Hornsby RSL

Wow, what a day - full of useful information about the AS/NZS4187:2014, Product Families and validation of steam sterilisers and washer disinfectors.

The morning began with registration and it was wonderful to see some new members as well as valued delegates wanting to learn more about validation of steam sterilisers & washer disinfectors & the development of product families – more importantly, validating the variety of product families we are responsible for processing.

Andy Gay General Manager & consultant for 'Process validation & Design', previously known as Steriliser Validation Australia. Andy has an Engineering background and his experience in health began in 1987 when he worked in the Public & Private sector over 18 years. He began his consultancy work for the sterilising industry in 2005. He has contributed to the development of AS/NZS4187:2014; represented Hospital Engineers on the HE028 (Australian Standard) and ISO/TC198:1,3,6 & 13 – 3 being for steam sterilisers, 13 being for washer disinfectors.

WHAT'S NEW IN AS/NZS4187:2014?

-the language and layout...the terminology and layout of the standard is different to previous. Finally 'Quality Management' is at the beginning of the standard – where it belongs. This is a critical component of the standard and forms a framework for compliance requirements. The standard talks about Product Families, Reprocessing Agent Characterization, Process and Equipment Characterization. Andy provided a brief explanation of these terms.

-adoption of ISO standards...the AS/NZS4187:2014 provides guidance to Reprocessing of Reusable Medical Devices in Health Service Organisations for the Australian and New Zealand sterilizing industry. It mirrors up to 22 ISO standards and some EN standards. The AS/NZS4187:2014 must be read in conjunction with the relevant ISO standards.

VALIDATION OF PROCESSES:

The message of the day emphasized the need for every part of medical device reprocessing must be tested and validated.

To enable this to happen effectively, medical devices need to be categorized into product families. ISO/TS17665-3 extensively explains how to develop product families. Testing should be done to validate each product family.

-automated cleaning processing...there is an emphasis on validation of automated washer/disinfectors, taking into consideration the design of instrumentation and evidence of the AO value of thermal disinfection. Efficacy of the cleaning process in addition to thermo-metric testing to ensure thermal disinfection of equipment and instrumentation for staff and patient safety.

-sterilization...validation of our steam sterilisers is not new, each year we know that validation must happen. Traditionally, validation has consisted of differing load types ie. heavy and mixed loads are normal testing criteria. Consideration of instrument design and material composition must now be identified and tested, as evidence has shown that some materials such as plastics and silicones require additional holding times to achieve sterilization – in particular for cannulated instruments.

It was interesting to learn that low temperature sterilisation does not yet have a standard of its own, hence the preference for steam sterilization where possible.

Evidence of validation should also include but not be limited to packaging procedures, including sterile barrier systems, delivery systems and storage areas.

Andys' discussion left delegates inspired and thirsty for more information about requirements for the AS/NZS4187:2014, validation and the development of Product Families.

Delegates were asked for topics of interest they would like to see workshopped in the future. No issue is too small to consider.

SRACA NSW will be hosting a workshop in Ballina on April 1st, 2017.

Delegates were informed that the Clinical Excellence Commission is working on a new compliance audit tool for the AS/NZS4187:2014. They have also issued an Advisory Notice for compliance to the AS/NZS4187 – this should have been received by each Health Service Organisation-the link has been provided for your information.

https://www.safetyandquality.gov.au/publications/advisory-a1603-reprocessing-of-reusable-medical-devices-in-health-service-organisations/

A big thankyou to Hornsby RSL for their outstanding service and traditional Christmas lunch on the day – it really was delicious and enjoyed by all.

An extra big thankyou to Andy Gay for making time in his busy schedule to share his expertise in AS/NZS4187:2014 and introduction to Product Families – the information provided is valued and greatly appreciated.

On behalf of the SRACA NSW Committee, I wish you all a very Merry and safe Christmas with your families and loved ones

Tracey Worthington

Education Officer – SRACA NSW