more frequently depending on the manufacturer's compliance status and the risk class of the

products. Surveillance audits are normally shorter audits and do not cover every applicable aspect of the quality management system. Surveillance activities may also be associated with product compliance monitoring activities, such as monitoring of non-standard conditions on the certificate, or follow-up of post-approval recommendations and agreements.

For overseas manufacturers, the TGA may request EU Notified Body or CMDCAS registrar audit reports, with the view to abridging the TGA surveillance activities. If those reports are available, and provide evidence of a thorough and comprehensive assessment, then the TGA may abridge the surveillance activities and charge reduced fees. However, the TGA reserves the right to conduct its own surveillance irrespective of such reports.

Recertification

TGA Conformity Assessment Certificates are normally issued for a 5 year period.

If the manufacturer intends to continue supplying the devices covered by the certificate in Australia, they need to apply for recertification prior to the expiry date.

An application to re-issue an existing TGA Conformity Assessment Certificate will need to be submitted to the TGA, allowing sufficient time for processing prior to the current certificate expiring. Recertification applications are lodged via the same process utilised for new applications. See ***Applications for certificates*** earlier in this Section.

An application fee and assessment fee are payable for the recertification. Assessment fees are levied according to the level of assessment required.

Recertification will normally be associated with an onsite quality management system audit, dependent on the timing of the last TGA surveillance audit.

The manufacturer will be asked to provide a comprehensive concise summary of:

- all design, production and labelling changes implemented since the certificate was issued
- clarification of the current critical suppliers
- stability reports
- performance reports - product/production validation
- postmarket performance data for each device including adverse events, recalls and alerts since the certificate was issued
- review of:
 - significance of new safety and performance standards since certification
 - risk management file for currency and relevance
 - clinical evidence for currency and relevance, including new clinical literature, clinical trial data or other clinical data (e.g. customer surveys etc).

Declaration of Conformity

Once the relevant conformity assessment evidence has been obtained, the manufacturer of an IVD is required to make an Australian Declaration of Conformity which declares that the device complies with:

- the applicable provisions of the Essential Principles
- the classification rules
- the conformity assessment procedures.

The declaration also requires the manufacturer to provide details that are relevant to the conformity assessment procedure and the manufacture of the IVD covered by the declaration. These details include:

- manufacturer's name and address
- details of the:
 - scope of the declaration (including product identification information)
 - certification
 - classification
 - nomenclature code
 - conformity assessment standards (quality management standards)

The responsibility for the classification and the conformity assessment of an IVD rests with the manufacturer of the IVD. The choice of an appropriate conformity assessment procedure, which will be governed by the class of the IVD, is also the responsibility of the manufacturer.

The wording of the Declaration of Conformity will depend on the conformity assessment procedure chosen by the manufacturer.

Templates for preparing draft Declarations of Conformity under each of the 4 different conformity assessment procedures pertaining to IVDs, as set out under Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*, are available on the TGA website at <http://www.tga.gov.au/industry/ivd-forms-declaration-conformity.htm>.

The Declaration of Conformity can be signed and dated by the manufacturer of the IVD or a person authorised by the manufacturer. The declaration must set out the name and position of the person signing the declaration

If requested, the sponsor or manufacturer must provide the TGA with a copy of the Declaration of Conformity.

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Therapeutic Goods Administration

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