

Proposed changes to the Australian Standard for microbiological safety in laboratories (AS/NZS 2243.3)



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The Australian/New Zealand Standard for safety in microbiological laboratories and containment facilities, AS/NZS 2243.3:2002¹, is currently undergoing revision. This update reflects requirements for the safe handling of microorganisms in all four containment levels of laboratories and containment facilities (PC1-4); it also covers the requirements for animal, plant and invertebrate containment facilities. The committee has endeavoured to ensure harmonisation with publications by the Office of the Gene Technology Regulator (OGTR) and Australian Quarantine and Inspection Service (AQIS) to facilitate implementation by laboratory managers and scientists.

The objective of this Standard is to provide management and staff with requirements and guidelines that promote microbiological safety. In addition to a general update of the entire Standard, changes are proposed as follows: review of the assignment of microorganisms into the four Risk Groups (RGs); separate definitions of the four RGs for plant pathogens and invertebrate pathogens; complete revision and expansion of sections on plant and invertebrate containment facilities; update of transport requirements; and addition of diagrams showing design principles for PC3 and PC4 laboratory containment facilities. The committee has considered the public comments received and the new version of AS/NZS 2243.3 is expected to be published late in 2008.

Australian Standards and committees

One of the most frequently questions asked of biosafety officers and managers is who made up that rule? Tracing back, it is often found to be a requirement in AS/NZS 2243.3. This Australian/New Zealand Standard is prepared by a committee drawn together for this purpose by Standards Australia and Standards New Zealand. The

members of the committee are experts or have a lot of knowledge and experience in a particular area of microbiology. In addition there are representatives from various societies and organisations who make valuable contributions and assist in ensuring harmonisation between the various publications – not an easy task! The current committee membership consists of representatives from the OGTR, the Public Health Laboratory Network (PHLN), the AQIS, the ASM Standing Committee on Biosafety, the Australasian Plant Pathology Society, the Sterilizing Research Advisory Council of Australia, CSIRO and universities, Biosecurity New Zealand and the New Zealand Microbiological Society, as well as a biocontainment engineer and specialists in virology and bacteriology. A Standards Australia project manager pulls all the work together and oversees the production of the Standard.

This Standard, AS/NZS 2243.3, is one of a series of 10 Standards on safety in laboratories (Table 1). It should therefore be read in conjunction with Part 1, which is on the planning and operational aspects of laboratory safety, and any other applicable parts of the series. In addition, when planning to construct new or upgrade existing laboratories, AS/NZS 2982.1 (*Laboratory design and construction Part 1: General requirements*, which is currently also under revision) and the Building Code of Australia, published annually by the Australian Institute of Building, should be consulted.

Standards Australia periodically revises all its standards – the frequency depends on the topic and the technological/developmental changes in the area. Hence this Standard is one of those most frequently revised. If important changes are required between full revisions, an amendment is issued.

Proposed changes to the 2002 edition

Another question often asked is why do I need to know/bother about what is in the Standard and that someone has changed it? Many laboratory workers are not aware that their own institution's laboratory biosafety manual is frequently based on the requirements detailed in AS/NZS 2243.3, as are also the legislative requirements of both OGTR and AQIS. Presented here is a summary of the changes proposed by the committee for AS/NZS 2243.3 after 3 years of meetings followed by consideration of all the public comments.

Harmonisation with OGTR and AQIS

Since the 2002 publication of AS/NZS 2243.3, both OGTR and AQIS have produced updates of their publications. It became obvious that the requirements of the three sets of publications were very similar, but different in small and sometimes significant

ways. Managers and scientists who had responsibility for ensuring that two or three of these sets of documents were implemented in their laboratories were finding it increasingly difficult and time consuming to sort out these differences. In December 2005 a meeting was held between all concerned parties and it was agreed that, as far as possible, the publications of OGTR, AQIS and AS/NZS 2243.3 would be harmonised. Draft documents are exchanged between the organisations to facilitate this.

All parties have attempted to use the same words and phrases where possible. In addition, the committees have tried to ensure that if a requirement is mandatory in one document, it is mandatory in all three sets. However, it is worth noting that different terminology is used by Standards Australia and OGTR: the former uses 'shall' to indicate requirements that have to be met for compliance with a standard ('should' indicates a recommendation), while OGTR uses the word 'must' for the same purpose.

Revision of requirements for each of PC levels 1-4

All of the requirements for work in PC laboratories levels 1-4 have been reviewed and updated. In doing this, other overseas biosafety publications such as the WHO Laboratory Biosafety Manual ², the US Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual ³ and the Canadian Laboratory Biosafety Manual ⁴ were consulted.

Table 1. The Australian / New Zealand Standard 2243 series.

| Safety in laboratories AS/NZS 2243 series | | |
|---|---|---------------------------------|
| Part no. | Title | Most recent year of publication |
| 2243.1 | Planning & operational aspects | 2005 |
| 2243.2 | Chemical aspects | 2006 |
| 2243.3 | Microbiological aspects and containment facilities | 2002 |
| 2243.4 | Ionizing radiations | 1998 |
| 2243.5 | Non-ionizing radiations- Electromagnetic, sound & ultrasound | 2004 |
| 2243.6 | Mechanical aspects | 1990 |
| 2243.7 | Electrical aspects | 1991 |
| 2243.8 | Fume cupboards | 2006 |
| 2243.9 | Recirculating fume cabinets | 2003 |
| 2243.10 | Storage of chemicals | 2004 |

Most of the changes are minor, except for the requirement for autoclaves for PC3 laboratories, which is detailed here to alert designers of new laboratories. Whereas in the 2002 and previous versions there was the option for the pressure steam steriliser (autoclave) for the PC3 laboratory to be separate from the laboratory, the new draft requires that it shall be contained within the PC3 facility, preferably in barrier wall. This requirement applies to all types of containment facilities.

RGs and definitions

The definition of RG3 is now defined as "high individual risk, limited to *moderate* community risk", which is considered to better reflect the nature of the properties of some of the organisms in this RG.

The standard now provides new and separate definitions for the four RGs for plant pathogens and invertebrate pathogens. Due to the different properties of plants and invertebrates and their pathogens, it was not possible to provide a single definition for each RG that also applied to animals and humans.

As always with each revision, the assignment of microorganisms into the four RGs has been reviewed and updated. It is interesting to note that some of the overseas biosafety standards do not allocate organisms to RGs, but state that a risk assessment must be done to determine what level of containment must be used for their country ². There was agreement within the committee that AS/NZS 2243.3 should still contain the RG classification system. However, as the type of work being done with some specific organisms, or strain, can significantly increase or decrease the risk to the worker, an organism can be listed in more than one RG depending on the work being carried out. Examples of such work are diagnostic work versus concentrates, vaccine versus wild strain, or pathogenicity of different strains of avian influenza. To assist the reader, the order of the RG tables in Section 3 has been changed; tables for all RG2 microorganisms are now grouped together, followed by all RG3 tables and then RG4 tables.

Containment facilities

The sections on plant and invertebrate containment facilities have been rewritten and expanded to acknowledge the different types of hazards these present to the worker and the environment.

In addition, the requirements for animal, plant and invertebrate containment facilities are now independent of those for laboratories, i.e. each section is complete and can be read independently of the section for laboratories. In the current and previous versions, it has been necessary to read the requirements for laboratories in addition to those for animals, plants or invertebrates. Again, to assist the reader, the sections on animal, plant and invertebrate containment facilities have been moved forward and now follow on from the laboratory requirements.

An important and, it is hoped, very useful, addition to the new revision is appendices that contain diagrams showing the design principles of PC3 and PC4 containment facilities. The committee noted that, from inspections of proposed designs for

containment facilities as well as existing containment facilities, it appeared there were some problems in interpreting the requirements of the written words of the Standard. So the old saying 'a picture is worth a thousand words' was adopted and sketches depicting the design principles of containment facilities at levels 3 and 4 have been prepared and included.

Transport of infectious and other biological materials

This section has been updated and based on the *UN Recommendations on Transport of Dangerous Goods Model Regulations* (13th ed). It also includes the requirements of the new Australian Standard AS 4834 – 2007 (*Packaging for surface transport of biological material that may cause disease in humans, animals and plants*).

When will the new revision be published?

The revised version of the 2002 edition was issued for public comment in September / October 2007. Each revision is made available for input from the public for a period of 2 months for comment on all the proposed changes.

The committee then meets to consider all the comments – as there were 732 comments received, this meant four 2-day meetings were held. Although responses are not sent back to individuals, all comments are considered by the committee and most of them are accepted and incorporated into the Standard.

It then takes several months for the approval process, where the project manager prepares the final version and the committee votes on acceptance (or otherwise) of the draft. Once approved, the new standard is published. At the time of writing it is anticipated that the revised version should be available by the end of 2008.

References

1. Australian/New Zealand Standard AS/NZS 2243.3:2002 *Safety in laboratories Part 3: Microbiological aspects and containment facilities* Standards Association of Australia, Sydney.
2. World Health Organization. (2004) *WHO Laboratory Biosafety Manual* (3rd ed). Available at: http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/
3. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health. (2007). *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* (5th ed). US Government Printing Office Washington: 2007. Available at: <http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm>
4. Public Health Agency of Canada. (2004) *Laboratory Biosafety Guidelines* (3rd ed). Available at: <http://www.phac-aspc.gc.ca/publicat/lbg-lbmbl-04/index.html>

Denise Elson is an OHS consultant with special interests in biosafety, biosecurity and biocontainment. Denise worked at CSIRO's Australian Animal Health Laboratory in microbiological security and safety from 1985. She has been a member of the Standards Australia Sub-Committee for AS/NZS 2243.3 since then and is currently Chair of this committee. Denise has more recently been involved in conducting biorisk audits in overseas containment facilities.



The Standards Australia Sub-Committee for AS/NZS2243.3 (Microbiological aspects and containment facilities) at AAHL. L-R: Marie Gerrard, Mark Whattam, Sandy Thomas, Gordon McGurk, Rebecca Newton, Phillip Hill, Margery Kennett, Jeff Cates, Barry Wards, Gordon Abraham, Denise Elson, Norbert Ryan, Neil Walls & Carol Foster. Absent: Sarah Thornton, Jacky Edwards, Sue Cornish & Patricia Short.