Re: 2013-02/001

22 January, 2013

Standards Hub
Australia
GPO Box 476
Sydney NSW 2001
AUSTRALIA

Tēnā Koutou

AS/NZS 4187 Draft Reprocessing of reusable medical devices in health care service organisations

The New Zealand Nurses organisation welcomes the opportunity to comment on the above standards for health care. NZNO is the leading professional body of nurses and nursing union in Aotearoa New Zealand, representing over 46 000 nurses and health workers. Te Runanga o Aotearoa is the arm through which our Te Tiriti o Waitangi partnership is articulated. Our members include nurses, midwives, students, kaimahi hauora, health care workers and allied health professionals.

We have consulted with relevant members and staff, including Alison Stewart and Sue White who represent Aotearoa New Zealand of the H-023 Committee updating AS/NZS 4187; we have also discussed some technical aspects with other colleagues.

In general the revised standards are supported, in particular for:

- minimum standards being brought into line with ISO and European standards (though we note the latter are not uniformly implemented throughout Europe),
- the stated imperative to "focus on reuse considerations" - NZNO strongly supports the responsible and efficient use of resources; and
- advice regarding ways to progress transition to best practice.

Two issues have been raised with regard to medical equipment which we bring to your attention: the labelling and testing of medical devices which, in some cases, may be misleading and therefore put New Zealand nurses at risk under the Health Practitioners Competence Assurance Act (2003) (HPCA Act), and the lack of enforced standards for crate weights in New Zealand for sterilisers, which NZNO's College of Emergency Nurses (CEENZ) has raised as a health and safety issue.

Labelling and Testing of Medical Devices

Under the HPCA Act all regulated health practitioners are responsible for their professional practice which includes ensuring that any medical equipment used has been correctly maintained as is safe to use. Nurses use, and educate consumers to use, a wide range of medical equipment and largely rely on the periodic inspection labels to verify that the equipment/device has been inspected and is both safe to use and performs its function.

We understand that because of changes to standards regimes, notably the revised AS/NZS 3551, some equipment may be labelled when only part of the testing, for example, for electrical *safety*, has been carried out, potentially giving the impression that the equipment has been fully tested and is confirmed as *operating* correctly. This is not uncommon - medical devices are still tested to AS/NZS 3760 and/or for electrical safety only and there is an allowance for some medical devices (AS/NZS3551 Section 10 Assessment intervals paragraph five) to be untested after the initial acceptance testing, following a documented risk assessment. In these instances, the operator has no way of determining what devices this applies to, or a safe life expectancy of the equipment. The lack of standard labelling, which has been omitted from the new standard, exacerbates the risk of harm due to error, and of nursing and medical practitioners being held liable if an incident occurs in which a medical device has not been correctly maintained.

To reduce the risk of both patient and practitioner harm, NZNO **recommends** that any potential ambiguity from labelling be addressed, notwithstanding previous failed attempts to arrive at a single, standardised label. We note that AS/NZS 2500 2004 states that the operator should confirm that the equipment has a current periodic inspection label, and we believe that this should incorporate all aspects of safety and operation for medical devices. A test label should only be attached to a piece of medical equipment if it has been determined that the equipment is both *safe* to use in accordance with AS/NZS 3551 and is *operating* as intended.

Crate Weights

The maximum tolerated weight for crates in Australia is seven kilograms, and a five year plan for phasing out travel bins requiring lifting from the floor has been implemented. By contrast, nurses in Aotearoa lift crate weights of up to 15 kg; theatre nurses who have reviewed the weight of surgical instrument crates in Canterbury hospitals found that such particularly heavy crates comprise about half those lifted daily. Currently there is no standard safe way of identifying heavy crates - stickers have been unsuccessful because they are easily detached - and this constitutes a significant health and safety risk. A report to the national committee of the Perioperative Nurses College of NZNO (PNC) which reviews international standards for maximum crate weights, which vary considerably and are inconsistently enforced, recommends that **recommends** that urgent attention is given to mandating and enforcing the 7 kg maximum crate weight standard in New Zealand as well as Australia. NZNO supports this recommendation.

In conclusion NZNO recommends that you:

- **note** our support of the draft standards
- **note** that there is a potential for ambiguity in current labelling standards for the safety of medical devices which put both consumers and practitioners at risk;
- **agree** that a single standard labelling system for the safe use and operation of medical devices needs to be developed and implemented throughout Australasia;
- **note** the disparity between maximum crate weights tolerated in Australia and in New Zealand; and
- **agree** that a standard maximum crate weight of 7kg should apply in both countries.

We trust the above is useful and would be happy to provide further information if required. Once again, thank you for the opportunity to provide feedback.

Nāku noa, nā

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