NEW ZEALAND STERILE SERVICES ASSOCIATION
Te Ratonga Whakahoromata Taputapu o Aotearoa

Supplyline

AUGUST 2016







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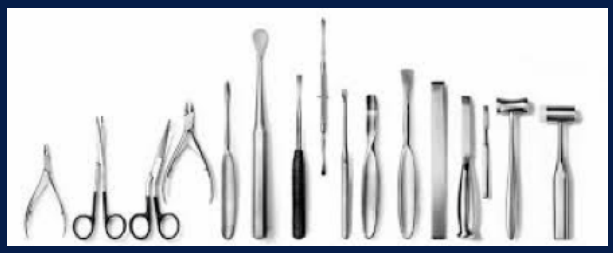





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Editor's Note

Greetings everyone to the penultimate issue of the year. The conference is nearly upon us and we will soon see the hard work and preparation of the organising committees hard work come to fruition. (Nicki Quested deserves a very special mention for securing such fantastic presenters and the tireless work she has put into this year's conference). I hope you will all get the opportunity to attend at least one of the days to hear some of the excellent presentations that are arranged. If not, I hope to publish some of them the Supplyline issue following the conference so we can all benefit from them.

I have been receiving some brilliant feedback; thank you all who have taken the time to contact me. Some of the suggestions I will have to take to the executive for approval but I will hopefully be able to implement them in 2017.

Two members of the association that I have been speaking with have really sparked some interesting topics of debate for me. With the first member our conversation was left with a question "Do I expect too much?" This really made me think about what we expect from work colleagues, the healthcare provider we work for and how we work within a multi-disciplinary health care team. So I would like you to think of your expectations and whether they are realistic and what expectations others have of you and are they fair?

The second member asked me how do we increase knowledge within a work environment and should we be allowing team members time off to read items such as Supplyline? Again this leads me to a question; who should take responsibility of extra training for Sterile Service personnel? I ask the question should it be the health care provider you work for or a personal responsibility.

In the last issue, the article 'These 3 Questions will Immediately increase your Emotional Intelligence' by Justin Bariso has really got me thinking about how I approach my daily working life and several times I have asked the questions Does this need to be said? Does this need to be said by me? And Does this need to be said by me now?

That's a lot of questions! Hopefully it gets you thinking and I'd be interested to know your thoughts.

President's Message

Hello everyone.

I really cannot believe that it is nearly conference time again. My staff is asking me when I am putting out the Xmas roster and already my grandchildren are saying that it will soon be Xmas. Honestly I don't think that I have recovered from last Xmas yet.

It is an exciting time, the NZSSA annual conference being held in Auckland in September will soon be upon us. We have an excellent programme and line-up of speakers including Martin Williams from the UK and Sharon Green–Golden from the USA. If you have not had the privilege to hear these two excellent speakers before then you really need to come to Auckland and hear them talk. I have heard some manager's state that they are foregoing Auckland in order to attend the WFHSS congress in Brisbane. However Auckland is not all about managers, it is about the technicians and their learning also, so we do hope to see a lot of your team members attending.

The WFHSS will be held in Brisbane in October and all the arrangements are in place for the scholarship winners to attend. Two NZSSA members have been selected to present at the Brisbane Congress. They are Alison Stewart and Mohammed Al Shadiefat. Well done to both for being selected.

In June Martin Bird coordinated a meeting for NZSSA members in Dunedin. I attended along with Alison Stewart who presented on the standards. There was an excellent turnout with technicians travelling from as far as Invercargill to attend.

Then in July Sue Woods organised the leaders forum in Christchurch. We had leaders from as far as Northland attend as well as the South Island members.

I presented on the proposed changes to the registration criteria and Alison again presented on the standards. I was impressed by the numbers of questions and the interest in the topics. The question that was top of everyones list was "I am constantly being told by sales persons that I have to do this or that before December 2016 or I shall not be complying with the standards". The answer is "please show me where does the standard state you must comply". Where the standard states "Shall" then it is mandatory, otherwise most statements are recommendations. Perhaps it is an opportune time to reread the standard.

What I did get from these two meetings is there is a real need to get out and about to meet our members who are not in the main centres. Therefore next year we are planning to hold a forum in Gisborne and leaders meetings in Auckland and Christchurch. I would love to get out to meet more of you in your home regions and workplaces. Therefore if you want your executive to visit you please email me and I will try and get either myself or one of the team to come along.

This edition of Supplyline is about highlighting our hardworking technicians from around the country. We could not do what we do without you.

I look forward to seeing you all at the conference in Auckland.

Shelagh Thomas

President NZSSA

Upcoming Events

Lower North Island Meeting

Venue: Wakefield Hospital Education, 3rd Floor, Florence Street, Newtown, Wellington
Organisers: Kerry Nicholls, kerry.nichollos@wakefield.co.nz, Leonie Jack, leonie@intermed.co.nz
Sponsored by: Intermed
Dates: 5th November
Time: 0900 – 1300

These meetings are for anyone involved in reprocessing reusable medical devices. The agenda includes presentations, activities and networking so not time for snoozing! If you are based in the lower North Island region or feel like a weekend in Wellington you are most welcome to attend. Attendance is free.

Networking Meetings

Venue: Colonial Court Motel & Conference, 305 – 307 Fitzherbert Avenue, Palmerston North (accommodation available at the motel)
Organisers: Shirley Newport, shirley.newport@gmail.com, Sheryll Chivers, sheryll.chivers@gmail.com
Sponsored by: Protec Solutions
Dates: 26th August, Christmas Meeting TBC
Time: 1730hrs - 2100 approx

These networking meetings are a great opportunity to meet people in the sterilizing industry and to ask questions and discuss topics of interest. A certificate for two hours education is given at the meeting. Bring along your questions and discussion topics, attendance is free. It is BYO drinks and nibbles and dinner is ordered from a local restaurant and the cost divided between attendees.

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HALYARD

FORMERLY KIMBERLY-CLARK HEALTH CARE

Lessons learnt: Set up of a new reprocessing department Macquarie University Hospital, Sydney, Australia

Rael Castillo
SSU Manager at Macquarie University Hospital, Sydney, Australia

Lessons learnt: Series 1. Setting up a new SPD, what's in it for us as reprocessing leads: IFUs, equipment and instrument traceability software.

I was fortunate enough to set up a new reprocessing department. I knew it would be challenging. Literally a week after commencement on the role, instantaneously the respect for my mentors has grown exponentially.

One of the most intriguing issues that struck me was the IFUs. I was setting up our Instrument Traceability System, which at some point in time I will discuss in detail in the next series or so, and it struck me so hard.

The complexity of the medical device, the technological advancement, wide array of structural composition, specialised functionality check requirements, maintenance checks among others.

It is with strong conviction that we have to rely on ISO: 17664 Sterilization of medical devices—Information to be provided by the manufacturer for the processing of re-sterilizable medical devices. Yet we have challenges sourcing this sometimes, I was lucky that the reps at this point are compliant enough for obvious reasons, leads me to believe this unequivocal partnership is crucial in delivering expectations. In this part of the series I will discuss issues that I encountered whilst I was entering data on my instrument traceability system. Please note that all the information is set up in the system based on the recommendation of the individual IFUs.

Interesting to note:

- "It is the responsibility of the healthcare facility to validate Cleaning (decontamination), Disinfection and Sterilisation (both process and equipment) to attain a level of quality that is safe for patient reuse. So yes we did, but first and foremost we have to identify the demands of our inventory, then we can set the parameters on our equipment for appropriate cycle types (within acceptable limits- I will discuss at another series) and processes for validation.

- Most Reusable Medical Devices (RMDs) have both manual and automated decontamination recommendations validated in situ (I am not aware of anything validated by any RMD provider outside the comfort of their own lab). I would be happy to know. So now you can have the ability to choose options and take into account the capital equipment available for use. Most RMDs can withstand the rigors of a validated washer disinfector.

- Items that are able to withstand automated (washers/disinfectors) washing have specific recommendation of detergent use, concentration, pH, length of all wash stages, temperature and exposure times etc. which are all validated in situ. This means you end up buying the same Chemistry as per recommendation or go to manual cleaning/decontamination, 99% of the time you end up with the latter simply because these Chemistries are not available locally. Remember you need to validate your process.

- RMDs have numerous sterilization process recommendations. For Steam (Temperature, Pressure, Temperature): look for the terms “MUST NOT EXCEED (134C or 121C....)”; MUST NOT EXCEED (203kPa...) “MINIMUM OF (3, 4, 8 minutes.... exposure time)”. Look at the finer details; this will be a basis of having to identify what cycles you would require operationally. Refer to ISO 17665 Sterilization of health care products—Moist heat, ISO: 17665-1 Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices and ISO/TS: 17665-2 Part 2: Guidance on the application of ISO 17665-1. Recommendation as per IFU is set in Traceability software.

- Temperature, pressure and moisture sensitive items go through low temperature process. Read ISO: 14937 Sterilization of health care products—general requirements for characterization of a sterilizing agent and the development, validation and routine control of sterilization process for medical devices. Recommendation as per IFU is set in Traceability software.

- Usage (is it actual patient use and/or reprocessing), expiry dates, maintenance schedules, lifespan..... Information is set in Traceability software.

- Functionality checks like electrosurgical insulation, continuity, etc. Sharpness, angle mechanism, assembly and disassembly if part of a whole. Information is set in traceability application.

- Among others what is the common denominator is setting up the information in your Instrument traceability system. Now you have the ability to identify the requirements for individual RMD in the report, essentially these processes and cycles need to be in place on all equipment. All reprocessing equipment including sinks, washers, cabinet dryers, sterilizers, biological incubators must be linked to the Instrument tracking software, for your ability to track a device live at any time. Also too the «footprint» is established in all stages of reprocessing, releasing protocols, reporting, monitoring among others serves you well. Interface can be facilitated by IT guys and equipment providers. You can also identify here, complex devices and link staff competency for reprocessing role structure.

- Then you’ll have for example: Manual cleaning and automated cleaning or a combination of both for stage 1. You will know you can have a neutral, enzymatic, mild alkaline for your manual cleaning and more potent chemistries and additions for the automated. You will need cleaning implements for your manual wash like medical air gun, leak testing, flushing, and the lot. You will perhaps need to add to the drying time of instrument cycles on your Neurology and Orthopaedics devices and all the basic, MIS, anaesthetic, hollowware, gentle, utensil cycles and additions as required; now validation and thermometric measurements will be in place. Also too, your heat labile semi critical devices that need to be high level disinfected will be identified. Verification of the manual cleaning must be in place; to monitor this I use ATP bioluminescence which can be used on automated process as well with reporting capabilities linked to your Instrument software.

Lessons learnt: Set up of a new reprocessing department Macquarie University Hospital, Sydney, Australia cont'd

- You will have a list of the cycles required specially for your steam sterilization. You will now need to "group" your devices according to requirements of reprocessing. If no information is available, you should do your own penetration times for specific groups. For example, a cannulised Hex screw driver will take between 7 - 11 minutes to reach 134 Celsius in its inner core, if the recommendation was 3 and a half minutes at 134 Celsius, simply means 3 and a half plus 7 (if in your study it took that amount of time to reach 134) = 10 and a half minutes of exposure time to 134 C. Similar instruments to this nature will be grouped accordingly. Group products according to data set in the Instrument tracking system if available, if not manually set this up. You'd be amazed you comply in part with ISO 17665-1 and ISO 14937. Continue to list all cycles that you require to validate. Remember validation is according to your own federal compliance as guided and according to the demands of your inventory.

- Low temperature sterilization is pretty straightforward and the device manufacturer can help you with this. Inventory requirements must be given consideration in choosing the right low temperature steriliser.

I have tried my best to recollect what I have done but my 50 odd summers would have its toll. I just decided to share this information after a while and am happy to discuss in detail what you need to verify at my work email: roel.castillo@muh.org.au

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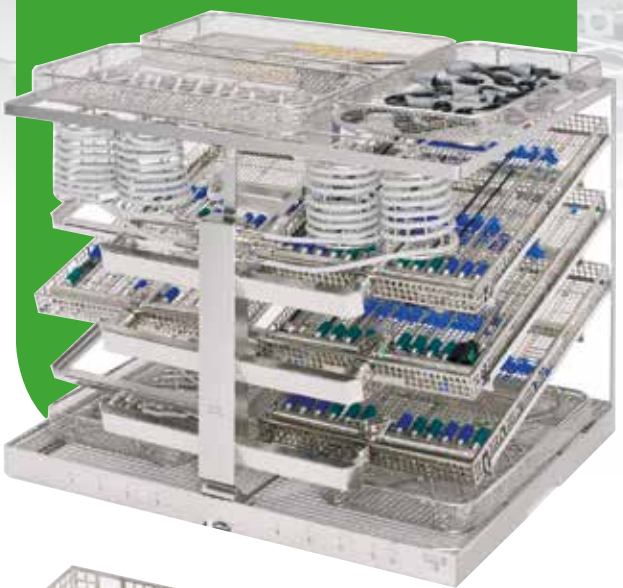

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The Birth Of The Internet Of Labs (IoL)

Arthur Trapotsis
CEO
Consolidated Sterilizer Systems

www.consteril.com

The Internet of Things (IoT) is all around us. From adjusting thermostats online, to starting a car from an app, to viewing security camera video on a website, internet connected devices have already revolutionized the consumer market.

If you're not familiar with IoL, think of it as a series of interconnected devices that are able to communicate with each other and transfer data back and forth over a network. This data, which is easily accessible by humans, is invaluable in today's ever-evolving tech world by allowing everyday devices and tasks to become more automated and integrated with the natural pace of our lives.

While IoT has rapidly permeated all types of consumer products, up until recently, it has not integrated with laboratory equipment. This is not surprising as lab equipment technology advances much more slowly than that of consumer goods. But things are changing!

The Internet of Things in laboratories, or as I like to call it, the Internet of Labs (IoL), is about to take off — and in a short time all laboratory equipment will be connected to the cloud. This type of "Smart" equipment will enable researchers to be more productive by allowing them to remotely perform experiments, run processes, monitor tests, collect data and more.

From my perspective (a lab equipment manufacturer who is about to launch a cloud-connected device) I see the many useful things that can come from IoL. For example, data currently collected from our devices in the form of "paper printouts" will soon be accessible via computer, tablet and smartphone from anywhere in the world. Imagine all of the data from your lab equipment available when you need it, where you need it. The pace of research and development is bound to speed up.

Using our cloud-connected steam sterilizer as an example for what's possible, the following is a list of some of the incredible benefits that can be expected as a result of the Internet of Labs.

1. Increased Productivity — Productivity gains are realized by minimizing downtime, reducing waiting time and allowing researchers to work on multiple pieces of equipment remotely. Many laboratory personnel utilize sterilizers that are in another room or on another floor and are unsure when/if the sterilizer cycle has been completed. Believe it or not, but simply checking (i.e. walking to and from the autoclave) can take up quite a bit of time and interrupt other workflows. IoL allows for alerts (e.g. Cycle Over) to be sent to a desktop or mobile device.
2. Improved Traceability — Our clients are often interested in knowing how many times the sterilizer has been run in a given month and by whom. The Internet of Labs allows visibility into this valuable data, putting it right at your fingertips.
3. Eliminates Wasteful Work Practices — Implementing a LEAN culture in a laboratory is one thing, but having the tools in place for continuous improvement is another. The Internet of Labs can help with LEAN initiatives in that it eliminates wasteful processes within a laboratory setting – processes such as the aforementioned unnecessary movement from room to room and collection of wasteful sterilizer printouts.
4. Workflow Advancements — Need help scheduling sterilizer usage or setting up maintenance? Cloud-connected sterilizers will help reduce unexpected wait-time by allowing researchers to schedule equipment use (think virtual calendar). In addition, maintenance reminders will alert researchers about PMs ahead of time, allowing them to be proactive about maintenance instead of reactive. Once scheduled, simply upload the maintenance dates into the aforementioned virtual calendar and everyone is on the same page.

As the idea of the Internet of Labs continues to evolve, laboratories must continue to adapt and prepare for future changes to their processes. Hang on tight and don't be the last to get connected. If you have any questions, or further ideas about the Internet of Labs, please don't hesitate to contact me.

NZSSA Annual Conference 2016
Pullman Hotel Auckland
21 - 23 September 2016, Wednesday to Friday
IN OUR OWN BACKYARD

The focus this year is New Zealand, the issues and what we can use from experience abroad to enhance our environments. The city of sails welcomes you to the 42nd NZSSA annual conference. Auckland is place and the venue is right in the heart of the city. We look forward to seeing your there and hopefully you can stay on and enjoy some of the sites of Auckland over the weekend.

WEDNESDAY 21 SEPTEMBER

Trade Exhibition Opening
Regatta Rooms, Pullman Hotel
1800 – 2100 hours
Once again our trade exhibitors are solidly supporting the NZSSA and the sterilising industry of New Zealand. Make sure you are there to see what's new and make the most of comparing products and broadening your understanding of the products and their purpose.

THURSDAY 22 SEPTEMBER

Conference Dinner
Ballroom, Pullman Hotel
1800 hours – Midnight
This is going to be a fun filled evening celebrating New Zealand. There will be a photo booth as well as a band following dinner. Dress for the evening – something representing New Zealand culture.

Confirmed speakers:
Key note speaker: Urzilla Carlson
International speakers:
Martin Williams, Decon Solutions UK
Sharon Greene-Golden, USA IACHSM Past President
Martin and Sharon have spoken in NZ previously and their acceptance to present again is wonderful.

The programme is under development and will include:
Exhibition opening Wednesday
Plenary sessions and panel discussions Thursday and Friday
Annual General Meeting Friday
Conference Dinner Thursday

Registration:
Registration costs have been retained at 2015 values except for the early-bird Member full registrations. A $30.00 discount has been applied this year for these registrations if received and paid before 7 August 2016.

Watch the website for updates: www.nzssa.org

REGISTRATION FORM
42nd Annual NZSSA Conference
21 - 23 September 2016
Pullman Hotel, Auckland

Program information: www.nzssa.org

First Name: _____ Last Name: _____

NZSSA member: YES / NO (circle one) **Membership No**. _____

Hospital / Company: _____

Role / Position: _____

Mailing address: _____

_____

Contact phone no: _____ Email: _____

Special dietary requirements:

Do you have any special food requirements (eg. diabetic, gluten free, vegetarian, cultural) **YES / NO** (Circle one)

If yes, please state your requirements:

Registration & Function Details: (Tick all that applies including when attending functions with no cost)

	Standard (Up to 7 August)	Late (8 August onward)				
NZSSA Member (Membership number must be provided & membership must be current at the time of the conference)						
2 Day registration	☐ **$450.00**	☐ $550.00				
1 Day registration	☐ **$240.00**	☐ $275.00	☐ Thursday	☐ Friday		
½ Day registration	☐ **$120.00**	☐ $137.00	☐ Thursday	☐ Friday	☐ AM	☐ PM
Non NZSSA Member						
2 Day registration	☐ **$580.00**	☐ $665.00				
1 Day registration	☐ **$290.00**	☐ $332.00	☐ Thursday	☐ Friday		
½ Day registration	☐ **$145.00**	☐ $166.00	☐ Thursday	☐ Friday	☐ AM	☐ PM

Social Events (no penalty for late registration applies to these costs)

*Welcome & Exhibition Opening	☐	Partner ☐ $45.00
*Conference Dinner (Thursday)	☐ $80.00	Partner ☐ $80.00

Registration Total $_____

* If only attending the welcome and / or dinner you need to pay the cost identified.

Payment methods:
Cheque: made payable to: NZSSA Conference
Credit Card: via the link on the website
Electronic Transfer: Transfer to Westpac NZSSA Account **03 0156 0173557 – 00**

- Reference: your surname
- print off a copy of the transaction and enclose with the Registration form

Invoices for conference costs will be issued on request. Please contact NZSSA Treasurer.
Registration Forms and payment or details of payment should be sent (hard copy or via email) to:
NZSSA Treasurer, Alison Stewart, 28 Brighton Street, Island Bay, Wellington 6023 or Email: acestewart28@gmail.com

A full refund, less an administration charge of 10%, is given for cancellations received in writing **by 9th September 2015.** After this date, any refunds will be at the discretion of the Organising Committee.

9 August 2016

Dear NZSSA Member

The Annual General Meeting (AGM) of the New Zealand Sterile Services Association (NZSSA) will be held at the NZSSA annual conference in Auckland on Friday 23 September, 8.30am at the Ballroom, Pullman Hotel. A working breakfast will be served to all members attending the AGM.

The Agenda, remit and supporting information that will be voted on at the AGM are included here. If you have any items you would like added to the agenda please email the Secretary, Jenny Carston jenny.carston@bopdhb.govt.nz , by 7 September. 2015 AGM documents are on the NZSSA website for your reference. A limited number will be available at the meeting.

If you are unable to attend the meeting you may still have a vote by nominating a proxy to vote on your behalf. Your proxy must be a current member of the NZSSA. If you wish to nominate a proxy please complete the form below and give it to your nominated proxy who must then give it to the NZSSA Secretary prior to the AGM.

If you are not able to attend the AGM, apologies can be sent to the secretary before 7 September or can be lodged at the meeting by your proxy.

We look forward to seeing you in Auckland. If you have any questions please do not hesitate to contact me.

Kind regards
Jenny Carston
NZSSA Secretary

Encl. proxy form
AGM 2016 Agenda & remit

NZSSA PROXY VOTING FORM

I …….. of ……

Being an Ordinary member of the New Zealand Sterile Services Association Inc.

Hereby appoint ……. (name and member no.) as my proxy to vote for me and on my behalf at the General Meeting of the Association to be held on the 23rd day of September 2016.

And at any adjournment thereof

As witness my hand this ……..day of …….. 2 ……

Signed ……

NZSSA Membership number …….

To be handed to the NZSSA Secretary prior to the AGM

New Zealand Sterile Services Association

Annual General Meeting – 2016

Date: **Friday 23rd September**

Time: **0800 - 0900**

Venue: **Ballroom, Pullman Hotel, Auckland**

Agenda

	Topic	Presented by
1.	Apologies:	
2.	Minutes from 2015 AGM	
3.	Matters arising from minutes of 2015 AGM	
4.	Correspondence sent and received	Jenny Carston
5.	Presidents report	Shelagh Thomas
6.	Secretary's report	Jenny Carston
7.	Treasurers report	Alison Stewart
8.	Auditors report	Alison Stewart
9.	Remit for change of name	Shelagh Thomas
10.	Conference 2017	Nicki Quested
11.	General business	

REMIT

Proposed by:	**Seconded by:**
Shelagh Thomas NZSSA President	Martin Bird Executive Member

Remit:

Amend the name of the Association to New Zealand Sterile Sciences Association

Explanation & statement of case:

The Association has not had a name change for a long time. There have been previous discussions about changing the name but when this has been proposed the suggested names were not felt to describe our Association or industry appropriately. Since these discussions there has been a move toward sterilising technology associations and the reprocessing of reusable medical devices being recognised as part of the sciences.

In line with this growth of recognition of the industry and the name change of the WFHSS to World Federation for Hospital Sterilisation Sciences I feel it is an appropriate time to adjust the Association's name by changing the word Services to Sciences;

New Zealand Sterile Services Association

To

New Zealand Sterile Sciences Association

This retains the current anachronism, NZSSA, which is seen as a positive by the current executive body and ensures the Association remains readily recognisable both locally and internationally. This also means that there is a low level of redevelopment of branding.

I, Shelagh Thomas, therefore put forward the motion that the name of the association be amended to New Zealand Sterile Sciences Association with relevant changes to branding made.

This remit to be sent to:	**Date Submitted:**
Jenny Carston	**17 June 2016**
NZSSA Secretary	**Who submitted the remit:**
jenny.carston@bopdhb.govt.nz	Shelagh Thomas

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Problems associated with reprocessing of reusable implants*

K.-P. Schneider

reprocessing of reusable implants gives rise to manifold problems. often, the implementation of the applicable guidelines (e. g. the recommendation jointly compiled by the robert Koch institute [rKi] and the federal institute for drugs and medical devices [BfArm], the medical devices directive [mdd] and the medical devices operator ordinance [mPBetreibV]) causes difficulties in the overall reprocessing process employed for reusable implants, and can detract from the high quality of the results aspired to. Unfortunately, not all manufacturers' instructions yet meet the current guidelines and recommendations, thus hampering reprocessing of implants.

the situation is further compounded by the reprocessing problems arising in the washer-disinfectors (Wds), in particular with regard to perforated implants or implants with blind-end bores. here the manufacturers of washer-disinfectors equipped with such loading trolleys are also called upon to assure validated reprocessing based on a quality management system. this they can do, for example, by fitting Wds with nozzles that, in terms of flexibility and density, are tailored to today's increasingly more complex implants.

the manifold nature of implants calls for a large body of expertise, something that can only be assured through personnel training. Besides, there is the issue of keeping a record of the number of reprocessing cycles or of whether it is more advisable to switch over one's system, if feasible, to single-use devices. however, since in our institution we continue to use reusable implants, getting to grips with these processes continues to be a challenge for all staff members.

if one wants to opt instead for the alternative solution of single-use implants, that choice is partially restricted since not all implants are available in sterile form. that decision also has implications for the logistics as a whole, e. g. greater storage space is required. there is also the issue of how to deal with resterilizable implants whose packaging has been inadvertently opened. Since there is no guarantee that both systems will not get mixed up with each other (i. e. reusable and single-use implants), the various procedural steps and instructions must be set out in the quality management system.

Such decisions have vast implications for the Central Sterile Supply department (CSSd) ranging from how to design the CSSd through choosing implant manufacturers, and their reprocessing instructions, to storage and ordering logistics. this article now describes the problems encountered in everyday practice and how to overcome them.

Key Words

- implant
- reprocessing
- manufacturer's instructions
- quality management

Introduction

reprocessing of reusable implants gives rise to manifold problems. these manifest already at the time of designing a CSSd, continuing with reprocessing and storage of the implants. for example, successive changeover from reusable to single-use implants would cause a logistical shift from the CSSd to the surgical department (or).

this publication is aimed at giving all personnel entrusted with medical device reprocessing an insight into the problems associated with reusable implants, their logistics and reprocessing.

Logistics

Selection

reprocessing in its entirety should be based on a validated process. But when selecting implants, decisions on the use of the implants and the choice of manufacturer are generally made by physicians, with no thought given to reprocessing problems.

And in today's climate economic aspects must not be forgotten (tied-up capital). these play an increasingly greater role and can also have negative implications for e. g. the quality of materials and workmanship.

Storage

the warehouse or storage cabinet space should be sufficiently large since the number and variety of implants can change enormously over the coming years. in some cases the available space will be allocated, for cost or space reasons, for other purposes, giving rise later to widespread restructuring, which could incur higher costs than initially estimated.

the storage cabinets should have dust-proof closing mechanisms and, because

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* extract from a final assignment for Specialist training Course iii for managers of Central Sterile Supply departments (fht Bad Kreuznach, Germany 2011/2012)

Fig. 1: Storage cabinets

of the large assortment of implants, should be designed to accommodate different implants in a clearly organized way (fig. 1). A department-specific classification system should be devised, since implants will not be taken back in the event of damaged packaging.

When changing over from reusable to single-use implants, a tray or packing list must also be drawn up in most cases, and the cabinets in the CSSd inspected. this means that not only is the space requirement, but indeed the entire logistics, now shifted from the CSSd to the or.

Hygiene, disinfection and cleaning policy

the cleaning intervals for storage cabinets should be defined by the infection control specialist in the hygiene (infection control), disinfection and cleaning policy. Competencies should be regulated in the quality management manual.

Personneltraining

in view of the large variety of implants and ongoing developments in medicine, CSSd staff are finding it increasingly more difficult to keep abreast of such trends. therefore, regular training for staff is indispensable. in general, ongoing training to keep up to date is provided only for or staff and not for their CSSd counterparts since reprocessing issues are not the main focus of such training courses.

Reprocessing of implants

Manufacturer's instructions

important criteria for reprocessing include the manufacturer's instructions, which, however, do not always explain reprocessing in a satisfactory or detailed manner. A pan-european regulation on the content and structure, such as e. g. definition, process description, would greatly enhance several aspects of reprocessing.

in our institution it is predominantly implants belonging to the firm Synthes which are fitted. Based on the relevant instructions, *all implants supplied in a sterile state must be cleaned and subjected to steam sterilization using a validated process before they are first used* (1). Since in our establishment the cabinets storing unsterile implants are installed on the clean side, the implants must be handed over on the unclean side. for this procedure to work properly, a meticulous record of consumable materials must be kept in the or.

A few quotations from the manufacturers' instructions help to explain the problems encountered:

A statement by the firm Synthes on reprocessing is revealing in this context: *Implants may be processed several times as long they are not soiled by blood, tissue, and/or bodily fluids/matter; but should be treated as single-use products (see «Single-Use Products»). Repeated processing cycles that include ultrasonic cleaning, mechanical washing and steam sterilization have minimal effects on implants. Implants should not be processed or transported with any type of soiled material* (1).

Single-Use Products: *Products intended for single use must not be re-used. Re-use or clinical processing (e. g. cleaning and re-sterilization) may compromise the structural integrity of the device and/or lead to device failure. This may result in patient injury, illness or death. Synthes does not recommend clinical processing of soiled implants* (1).

the firm Königsee explicitly states in its operating manual: *If implants had already been in contact with a patient or had been contaminated, they must not be reused* (2).

if one takes for example the case of a bone operation, one must ask oneself how the implants can remain free of substances such as blood, tissue and/or body fluids, since in some cases they are present in duplicate and the screws are stored on screw racks or on trays (fig. 2).

When withdrawing screws intraoperatively from a screw rack, it is virtually impos-

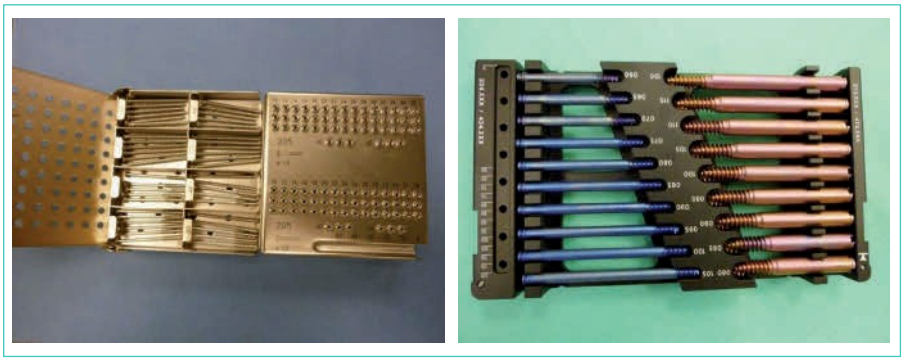

Fig. 2: Screw rack and tray

Fig. 3: Discolorations caused by oxidation

sible to rule out contamination of the remaining screws in the screw rack, even if a screw forceps is used.
So if one proceeds according to the aforementioned instructions, then the implants should be kept fully separate for reprocessing from the instruments, and the implants that were not used, which likewise could also have been contaminated with substances such as blood, tissue and/or body fluids should, if necessary, be discarded. this in turn would mean that the Wd capacity would not be sufficient in most cases and would inevitably result in a dramatic rise in the number of batches reprocessed. Such a process would also call for an enormous amount of extra manpower on both the unclean and clean sides. Switchover from reusable to single-use implants could be an option to contemplate.

Cleaning

A validated process that complies with the pertinent standards must be used for cleaning. the reprocessing instructions generally specify a ph value, something that is stipulated for titanium and steel implants. When it comes to choosing which brand of chemical products to use, one must ensure that the specified values are observed since otherwise the implants could be damaged, with attendant liability claims. to minimize the risks of that happening, one could opt for a detergent approved by the manufacturer for all types of medical devices, such as implants, instruments and cases.
if such a detergent system that is well tolerated by the materials is used, the risk of any confusion between programmes is greatly reduced, and this also confers economic benefits such as a smaller number of programmes, something that in turn results in lower maintenance and validation costs.
discolorations are often seen on titanium implants. According to the manufacturers or the Study Group instrument Preparation (AKi), a body that deals with reprocessing issues, such discolorations are not to be confused with corrosion, being merely a cosmetic effect. these discolorations (oxidation) are generally caused by ambient conditions such as temperature, chemical substances and moist heat (fig. 3) (3). implants should be thoroughly rinsed and purged, rather than immersed in a bath, to rule out entrainment of blood residues, solid components or chemicals. there should be no organic residues, therefore the final rinse water should be of a standard similar to that of demineralized water. regardless of how implants are stored, whether obliquely, straight or fitted, the entire reprocessing process must be executed in line with the pertinent standard (eN iSo 15883).

Drying and release of WD contents

Since residual moisture (puddle formation) can build up in implants, in particular in those featuring dead-end bores, thus posing a risk of entrainment of the cleaning solution, proper storage of the implants is crucial not only for cleaning, but also for drying.
this demonstrates once again just how important it is when designing a CSSd to give some thought to the vast assortment of implants available and to which implant to choose (reusable or single use) as well as to the quality of the washer-disinfectors and their accessories.
in our institution we do not use a drying accelerator in the cleaning programme since the responsible infection control specialist has objected to this. that means a longer programme, because of the extra drying time, and this process gives rise to problems when releasing the implants because of issues with dryness.

Visual inspection/care

Visual inspection constitutes the most important and onerous process step before packing the implants. Since the screws have dead-end bores and are stored in a screw rack, it is very difficult to inspect them for integrity, with this being even more laborious in the case of perforated screws (fig. 4).
Gentle purging with medical compressed air is indispensable. Perforated screws can be inspected on the rack by shining a light through them (light source beneath the screw rack), since otherwise each individual screw would have to be held against the light to ensure their lumens are free of residues. this task is very onerous but absolutely necessary for qualified reprocessing.

Packing, sterilization and storage

implants must be packed in compliance with the provisions of eN iSo 11607 (4) and the implants must be protected against mechanical damage.

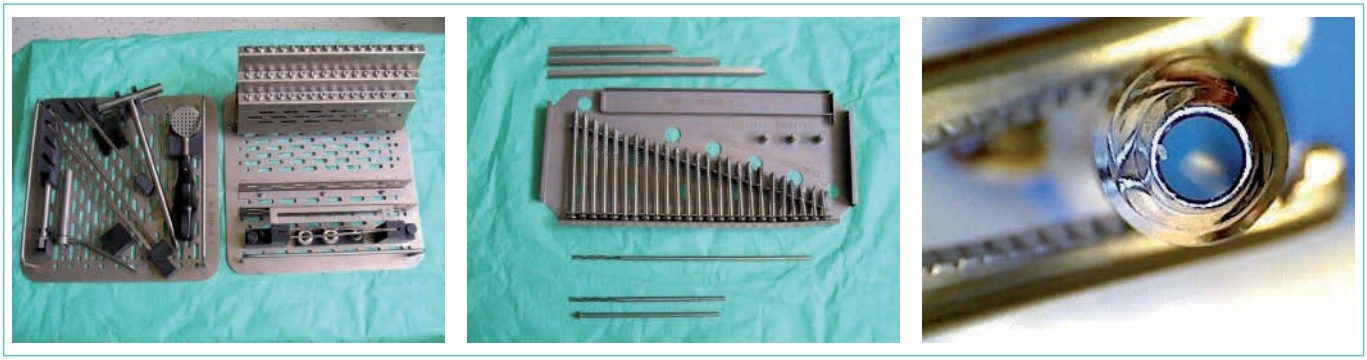

Fig. 4: Perforated screws

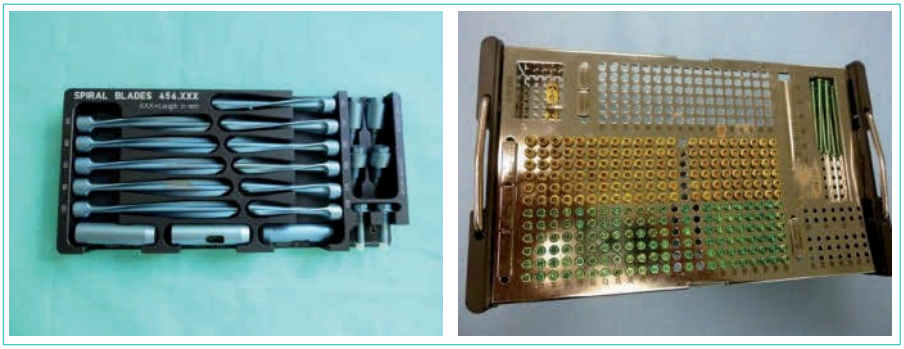

Fig. 5: Cleaning and storage trays

Steam sterilization is performed using a validated process that meets the pertinent standards, generally meaning that in effect a pulsed vacuum process (134 °C/ 5 min) is used.

As regards storage, special storage conditions apply for products labelled as «sterile». A clean and dry environment must be guaranteed, and the products must be protected against solar radiation, temperature effects and humidity. the rooms must be free of vermin. expiry dates must be checked regularly.

Special problems with reprocessing of reusable implants

Exclusion criteria

When the used instruments and implants reach the CSSd for reprocessing, it is very difficult to identify which were already used on a patient, e. g. were implanted for test purposes. equally challenging is the inspection of mixed implants since only a small sign (or an S for Sterile shown after the order number) is imprinted on the implant to distinguish between single-use and reusable implants.

Generally it is only on the clean side that implants can be excluded, since here staff dispose of magnifying lamps.

to rule out the risk of confusion, it would be helpful if or personnel would sort out the used and contaminated implants already in the or.

Cleaning problems

the cleaning and disinfection problems derive from, among other things, the manufacturer's instructions on how to deal with implants before and after delivery as well as how to position the implants on the corresponding loading trolley. Since in many cases there is no perfectly matching loading trolley/attachments to accommodate the highly diverse assortment of implants, staff need in-depth knowledge and improvisational skills. this holds true in particular for reprocessing of perforated implants, where there is a risk of foreign bodies being carried into the lumens. the smaller the implants, the greater the challenge posed by reprocessing.

there are special cleaning and storage implant trays to assure good rinsing but these can be obtained from the manufacturers only as additional options for implants (fig. 5).

Some manufacturers use plastic trays or insufficiently perforated trays, which cannot always assure adequate rinsing. When using such trays, the implants must be removed from the tray for cleaning/disinfection (fig. 6).

Perforated implants

things are no easier when it comes to reprocessing of perforated implants and implants with dead-end bores. the Wd loading trolleys are not specially designed for reprocessing of implants, such as e. g. perforated screws. for implants a large number of different diameters are generally used (fig. 7).

Being hollow bodies, all implants should (must) be connected to the respective Wd fittings for reprocessing in the Wd, to ensure thorough cleaning of lumens. most of the loading trolleys used for minimally invasive surgical (miS) instruments do not have a sufficient number of fine slide-on connectors to accommodate the large number of screws. in this regard, too, the manufacturers of the insertion trolleys could be called upon to increase the number of nozzles and the (nozzle) jet intensity.

Since a large number of procedures, with attendant risks, are used for this type of reprocessing, a pan-european regulation should be drafted, stipulating that perforated screws must only be used once to rule out as far as possible the risk of contamination to patients.

Liability risk (Example: screws)

reprocessing cycles comprise different steps such as ultrasound, steamer, mechanical cleaning and sterilization. Anyone dealing with such materials should bear in mind that frequently repeated reprocessing cycles can damage the implants.

one aspect not to be overlooked is the management of implants in the or. it is not always possible to distinguish between screws that were only briefly inserted, and then – because they are too long – immediately removed again.

Since titanium is a softer material than steel, it is also more sensitive to mechanical damage. if one takes a closer look at the screws from a screw rack, one can detect, among other things, slight grinding marks on the titanium implants. Such

Fig. 6: Plastic tray

Fig. 7: Perforated screws of different diameters

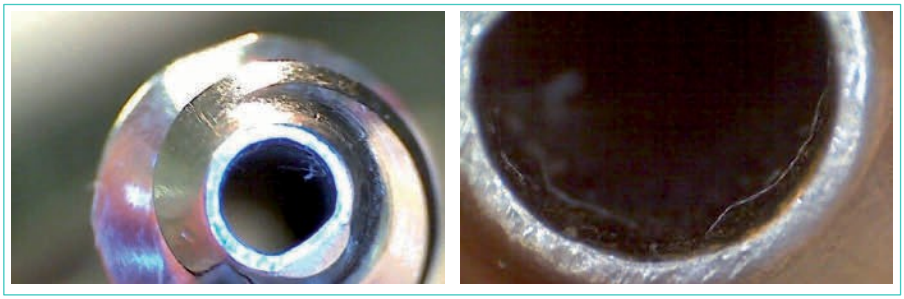

Fig. 8: 3.5 mm perforated corticalis screw from original packaging without reprocessing

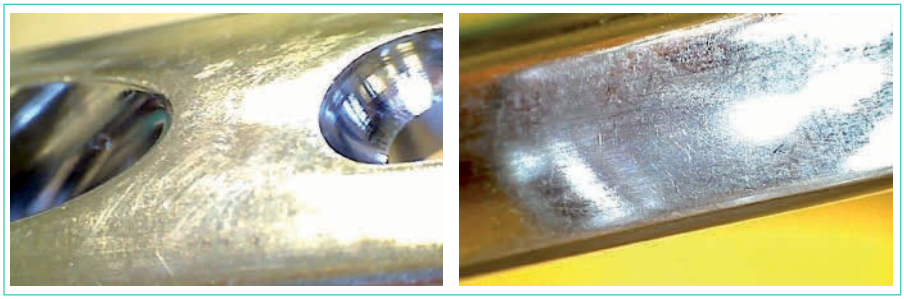

Fig. 9: Damage sustained from incorrect storage/surface damage in steel plates

screws must no longer be released for implantation.
figures 8 and 9 show damage sustained from incorrect storage, whereby some of the images were recorded using a USB microscope.

Traceability and documentation
the implants are removed from the factory packaging before they are decontaminated for the first time. the packaging features two barcodes (fig. 10; long barcode = encoded article number, short barcode = batch no.). these are of no further relevance once the implants have been removed since the reusable screws are transferred to a screw rack, and before implantation in the or they are not individually registered on the basis of the imprinted serial number. once the packaging used for smaller implants has been opened or discarded, traceability of the implants can therefore no longer be assured, since they themselves do not feature a distinguishing mark (fig. 11).
larger implants feature a batch number, via which they can be traced back to the manufacturer, but this is assured only until the time they are implanted since here no individual record is kept as is the case for single-use implants. only after metal removal is traceability assured.

it is difficult, or even impossible, to estimate the number of reprocessing cycles to which any reusable implant will have been exposed. in general, the «first in, first out» principle applies, but this is not always observed, thus creating a situation whereby there are «sterilization corpses». Where the patient is concerned, there is no way of knowing how old or new the implant is or whether it had been reprocessed once or 1000 times.
Conversely, single-use implants come in their packaging and feature a documentation number.

Conclusion

the manufacturer's instructions play the most decisive role in reprocessing of reusable implants. Unfortunately, these are not standardized and often have shortcomings.
if there was pan-european legislation and the implant manufacturers would produce only sterile, single-use implants, then the reprocessing problems would be overcome. in economic terms, all manufacturers would then have to fulfil the same preconditions, making it easier to grasp pricing arguments since certain discussion aspects, such as reprocessing, would no longer be relevant.

A switchover to single-use devices would have implications especially for the or. Because of the manifold nature of implants and of packaging sizes, more space and storage facilities would have to be allocated in or side rooms. that would mean a logistical shift and possibly also the need for increased manpower, since or staff would then also have to take charge of inspecting sterile supplies and expiry dates. regardless of which method is used, the quality must always be such that the implants will pose no danger to patients. in recent times there have been several media reports on gross abuses and fraud (e. g. breast implants), where it was the quality of the implants, and not sterility or reprocessing, which was at issue. So opting for single-use implants, unfortunately, would not always provide a 100 % solution. Where the issue of quality is concerned, we must wait and see how the market develops. ■

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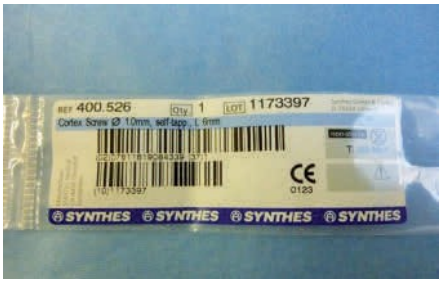

Fig. 10: Factory packaging with barcodes

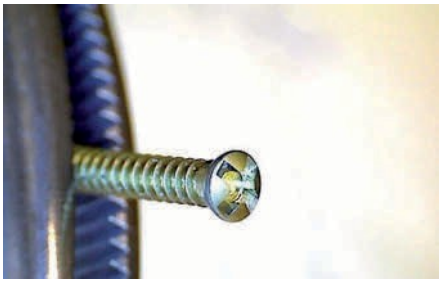

Fig. 11: 1.3 mm screw without mark, therfore no traceability

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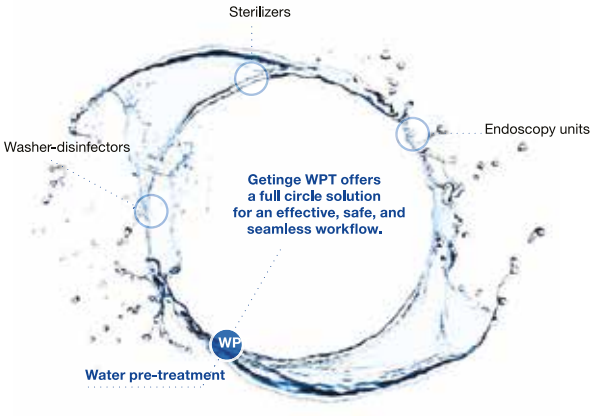

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AS/NZS 4187-2014 Reviewing Perfomance Qualification Reports

Written By
Steven Gorrie
Compliance & Review Systems Ltd

Email crs_manager@yahoo.co.nz

Over the years I have made and read and reviewed many reports and have found that through repetition it is actually easy to get one of four results. Surprisingly it is not as easy as you would think to get it perfect every time first time.

Four Results

- The perfect report. No mistakes, no problems, no errors.
- Mostly perfect. Grammar errors or spelling mistakes. Some missing detail.
- Serious mistakes and errors but the machine validation is still assured.
- Drastic failure report. It says pass but data shows failure outside of accepted parameters.

Three out of the four scenarios are not scary. Of course one of them is perfect and is what you expect and hope for each time. The fourth scenario luckily is rare but it does still happen. The remaining two are just inconvenient or annoying.

Incorrect cycle data, missing calibration sheets, adding mistakes when totalling load weights, spelling mistakes, cycle times or numbers wrong, these and many more are typical examples of what can be wrong in a report. They are not a major problem but do need explaining and fixing so that the report kept in a unit will be accurate and not cause embarrassment if read by an auditor or other person. It is obvious with the data in the report that the equipment is safe and performing the task reliably and repeatedly. If picked up in the new review process and adjusted by the provider in a timely manner it shows that the system works and the checks and balances are appropriate. If however they are picked up 6 months nine months 11 months later it shows that the system is flawed but by sheer luck and not by planning the machine was safe and the report was not correct.

The worst case however is scary, dangerous and if not caught could be compromising to operators safety, patients and theatre personal safety and machine safety. It could show that the machine is way above the temperatures required and is overdoing cooking and damaging the life span of the RMD's and could be harming the machine itself. This is bad but preferable to the other could be. It could be showing that disinfection or sterilization is not taking place and the machine is faulty and not able to recognize it. Wow what happens if this isn't picked up for 4 weeks, 6 months, 9 months or ever until next year's validation.

Ironically sometimes these reports have already been proof read and signed off by the validation company and sometimes the hospital. It can be that the report has never been read thoroughly but skimmed through or flicked through. Busy people make mistakes or just expect prior checks and balances to have worked so don't do their review thoroughly. Untrained people don't know what to look for or focus on the wrong areas.

This is why the report needs to be examined and checked by a responsible person or company that has

- The experience and knowledge to understand the information in the report.
- The work schedule that allows for a detailed examination of the report. Not just 10 minutes.
- The ability to perform this task in a timely manner. 24 hours from receipt of the report.
- The ability to see what is missing from the report and what should be there.

Plan to Succeed not Fail to Plan

Previously I have written articles and spoken about validations and the companies that do validations that have covered many areas to keep watch on. In today's modern workplaces there are many changing factors that can throw a spanner in the process,

- new technology been introduced to carry out performance qualifications almost every other year, this technology while new and innovative has some weaknesses and delays to diagnosing performance. Unfamiliarity with the equipment and its capabilities can lead to problems.

- Validation staff changing or lack of experience. The years of experience of your validation technician has a big impact on the potential quality of the report. The lack of experience creates the absolute need for a fine tooth comb through the report. A lack of experience can mean that a machine fault is not picked up until much later.

- Hospital staff assisting with the validation. They also need experience and training and the confidence to be an integral part of the validation and to keep the process pure and without compromise and to raise any concerns during the process.

- The process. With so many hospitals across the country of varying sizes and capabilities and with the large number now of equipment providers there is many different report structures and validation equipment. Not all reports actually have the correct data included or meet the requirements of national standards. Without peer review a bad process can be repeated for many years. One example I have come across is where a large steam sterilizer was validated with only a few probes where we know that a minimum of 8 is required for the chamber size and that across the country 12 probes is very common. The new standard calls for an ideal situation as the same number as when the sterilizer was first commissioned, again usually 12.

- Critical parameters, For the new standards your equipment manufacturer or supplier needs to provide you with a list of any critical parameters that are not included in your previous reports but from now on needs to be included in future reports. These are parameters that are critical to the whole process but typically not sterilizing or disinfection phases which have always been recorded.

AS/NZS 4187-2014 Reviewing Perfomance Qualification Reports cont'd

- Visual observation, remember that hospital staff should always be a part of the visual observation of dryness for sterilizer loads and cleanliness efficacy for washer disinfectors. Validation technicians should never be left alone to perform this work late into the evening or over weekends.

- Test loads. In some hospitals it is hard to set aside a truly representative load for the day or two that the validation takes. Often there are particular sets that are needed in surgery and there are not enough stock levels. For the performance qualification to be valuable it needs to truly representative of normal practice. Don't make up a heavier load than normal but also don't make up a lighter or lesser load than is normal as both are not representing normal practice.

- Timely Manner, for each hospital it may be different however my thoughts are-
  - Performance reports should be received within 10 working days maximum
  - Reports should be reviewed quickly- 24 hours to 3 days
  - A maximum delay time should be set before the machine is taken out of service ie: 30 days

WITH THE NEW STANDARDS WE ARE NOW LOOKING AT REVIEW AND COMPLIANCE

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