

REPLACEMENT EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Conformity Assessment Standard for Quality Management Systems) Order 2019

The *Therapeutic Goods Act 1989* (“the Act”) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in, or exported from, Australia. The Therapeutic Goods Administration (“the TGA”), which is part of the Department of Health, is responsible for administering the Act.

Conformity assessment procedures are manufacturing standards specifically designed for the manufacture of medical devices and are set out in Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (“the MD Regulations”). Section 41DC of the Act provides that the Minister may, by legislative instrument, determine a conformity assessment standard for specified quality management systems and that the standard may be limited to particular kinds of devices. Compliance with a standard is treated as an application of the parts of the conformity assessment procedures specified in the standard, for a quality management system (“QMS”) identified in such a standard.

The *Therapeutic Goods (Conformity Assessment Standard for Quality Management Systems) Order 2019* (“the Order”) is a legislative instrument made by a delegate of the Minister for Health under section 41DC of the Act. The Order constitutes a conformity assessment standard for the quality management systems identified in the Order.

The effect of the Order is to provide an alternative means for manufacturers of medical devices to demonstrate that they have applied those parts of the conformity assessment procedures that relate to implementing and maintaining a QMS in relation to its manufacture of medical devices. The Order does this by reference to a number of standards published by the International Organisation for Standardization (“the ISO”).

The Order has the effect that if a manufacturer’s QMS complies with the standard specified in the Order, it will be treated as having had applied to it those parts of the conformity assessment procedures specified in the Order.

The Order also repeals and replaces the previous Conformity Assessment Standards Order (Standard for Quality Management Systems and Quality Assurance Techniques) 2008 (“the former Order”), which would otherwise sunset on 1 April 2019 under the sunset provisions of the *Legislation Act 2003*.

Background

Under section 41DA of the Act, the regulations may set out requirements relating to the obligations of medical device manufacturers, to be known as the conformity assessment procedures. Conformity assessment procedures are manufacturing standards specifically designed for the manufacture of medical devices, which represent benchmarks for ensuring that devices will be produced in such a manner that they meet the specifications under which they were approved for general marketing, and for ensuring that the conditions under which

the devices are manufactured will provide an assurance that the safety and quality of the devices are within acceptable parameters.

The conformity assessment procedures may be limited in their application to one or more medical device classifications, or apply differently to different medical device classifications, different kinds of medical devices or different kinds of medical device manufacturers. One requirement of the conformity assessment procedures is that a manufacturer of a kind of medical device must implement a QMS for the design, production, packaging, labelling and final inspection of the kind of device, and that such a system must ensure that each kind of device to which the QMS is applied complies with:

- the Essential Principles, which are minimum benchmarks for the safety and performance of medical devices, set out in Schedule 1 to the MD Regulations;
- the medical device classification rules, set out in Schedules 2 and 2A to the MD Regulations; and
- the conformity assessment procedures set out in Schedule 3 to the MD Regulations.

Sponsors applying to include a kind of medical device in the Australian Register of Therapeutic Goods (“the Register”) (i.e. to seek marketing approval) must certify that either appropriate conformity assessment procedures have been applied to devices of that kind, or that requirements that are comparable to such procedures have been applied to devices of that kind and, in either case, that the sponsor has sufficient information to substantiate that application, or that arrangements are in place with the manufacturer to be able to obtain such information from them within the period specified in the regulations.

A kind of device may be cancelled from the Register if the Secretary is satisfied that the certification made in relation to the application of such procedures was not, or is no longer, correct in a material particular (paragraph 41GN(1)(f) of the Act refers). Criminal offences or civil penalties may also apply for sponsors and manufacturers of medical devices that are supplied in circumstances in which the conformity assessment procedures have not been applied (except where an overseas regulator conformity assessment document is in place in relation to the device).

Section 41DC of the Act allows the Minister to make a legislative instrument determining that the matters specified in such an order constitute a conformity assessment standard for the quality management systems identified in the order. This has the effect that where a medical device manufacturer’s QMS complies with the order, the QMS is to be treated as having had applied to it those parts of the conformity assessment procedures specified in the order.

The purpose of a conformity assessment standards order is to provide medical device manufacturers with a flexible option of demonstrating that it has applied the conformity assessment procedures to the kinds of medical devices that it is manufacturing, through being able to demonstrate that it has an effective QMS in place that is consistent with international benchmarks. Compliance with one or more conformity assessment standards is not mandatory, but designed to offer a more flexible and quicker means of demonstrating compliance with conformity assessment procedures.

Subsection 41MG(1) of the Act makes this clear by providing that the criminal offence and civil penalty provisions in the Act that relate to failing to apply the conformity assessment procedures (sections 41ME, 41MEA and 41MF) do not apply to the extent that a QMS,

which has been applied to a manufacturer's or sponsor's devices, complies with one or more applicable conformity assessment standards.

The former Order was registered on the Federal Register of Legislation on 24 November 2008, and identifies a number of ISO standards as constituting conformity assessment standards relevant to the implementation of the manufacturer's quality management system and quality assurance techniques. In order to reflect developments and improvements in medical device manufacture since then, there is now a need to replace the former Order with a new conformity assessment standards order that updates the range of ISO standards specified.

In particular, the standard ISO 13485:2003 *Medical device—Quality management systems—Requirements for regulatory purposes* is an important standard that was created to support medical device manufacturers in designing quality management systems that establish and maintain the effectiveness of their processes, and was adopted by the former Order. Its purpose is to ensure the consistent design, development, production, installation, and delivery of medical devices that are safe for their intended purpose.

In 2016, the ISO published a new revised version of ISO 13485 (ISO 13485:2016), to replace ISO 13485:2003. The ISO provided for a 3 year transition period in which ISO 13485:2003 and ISO 13485:2016 coexisted, allowing users to transition to the updated standard. This transition period ended on 1 March 2019, after which time the ISO only recommends ISO 13485:2016 as the acceptable standard for quality management systems. The TGA published notifications in relation to medical device manufacturers and sponsors about this transition period on its website (www.tga.gov.au) on 9 August 2016, and 1 March 2019.

Given the end of the ISO's transition period and its endorsement of ISO 13485:2016 from 1 March 2019, and that the former Order would sunset from 1 April 2019, the Order repeals and replaces the former Order with a new order that, in particular, substitutes the references to ISO 13485:2003 with references to the new ISO 13485:2016.

This follows the recent action of other comparable overseas regulators to replace requirements relating to ISO 13485:2003 with ISO 13485:2016, such as Health Canada from 1 January 2019, and the European Union ("EU") from 31 March 2019.

In comparison with ISO 13485:2003 the adoption of the new ISO 13485:2016 includes, in particular, requirements that:

- all processes that are part of a manufacturer's QMS be developed using a risk-based approach, including outsourced processes;
- a comprehensive technical file be maintained for each manufactured device that includes a description of the device, relevant specifications and other records; and
- relate to the validation of computer software used in the QMS, complaints handling and regulatory reporting processes, the validation of processes for sterilisation and sterile barrier systems and defining and assessing the competencies of personnel.

A number of the other ISO standards, or parts of ISO standards, referred to in the former Order have also been updated by the ISO since that order was first introduced, for example:

- ISO 11137-2:2006 *Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose* has been revised by ISO 11137-2:2013 *Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose*; and

- ISO 13408-1:1998 *Aseptic processing of health care products—Part 1: General requirements* has been revised by ISO 13408-1:2008 *Aseptic processing of health care products—Part 1: General requirements*.

These international standards are important documents that are developed and updated by groups of international experts (with some involvement of Australian representatives). Updates to the international standards reflect changes to international best practice and the emergence of new technologies and manufacturing procedures, and the adoption of more up to date versions of the standards by the Order is designed to ensure that it reflects current and internationally consistent requirements for QMSs.

Consultation

The TGA has notified stakeholders of the end of the transition period for ISO 13485:2003 and subsequent plans to repeal and remake the order through letters sent to Australian medical device manufacturers and a statement published on the TGA website.

The TGA tabled a draft of the new Order at the Regulatory and Technical Consultative Forum (“RegTech”) on 28 February 2019, and invited comments on it from RegTech participants and their members. RegTech is comprised of the TGA and key medical devices stakeholders the Medical Technology Association of Australia (“MTAA”), the Australian Dental Industry Association (“ADIA”), AusBiotech, Pathology Technology Australia and the Association of Therapeutic Goods Consultants. In particular, it was highlighted for RegTech participants that the new Order would specify ISO 13485:2016 as the appropriate conformity assessment standard for QMS, and would also update the other standards specified in relation to the manufacture of sterile medical devices. Peak industry bodies provided feedback supporting the adoption of the latest standards in the Order.

The Medical Technology Association of Australia (MTAA) also recommended that the former Order be replaced with a more comprehensive CASO that references the EU’s harmonised standards (for the purposes of affording a presumption of conformity with the EU’s requirements) and the recognised consensus standards published by the United States’ Food and Drug Administration. This proposal will be carefully considered and discussed more broadly with stakeholders including the other RegTech participants.

Discretionary standards in relation to medical devices, like conformity assessment standard orders, are subject to a carve-out from the regulation impact statement process. This is because those orders are not regulatory in nature as they are voluntary standards that are available for use by stakeholders if they choose to do so (Office of Best Practice Regulation reference: 14416).

Incorporation by reference

The Order refers in Schedules 1 and 2 to a number of standards published by the ISO, including for example ISO 13485:2016. In accordance with section 14 of the *Legislation Act 2003*, the intention in each such instance is to adopt those standards as they are in force at the time of the Order’s commencement – that being, 31 March 2019.

Unfortunately these ISO standards are not available for free, as the publications are subject to copyright. The standards are available for purchase online from the ISO store at <https://www.iso.org/home.html> (e.g. \$223 for ISO 13485:2016). However, it is anticipated that the persons most affected by their adoption (manufacturers and sponsors of medical

devices) would be in possession of these documents in order to manufacture their medical devices (including in relation to the manufacture of medical devices that are supplied in other countries). As these ISO standards are important international benchmarks for the safe manufacture of medical devices, it would be infeasible from a regulatory perspective for sponsors and manufacturers not to adopt such benchmarks on the basis that they are not available for free (particularly given their adoption by other comparable regulators overseas). However, by prior written arrangement with the TGA, a copy of an ISO standard referred to in the Order may be made available for viewing free of charge at the TGA office in Symonston, ACT.

It should also be noted that the National Library's Trove online system (<https://trove.nla.gov.au/>) allows users to identify libraries in Australia that are open to the public where editions (in most cases, earlier editions) of these ISO standards, or related documents, may be viewed (for example, *AS ISO 11135-2002—Medical devices—Validation and routine control of ethylene oxide sterilization* is available at the Queensland University of Technology library, and a guide to ISO 13485:2016, *ISO 13485:2016—Medical devices—A practical guide*, by ISO technical experts and the National Standards Authority of Ireland, is available to be viewed for free at the University of Queensland Library (<https://trove.nla.gov.au/work/232207651?q=ISO+13485%3A2016&c=book&versionId=256355077>).

Members of the public may also approach any library that participates in inter-library loans to request an inter-library loan with such university libraries, or to obtain a photocopy of a particular part or monograph for personal study or research (but not for commercial purposes), at a usual cost of \$16.50 per request (enquiries should be made with local libraries, State libraries and the National Library).

The ISO store (<https://www.iso.org/home.html>) also includes a brief summary and “preview” of each ISO standard, including information about the ISO standard and its subject matter and intended purpose, as well as the foreword, introduction, scope, terms and definitions and table of contents (for example, the following link provides this range of information for ISO 25424:2018 *Sterilization of health care products—Low temperature steam and formaldehyde—Requirements for development, validation and routine control of a sterilization process for medical devices* <https://www.iso.org/standard/70822.html>).

Details of the Order are set out in **Attachment A**.

The Order is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

The Order is a disallowable legislative instrument for the purposes of the Legislation Act, and commences on 31 March 2019.

Details of the *Therapeutic Goods (Conformity Assessment Standard for Quality Management Systems) Order 2019*

Section 1 Name

This section provides that the name of the Order is the *Therapeutic Goods (Conformity Assessment Standard for Quality Management Systems) Order 2019*.

Section 2 Commencement

This section provides that the Order commences on 31 March 2019.

Section 3 Authority

This section provides that the legislative authority for making the Order is section 41DC of the *Therapeutic Goods Act 1989* (“the Act”).

Section 4 Definitions

This section sets out definitions for a number of terms used in the Order, for example “ISO”, and “standard”.

This section also makes it clear that a number of terms have the same meaning as given in the Act, for example, “conformity assessment procedures”, “manufacturer, of a medical device” and “medical device”.

Section 5 Conformity assessment standards—quality management systems

This section provides that the matters specified in a standard, or part of a standard, mentioned in column 2 of an item in the table in Schedule 1 to the Order constitute a conformity assessment standard for a QMS mentioned in Parts 1, 4 or 5 of Schedule 3 to the Regulations.

This section also makes it clear that where a medical device manufacturer’s QMS complies with a standard, or part of a standard, mentioned in column 2 of an item in the table in Schedule 1 to the Order, then the QMS is to be treated as having had applied to it those parts of the conformity assessment procedures specified in column 3 of that item.

Section 6 Conformity assessment standards—quality management systems for kinds of medical devices intended to be supplied in a sterile state

This section provides that the matters specified in a standard, or part of a standard, mentioned in column 2 of an item in the table in Schedule 2 to the Order, when used for a purpose mentioned in column 3 of that item, constitute a conformity assessment standard for a QMS mentioned in Parts 1 or 4 of Schedule 3 to the Regulations that relates to the manufacture of medical devices intended by the manufacturer to be supplied in a sterile state.

This section also makes it clear that where such a medical device manufacturer’s QMS complies with a standard, or part of a standard, mentioned in column 2 of an item in the table in Schedule 2 to the Order for a purpose specified in column 3 of that item, then the QMS is to be treated as having had applied to it those parts of the conformity assessment procedures specified in column 4 of that item.

One of the effects of section 5 and section 6 is that a manufacturer who manufactures kinds of medical devices that are intended to be supplied in a sterile state may demonstrate the

application of conformity assessment procedures to its devices by relying on the standards in both Schedule 1 and Schedule 2.

Section 7 Repeals

This section provides that each instrument that is specified in Schedule 3 to the Order is repealed as set out in the applicable items in that Schedule.

Schedule 1 Conformity assessment standards

Schedule 1 specifies standards and parts of standards that, under section 5, constitute a conformity assessment for the quality management systems identified in section 5. This Schedule also identifies the conformity assessment procedures that such a QMS will be treated as having had applied to it, if it complies with the standards or parts of standards specified in this Schedule.

Schedule 2 Conformity assessment standards for medical devices intended to be supplied in a sterile state

Schedule 2 specifies standards and parts of standards that, under section 6, constitute a conformity assessment for the quality management systems identified in section 6 when used by a manufacturer for a purpose mentioned in the Schedule. This Schedule also identifies the conformity assessment procedures that such a QMS will be treated as having had applied to it, if it complies with the standards or parts of standards specified for a purpose mentioned in Schedule 2.

Schedule 3 Repeals

This Schedule repeals Conformity Assessment Standards Order (Standard for Quality Management Systems and Quality Assurance Techniques) 2008.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011.

Therapeutic Goods (Conformity Assessment Standard for Quality Management Systems) Order 2019

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the legislative instrument

The *Therapeutic Goods (Conformity Assessment Standard for Quality Management Systems) Order 2019* is an order made by a delegate of the Minister under section 41DC of the *Therapeutic Goods Act 1989* (“the Act”) and commences on 31 March 2019. Section 41DC of the Act allows the Minister to make an order by legislative instrument, determining that the matters specified in such an order constitute a conformity assessment standard for the quality management systems (QMS) identified in the order, with the effect that where a medical device manufacturer’s QMS complies with the order, the system is to be treated as having had applied to it those parts of the conformity assessment procedures specified in the order.

The instrument is designed to provide an alternative means for manufacturers of medical devices to demonstrate that they have applied specified conformity assessment procedures in its manufacturing processes. Conformity assessment procedures are manufacturing standards specifically designed for the manufacture of medical devices and are set out in Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (“the MD Regulations”).

The instrument does this by reference to a number of standards, or parts of standards, published by the International Organisation for Standardization (“the ISO”). The instrument has the effect that if a manufacturer’s QMS complies with the standard specified in the instrument, it will be treated as having had applied to it those parts of the conformity assessment procedures specified in the instrument.

The instrument repeals and replaces the Conformity Assessment Standards Order (Standard for Quality Management Systems and Quality Assurance Techniques) 2008 (“the former Order”), which would otherwise sunset on 1 April 2019 under the sunset provisions of the *Legislation Act 2003*.

The purpose of such conformity assessment standards orders is to provide medical device manufactures with a flexible option of demonstrating that it has applied the conformity assessment procedures to the kinds of medical devices that it is manufacturing, through being able to demonstrate that it has an effective QMS in place that is consistent with international benchmarks. Compliance with conformity assessment standards orders is not mandatory, but designed to offer a more flexible and quicker means of demonstrating compliance with the conformity assessment procedures.

Subsection 41MG(1) of the Act makes this clear by providing that the criminal offence and civil penalty provisions in the Act that relate to failing to apply the conformity assessment procedures (sections 41ME, 41MEA and 41MF) do not apply to the extent that a QMS that has been applied to a manufacturer's or sponsor's devices complies with one or more applicable conformity assessment standards.

Given the end of the ISO's transition period and its endorsement of ISO 13485:2016 from 1 March 2019, and that the former Order would sunset from 1 April 2019, the instrument repeals and replaces the former Order with a new order that, in particular, substitutes the references to ISO 13485:2003 with references to the new ISO 13485:2016.

This follows the recent action of other comparable overseas regulators to replace requirements relating to ISO 13485:2003 with ISO 13485:2016, such as Health Canada from 1 January 2019, and the European Union from 31 March 2019.

In comparison with ISO 13485:2003, the adoption of the new ISO 13485:2016 includes, in particular, requirements that:

- all processes that are part of a manufacturer's QMS be developed using a risk-based approach, including outsourced processes;
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- relate to the validation of computer software used in the QMS, complaints handling and regulatory reporting processes, the validation of processes for sterilisation and sterile barrier systems and defining and assessing the competencies of personnel.

A number of the other ISO standards or parts of ISO standards referred to in the former Order have also been updated by the ISO since that order was first introduced, for example:

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- ISO 13408-1:1998 *Aseptic processing of health care products—Part 1: General requirements* has been revised by ISO 13408-1:2008 *Aseptic processing of health care products—Part 1: General requirements*.

These international standards are important documents that are developed and updated by groups of international experts (with some involvement of Australian representatives). Updates to the international standards reflect changes to international best practice and the emergence of new technologies and manufacturing procedures, and the adoption of more up to date versions of the standards by the instrument is designed to ensure that it reflects current and internationally consistent requirements for QMSs.

Human rights implications

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights ("the ICESCR"). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standard of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right. In *General Comment No. 14: The Right*

to the Highest Attainable Standard of Health (Art. 12) (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The instrument takes positive steps to promote the right to health by offering manufacturers of medical devices a flexible and efficient option of demonstrating that appropriate conformity assessment procedures have been applied to the manufacture of its medical devices, by reference to standards developed by the ISO and that are consistent with international best practice in relation to manufacturing medical devices. As such, the instrument will assist in ensuring the safety and satisfactory performance of medical devices, as well as their timely availability, in Australia.

Conclusion

The instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR as outlined above, and otherwise does not raise any human rights issues.

Miranda Lauman, delegate of the Minister for Health