

AUSTRALIAN MEDICAL DEVICES GUIDELINES

Conditions on Conformity Assessment Certificates Issued by the Therapeutic Goods Administration

Guidance Document Number 12

Version 1.6

DISCLAIMER

This document is provided for guidance only. It should not be relied upon to address every aspect of relevant legislation. Please refer to the *Therapeutic Goods Act 1989* as amended by the *Therapeutic Goods Amendment (Medical Devices) Bill 2002* and the *Therapeutic Goods (Medical Devices) Regulations 2002* for legislative requirements.

FURTHER INFORMATION

The Medical Devices Information Unit of the Office of Devices, Blood and Tissues of the Therapeutic Goods Administration (TGA) can be contacted by:

Telephone: 1800 141 144

Facsimile: (02) 6232 8299

Email: cab.medical.device.information@health.gov.au

Website: www.tga.gov.au/devices/devices.htm

Mail: PO Box 100

Woden

ACT 2606

© Commonwealth of Australia 2003

CONTENTS

Disclaimer	2
Further information.....	2
Amendment schedule	3
Introduction	5
Conditions imposed when a conformity assessment certificate is issued	6
1. Automatic conditions on a conformity assessment certificate.....	6
1. Entry and inspection powers	6
2. Review requirements.....	6
3. Notification of substantial changes.....	6
4. Payment of fees	6
2. Conditions that may be imposed when conformity assessment certificates are issued.....	7
3. Conditions imposed after a conformity assessment certificate has been issued	7
Suspension and revocation of conformity assessment certificates.....	8

INTRODUCTION

This guidance document is one of a series that has been produced to help explain the new regulatory system for medical devices in Australia that commenced on 4 October 2002. The new system has been established by the *Therapeutic Goods Act 1989* and the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Many other guidance documents are available in this series. The series was developed to assist a wide-ranging audience and additional documents can be included if there is enough demand. A separate guidance document is available describing the series.

Although each guidance document has been developed to provide information about particular aspects of the new medical devices regulatory system in Australia, it is expected that a certain amount of cross-referencing to other documents in the series will be inevitable.

A manufacturer, either in Australia or elsewhere, uses conformity assessment procedures to demonstrate that a medical device conforms to the essential principles of safety and performance specified in Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations). Depending on the procedure chosen, assessment of the final design, the controls implemented for production and the manufacturer's courses of action, an audit and assessment by the TGA may be required. If this is required and the inspection is successful, the TGA will issue a conformity assessment certificate to the manufacturer.

The conformity assessment procedures are defined in Parts 1 to 8 of Schedule 3 of the Regulations. For more information about these procedures please refer to guidance document number 3, "Conformity Assessment Procedures".

When a conformity assessment certificate is issued by the TGA, conditions will be imposed on the certificate under sections 41EJ, 41EK and 41EL of the Act. The certificate and the conditions imposed on it remain in effect until the end of the period specified on the document.

CONDITIONS IMPOSED WHEN A CONFORMITY ASSESSMENT CERTIFICATE IS ISSUED

Under the Act, three types of conditions may be imposed when a conformity assessment certificate is issued. They are:

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

1. Automatic conditions on a conformity assessment certificate

Under section 41EJ of the Act, there are four types of conditions that will be imposed automatically when a 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; and
- inspect those premises and the medical devices, and to take samples of the devices (which will be paid for by the TGA); and
- 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:

- the application of quality management systems,
- compliance with the essential principles, and
- any other conformity assessment procedures specified in the regulations,

relating to the certificate.

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; or
- product range; or
- the product design.

4. Payment of fees

Any prescribed fees for a review of a conformity assessment certificate will be paid when they are due.

2. Conditions that may be imposed when conformity assessment certificates are issued

When a 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; and
- the manufacturer's quality management system.

3. Conditions imposed after a conformity assessment certificate has been issued

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

The new conditions will relate to:

- one or more of the devices covered by the certificate, or
- to the manufacturer's quality management system: or
- 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 conformity assessment certificate after the certificate has been issued would be an appellable decision as it would be an 'initial decision' under section 60(1)(e) of the Act.

SUSPENSION AND REVOCATION OF CONFORMITY ASSESSMENT CERTIFICATES

If false statements are made in connection with a conformity assessment certificate, fines up to a maximum of \$6600 can be imposed (section 41EI).

Under section 41ET of the Act, if the TGA is satisfied that:

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

grounds exist for revoking the certificate by written notice to the person who has been issued with the certificate. However, if it is likely that the grounds for revocation do exist, conformity assessment certificates may be suspended prior to any revocation proceedings being put in place (section 41EM).

Suspension of a conformity assessment certificate leads to the suspension from the ARTG of the medical devices covered by the certificate. Supply of those devices in Australia is then suspended.

If a conformity assessment certificate is revoked, it will lead to the entry in the ARTG for the medical devices covered by that certificate being cancelled. Supply of those devices in Australia is then illegal.

Details of these procedures including the:

- notices of proposed suspensions,
- duration of suspensions,
- revocation of suspensions,
- automatic revocation of conformity assessment certificates
- immediate revocation of conformity assessment certificates,
- revocation of conformity assessment certificates,
- limiting revocation of conformity assessment certificates
- publication of revocations, and the
- dates of effect of revocations,

can be found in Divisions 3 and 4 of the Act.