AS/NZS 4815:2006

Australian/New Zealand Standard™

# Office-based health care facilities—Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment


This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-023, Processing of Medical and Surgical Instruments. It was approved on behalf of the Council of Standards Australia on 13 March 2006 and on behalf of the Council of Standards New Zealand on 24 March 2006.
This Standard was published on 6 April 2006.

---

The following are represented on Committee HE-023:

Australian Association of Practice Managers
Australian Chamber of Commerce and Industry
Australian College of Operating Room Nurses
Australian Dental Association
Australian Dental Industry Association
Australian General Practice Accreditation
Australian Health Industry
Australian Infection Control Association
Australian Nursing Federation
Commonwealth Dept of Health and Ageing
Dental Assistants Association of Australia
Department of Health, South Australia
Department of Human Services, Victoria
Federation of Sterilizing Research and Advisory Councils of Australia
Gastroenterological Nurses College of Australia
Medical Industry Association of Australia
Ministry of Health, New Zealand
New Zealand Nurses Organisation
New Zealand Sterile Services Association
N.S.W. Health Department
Queensland Health
Royal Australian College of General Practitioners
Rural Doctors Association of Australia

---

## Keeping Standards up-to-date

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about joint Australian/New Zealand Standards can be found by visiting the Standards Web Shop at www.standards.org.au or Standards New Zealand web site at www.standards.co.nz and looking up the relevant Standard in the on-line catalogue.

Alternatively, both organizations publish an annual printed Catalogue with full details of all current Standards. For more frequent listings or notification of revisions, amendments and withdrawals, Standards Australia and Standards New Zealand offer a number of update options. For information about these services, users should contact their respective national Standards organization.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia or Standards New Zealand at the address shown on the back cover.

---

*This Standard was issued in draft form for comment as DR 03655.*

Australian/New Zealand Standard™

# Office-based health care facilities—Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment

Originated as AS/NZS 4815:2001
Second edition 2006.



Jointly published by Standards Australia, GPO Box 476, Sydney, NSW 2001 and Standards New Zealand, Private Bag 2439, Wellington 6020

ISBN 0 7337 7369 9

# PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-023, Processing of Medical and Surgical Instruments and Equipment, to supersede AS/NZS 4815:2001, *Office-based health care facilities not involved in complex patient procedures and processes—Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of the associated environment.*

The Standard has been prepared for office-based health care facilities to implement procedures for cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and the maintenance of associated environments as applicable to their own professions.

**Where complex patient procedures and sterilizing processes, such as low temperature sterilization are performed in office-based health care facilities, reference to AS/NZS 4187 *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities* is required.**

Persons having responsibility for the safe provision of sterile health care products should be aware of available sterilization processes, methods of control, and physical characteristics of the product to be sterilized. Unless products are produced under controlled conditions, they will have microorganisms on them and are, by definition, non-sterile. The purpose of sterilization is to destroy these microbiological contaminants.

Certain processes used in the manufacture of health care products are considered to be ‘special’ (as described in the AS/NZS ISO 9000 series of quality management system standards) in that the result cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of a special process because efficacy cannot be verified by inspection or testing of the product. For this reason, sterilization processes must be validated before use, the process routinely monitored and the equipment maintained.

There are many references in this Standard to using the manufacturer’s written instructions. However, there are occasions when such instructions may still be inadequate and it is recommended that on-site testing be undertaken. Further clarification of these instructions should be sought from the manufacturer.

Reprocessing of items that may be contaminated with prions, capable of causing diseases such as Transmissible Spongiform Encephalopathies (TSEs), e.g. Creutzfeldt-Jakob Disease (CJD), is still being researched. Current knowledge indicates that these TSEs resist the processes specified in this Standard.

The terms ‘normative’ and ‘informative’ have been used in this Standard to define the application of the appendix to which they apply. A ‘normative’ appendix is an integral part of a Standard, whereas an ‘informative’ appendix is only for information and guidance.

Mandatory statements in footnotes to Tables are deemed to be requirements of this Standard.

The principal differences between this edition and the 2001 edition are as follows:

(a) New definitions have been added.

(b) Requirements regarding the use of sheaths/sleeves/protective barriers for instruments and equipment without these items first being cleaned, disinfected or sterilized, as appropriate, have been added.

(c) Table 7.1 has been modified to assist in a clearer understanding of the relationship between monitoring and validation.

(d) Performance tests for small steam sterilizers that use mechanical air removal systems e.g. Type B and some Type S cycles have been clarified.

(e) Validation requirements (Appendix F) have been upgraded.

(f) Measurement of temperature and pressure in steam sterilizers, or temperature only in dry heat sterilizers (Appendix G) has been modified.