Australian and New Zealand College of Anaesthetists (ANZCA)

Statement on the Minimum Safety Requirements for Anaesthetic Machines and Workstations for Clinical Practice

Background Paper

PURPOSE

Anaesthetic machines are fundamental to anaesthesia. They have continued to evolve in sophistication and functionality, becoming increasingly diverse and complex. ANZCA professional document *PS54 Statement on the Minimum Safety Requirements for Anaesthetic Machines and Workstations for Clinical Practice* seeks to ensure that the minimum standards accord with advances in technology. The safety requirements are intended to facilitate decision-making regarding the need to upgrade, replace, or retain anaesthetic machines in current use. The requirements should be interpreted in the context of relevant Australian and New Zealand standards.

SCOPE

This professional document is intended to apply to all anaesthetic machines used in the hospital environment. This document is not intended to apply to anaesthetic machines used in the field, nor is it intended to apply to ventilators or monitoring systems, which are often integrated in modern machines.

BACKGROUND

A review of *PS54*, then known as *T03 Minimum Safety Requirements for Anaesthetic Machines for Clinical Practice*, commenced in 2010. A meeting at ANZCA House on October 8, 2010 of reviewers appointed by ANZCA Council, Fellows with an interest in draw-over and disaster relief anaesthetic apparatus, and others with specific standards interest and experience, informed the review. The Faculty of Pain Medicine Board, ANZCA regional and national committees, and the ANZCA Trainee Committee were invited to comment on the proposed document. In accordance with *A01 Policy for the Development and Review of Professional Documents*, the resulting document was subject to a pilot phase, with feedback from stakeholders encouraged. In July 2011, during this pilot phase, the deadline for compliance was extended from January 2012 to January 2013 to allow manufacturers time to either develop the required modifications or additions to their machines, or to source adequate alternatives from other manufacturers which were compatible with their machines. Other amendments made at this time related to a high pressure relief valve or other means of automatically preventing dangerous high and/or prolonged pressures in the breathing system, and requirements for switching “off” an electronic anaesthetic machine.

As a result of the feedback received during the pilot phase, which required considerable deliberation, ANZCA Council agreed, in August 2012, to extend the timeline for compliance with the final revision. The extension of one year to January 1, 2014 was for the purpose of allowing manufacturers time to either develop the required modifications or additions to their machines, or to source adequate alternatives from other manufacturers, which are compatible with their machines. At this time the document was reissued as a professional standard, *PS54 Statement on the Minimum Safety Requirements for Anaesthetic Machines for Clinical Practice*, reflecting the decision to abolish the technical category of professional documents.

ISSUES

The document has been restructured for clarity: “mandatory” and “recommended” safety requirements have been amalgamated; “other” safety requirements are now detailed under “maintenance” requirements. Terminology has been aligned with the relevant standards documents. The issues of high and low pressures in the patient’s airway have been separated across two items (now items 3.16 and 3.17).

It was suggested that a statement, enforcing manufacturers’ requirements in relation to equipment testing, should be included in the document. The document development group, however, did not wish to restrict department or anaesthetist choice with respect to combinations of equipment and consequently this was not incorporated. In addition it was considered that the recommended testing of the anaesthetic machine by the anaesthetist before use would be sufficient to ensure the safe functioning of the machine.

At the close of the pilot phase, the title of the document was amended, consistent with the broader suite of ANZCA professional documents.

SUMMARY

Anaesthetic machines are fundamental to anaesthesia and have continued to evolve in sophistication and functionality, as well as diversity and complexity. This professional document seeks to ensure that the minimum standards keep pace with advances in technology, and to assist in selecting, maintaining and replacing anaesthetic machines.

DOCUMENT DEVELOPMENT GROUP

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CONSULTATION

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The following were also consulted:
Faculty of Pain Medicine Board
ANZCA Trainee Committee
ANZCA regional/national committees
Australian anaesthetic machine manufacturers and distributors

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