Sterilization in Australia

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Sterilization in Australia

Official Journal of Sterilizing Research & Advisory Council (NSW) Inc.

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PRESIDENT'S REPORT

Dear Members

Welcome to Volume 39 issue 2 of the Sterilization in Australia Journal.

The executive committee and especially David Bellamy our conference convenor have all been extremely busy with the organisation of the 2019 annual state conference. The conference will be held in September 18, 19, & 20 at NEX Newcastle, 309 King St Newcastle West 2302.

A great deal of effort has gone into the organisation of this conference with the speakers, the program, trade exhibition and the dinner. Our Committee believe it would be really wonderful to see all our members and associate members support & attend this conference, since this conference is predominantly for our members. We have kept the cost very low to try and encourage and make it affordable for all members to attend. So we really hope to see you all there. We have a masquerade theme Dinner so please be sure you wear your mask.

David Bellamy & I are the NSW representatives on the FSRACA and recently attended a face to face meeting held in WA on 23/08/19 to work with the FSRACA on a project HE-O23 standards allocated FSRACA.

Whilst we were there we discussed the Advisory AS18/07 version 2 trim number D18-28893 dated August 2019 reprocessing of reusable medical devices in health services organisation, this was issued by the Australian Commission. The FSRACA decided to draft a letter as the national body for decontamination & sterilization to the commission in regards to this advisory notice. As the standard was released in December 2014, 5 years ago and all HSO's should be moving forward

with this standard to compliance. Excluding sections 7 & 8 which are monitoring and validation we strongly recommend these two sections should very much be included not excluded. We will keep you informed of the outcome.

So as you can see we have all be very busy with sterilization business and are looking forward to some great education sessions and fun at our State conference. Hope to see you there with your mask.

Kind regards,
Lynne Noring
NSW SRACA President
02/09/19

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AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

NSQHS STANDARDS

ADVISORY

TITLE	Reprocessing of reusable medical devices in health service organisations
Advisory number	AS18/07
Version number	2.0
TRIM number	D18-28893
Publication date	August 2019
Replaces	AS18/07 version 1.0 published on October 2018
Compliance with this advisory	It is mandatory for approved accrediting agencies to implement this Advisory
Information in this advisory applies to	All approved accrediting agencies All health service organisations
Key relationship	NSQHS Standards (second edition): Preventing and Controlling Healthcare-associated Infections Standard
Attachment	n/a
Notes	Update assessment requirements related to water quality and ongoing monitoring of water quality.
Responsible officer	Margaret Banks Director, National Standards Phone: 1800 304 056 Email: accreditation@safetyandquality.gov.au
To be reviewed	January 2020

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

NSQHS STANDARDS

ADVISORY

AS18/07: Reprocessing of reusable medical devices in health service organisations

PURPOSE:

To describe the minimum requirements for health service organisations' compliance with Action 3.14 following the introduction and subsequent revision by Standards Australia of *AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organisations*.

ISSUE:

Action 3.14 of the National Safety and Quality Health Service (NSQHS) Standards (second edition) states:

> Where reusable equipment, instruments and devices are used, the health service organisation has:
>
> a. Processes for reprocessing that are consistent with relevant national and international standards, in conjunction with manufacturers' guidelines
> b. A traceability process for critical and semi-critical equipment, instruments and devices that is capable of identifying
>   - the patient
>   - the procedure
>   - the reusable equipment, instruments and devices that were used for the procedure

The Australian Standard AS/NZS 4187 is the national standard most commonly used to meet the requirements in Action 3.14. Standards Australia released AS/NZS 4187:2014 in 2014 and it became operational in December 2016. Standards Australia has withdrawn the previous version of this Standard. *AS/NZS4815:2006 - Office-based health care facilities—Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment* is commonly used in office-based practice, and is still operational.

Health service organisations and state and territory health departments have raised concerns with the Commission regarding implementation of *AS/NZS 4187:2014*. The Commission has commenced a review of implementation issues with *AS/NZS 4187:2014*. The intended outcome of the review is to clarify the minimum requirements needed to comply with Action 3.14 in the NSQHS Standards. The Commission review is expected to be completed by November 2019.

REQUIREMENTS:

To comply with the requirements of Action 3.14 until the review is complete and further advice is issued, health service organisations should:

a. Complete a gap analysis to determine the current level of compliance with AS/NZS 4187:2014 for all areas other than water quality input (Section 7 - Validation) and water quality monitoring requirements (Section 8 – Routine Monitoring and Control) and document the findings.
b. Develop and document an implementation plan using a quality improvement framework specifying timeframes, milestones and deliverables to support implementation for AS/NZS 4187:2014 for all sections of the standards except Section 7 and 8.
c. Demonstrate progress toward implementing the plan, noting health service organisations are permitted to:
    - Return to or maintain pre AS/NZS 4187:2014 water quality input requirements and water quality monitoring requirements
    - Revise or delay implementation plans until the Commission clarifies the minimum requirements to comply with Action 3.14 in November 2019.

Health service organisations that are newly established and eligible to undergo interim accreditation to the NSQHS Standards are expected to comply with requirements a and b above.

Accrediting agencies are required to:

a. Ensure a gap analysis is completed
b. Assess progress on the implementation plan at each accreditation assessment, excluding Section 7 and 8 of AS/NZS 4187:2014.
c. Rate Action 3.14 as satisfactorily met where a health service organisation demonstrates progress towards its implementation plan for AS/NZS 4187:2014.

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

NSQHS STANDARDS

Certificate III in Sterilisation Services

TAFE NSW Course No: HLT37015-01V01
National Course Code: HLT37015
Nominal Hours: 455

Course structure and units

This course includes 14 units. Use the links below to go to your online learning resources for each unit.

BSBFLM312 – Contribute to team effectiveness

BSBINM301 – Organise workplace information

CHCCOM005 – Communicate and work in health or community services

CHCDIV001 – Work with diverse people

BSBADM311– Maintain business resources

HLTINF001 – Comply with infection prevention and control policies and procedures

HLTSTE001 – Clean and disinfect reusable medical devices

HLTSTE002 – Inspect and pack reusable medical devices

HLTSTE003 – Sterilise loads HLTSTE004 – Manage sterile stock

HLTSTE005 – Care for reusable medical devices

HLTSTE006 – Chemically disinfect reusable medical devices

HLTWHS001 – Participate in workplace health and safety

HLTWHS005 – Conduct manual tasks safely

wsi.tafensw.edu.au

For full details on TAFE NSW fees and money matters please visit our website: wsi.tafensw.edu.au/fees

HEALTHCARE ASSOCIATED INFECTIONS REPROCESSING ADVISORY COMMITTEE

Summary report 23rd August 2019 teleconference

Update CEC HAI program

Members were informed that the temporary endoscopy project officer had completed her appointment with the CEC. The CEC-HAI team will complete the remaining work for the endoscopy project.

Clarification of the role of the HAI-RAC is as a peak advisory committee for reprocessing issues identified as potentially affecting NSW Health Organisations and provide support, resources and direction on these matters.

HAI RAC reprocessing reusable medical devices

CEC-HAI team have completed the Information for Clinicians Update for reprocessing of difficult to clean laryngoscopes. The update is in the process of finalisation for uploading onto the CEC-HAI webpage

Competencies for reprocessing staff

Terminology of the 2003 core competency index and content requires revision to align with reviewed NSW Health Policies, AS/NZ4187:2014 and ACSQHC.

Convening of a working party is planned for the next RAC meeting.

Endoscope update

The RAC was provided with an overview of progress of the first draft of the Guideline Infection Prevention and Control: Flexible Endoscopes.

Update 2021 compliance with AS/NZ4187:2014

The Commission (ACSQHC) is holding a stakeholder forum in Sept 2019 to discuss the issues surrounding compliance with AS/NZ4187:2014.

Next Meeting : Friday 29 November 2019, 9:30 am – 2:30 pm

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Australian Government

The safety of Australian patients comes first

An Action Plan for Medical Devices

Improving Australia's medical device regulatory framework

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An Action Plan for Medical Devices

Improving Australia's medical device regulatory framework

Australia's Regulatory System

The regulatory requirements for medical devices in Australia are some of the most stringent in the world. Compliance by industry with these requirements is never optional or voluntary. The obligations are based on globally aligned requirements that regulate different products according to their risk. While Australia recognises evidence provided to other international regulatory agencies, the Therapeutic Goods Administration (TGA) carries out additional reviews for medium and high risk devices.

Our current system

*** Risk based**
*** Global principles**
*** But with extra assurances**
*** Pre-market assessment**
*** Ongoing surveillance**
*** Compliance checks**
*** Enforcement for non-compliance**

There is room, however for further safeguards

Medical device regulation in Australia is based on scrutiny of the products before they are approved for the market, surveillance of products once on the market and compliance and enforcement activities. The TGA has a range of powers including compelling sponsors to provide information, suspending or cancelling supply or legal actions such as civil and criminal penalties if requirements are not met.

The level of review prior to the TGA approval depends on the risk that the medical device presents to patients or the end user. The approach balances the need to provide patients and the healthcare system with timely access to innovative new technologies with the appropriate level of scrutiny for product safety, performance and effectiveness.

Medical devices are categorized based on their risk, with more evidence required for higher risk medical devices such as pacemakers and joint replacements; and less evidence for lower risk medical devices like bandages and tongue depressors. The risk based classification system is used by international regulators including the United States, the European Union, the United Kingdom, Canada and Japan.

However more can be done to strengthen and improve Australia's medical device regulatory system and patient safety. Transparency can also be significantly improved. More information on individual medical devices can also be made available to users of medical devices, their families and healthcare professionals to help make informed decisions on the use of particular products.

Action Plan

This Action Plan is a three part strategy to strengthen Australia's regulatory system whilst continuing to be patient focused and have greater transparency. It outlines actions that continue to improve the safety, performance and quality of medical devices in Australia and improve health outcomes for patients who require medical devices. The Action Plan will:

- ✓ **Strategy 1: Improve how new devices get on the market**
- ✓ **Strategy 2: Strengthen monitoring and follow-up of devices already in use**
- ✓ **Strategy 3: Provide more information to patients about the devices they use.**

The Action Plan describes:

- a number of reform activities currently underway that the TGA will implement sooner; and
- additional ways to improve transparency and to increase public confidence in Australia's medical device regulatory system. The TGA will actively seek feedback on new ways to do these.

There will be open public consultations to seek feedback on proposed policies, regulations and the guidance materials developed. Decisions on specific policies and regulations will need to be made by the Government or by the Federal Parliament (if particular laws require change).

The TGA has been tasked to implement the Action Plan. The TGA will develop a separate document that provides more detail about the Action Plan, including more detail on proposed actions and activities. Collaboration with stakeholders including consumer groups on approaches for implementing the strategies is central. The TGA will work closely with consumer groups to develop a range of consumer focused documents that explain the options for further improvements to medical device regulation.

The TGA will ensure that all perspectives, but particularly of those consumers who use medical devices, are taken into account. Public reporting by the TGA will ensure that progress against this Action Plan is transparent to all.

An Action Plan for Medical Devices

Improving Australia's medical device regulatory framework

STRATEGY 1:
Improve how new devices get on the market

What happens now?

Every medical device must meet a set of requirements (called 'Essential Principles') before they can be approved for supply in Australia. To meet the Essential Principles, manufacturers must provide evidence, including clinical evidence on matters such as:

- **Safety requirements**
- **The chemical, physical and biological properties the device must have**
- **Protection from infection and microbial contamination**
- **Appropriate construction and environmental properties**
- **Information that must be supplied with the medical device**

For very low risk devices, a manufacturer can self-certify that their device meets the Essential Principles. For all other devices, a qualified body must assess the device and this evidence is used to show that the device meets the Essential Principles. This assessment (known as conformity assessment) can either be carried out by the TGA or a recognised qualified overseas body. Some medium risk devices are subject to further assessments by the TGA. Depending on the product, high risk devices either must be assessed by the TGA or be subjected to a detailed audit (review in addition to the reviews already done in Europe) by the TGA prior to supply in Australia.

What is proposed?

The TGA will strengthen its assessment processes and oversight of how devices are approved for use in Australia. The TGA will review whether the current processes around industry self-certification of low risk devices are appropriate.

With the fast-paced increase in the numbers of medical devices with software or digital components, the coverage of regulation in Australia will be broadened to ensure new and emerging technology such

as 3D printed devices and software apps are safe and provide reliable information to consumers. The TGA will establish a specialist unit to better evaluate emerging technology such as 3D printed devices and software apps, as poorly performing apps may pose a significant consumer risk. It will examine ways to better monitor device cybersecurity risks. The TGA will provide clearer guidance to industry on cybersecurity requirements for medical devices and the IT systems they connect with.

Strategy 1

- **More rigour in assessment processes**
- **More reviews of low and medium risk devices**
- **Higher level scrutiny of clinical evidence**
- **Ensure new and emerging technologies are safe**

Potential changes, to add further rigour to the assessment of medium and higher risk devices will be publicly consulted on before final decisions are made by the Government. The TGA will seek stakeholder views on whether more applications for medium risk devices should require mandatory audits by the TGA before being marketed in Australia. The TGA will also review the arrangements for medical devices that are used in clinical trials to ensure the use of these devices meet community expectations. In parallel, the TGA will publish clearer guidance documents so that all Australians and, in particular, industry understands the regulatory requirements before particular types of medical devices can be marketed in Australia. This includes first aid kits and single use procedure packs in surgery, and specific devices such as contact lens, lasers, brain stimulators and dermal fillers.

For higher risk devices, the TGA will consult on whether the Government should require greater levels and scrutiny of clinical evidence for certain groups of devices. These devices include spinal implants, devices that make diagnoses, diabetes management devices, medical devices used for IVF, and companion diagnostics (tests used to guide the choice of medicines for particular cancers or rare diseases).

Direct input from consumers on these actions will assist in designing how the Strategy will be implemented.

Actions

Early-mid 2019: Identify options for increasing oversight of the evaluation and market approval process for particular devices.

Early-mid 2019: Conduct public stakeholder consultations on proposed regulatory changes and guidance materials.

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Improving Australia's medical device regulatory framework

Mid-late 2019: Consult with stakeholders on proposed changes that affect or change industry fees and charges or change the regulatory burden on healthcare professionals of industry.

Mid 2019: Establish a specialist unit in the TGA to increase capacity in assessing and monitoring digital health.

End 2019: Draft regulatory changes as agreed by the Government.

End 2019: Increase the capacity of the TGA medical device review teams.

STRATEGY 2:
Strengthen the monitoring and follow-up of devices already in use

What happens now?

The TGA monitors the safety and performance of medical devices after they have been approved and made available to Australian patients. The TGA uses a wide range of sources of information, including the mandatory reporting of adverse events by industry, voluntary reporting from the public and from health care professionals and communications from other regulators. The TGA also analyses the medical literature and carries out post market reviews. However many incidents are not currently reported by private or public hospitals or by individual healthcare professionals. Recent incidents involving medical devices such as Transvaginal mesh have highlighted the need to access more complete data on adverse events and rapidly to share information about emerging safety issues to more promptly address threats to patient safety and to take quicker action.

What is proposed?

The TGA will accelerate implementation of medical device reforms announced from the Expert Panel Review of Medicines and Medical Devices Regulation. The TGA will introduce systems to improve its ability to identify problem medical devices earlier and to take action quicker. The new systems will also enable the TGA to confirm with other, international regulators whether they have also had significant reports of adverse events with particular products. The TGA's IT systems and analysis capability for adverse events will be enhanced to improve our assessment and investigation processes. Together with

health consumer organisations, we will also develop simpler ways for consumers to report adverse events (including using smartphone apps) and publicise how reporting of adverse events can improve the safety of products.

Strategy 2

- **Scope the introduction of unique device identifiers**
- **Enhance inspections and reviews to confirm ongoing quality and safety**
- **Explore removing reporting barriers including potential of mandatory reporting of adverse events by healthcare facilities**
- **Greater data analysis, information sharing and joined up systems with hospitals**

The TGA will work closely with healthcare facilities and state and territory health departments to find ways to increase rapid information sharing about medical device safety and effectiveness. This may include developing education programs and systems to help healthcare professionals and hospitals identify and report medical device incidents. We will also review any regulatory or legal barriers that may currently compromise the ability of the TGA to respond quickly to device safety reports received from hospitals.

To increase the extent and timeliness of adverse event reports, the TGA will consult publicly on options for:

- whether it should be mandatory for healthcare facilities to report adverse events/safety problems with medicine and medical devices to the TGA;
- removing some existing exemptions to require more timely and improved reporting of adverse events by industry to the TGA; and
- whether the TGA should have enhanced powers for recalls and other powers relating to cancelled devices.

Better tracking and traceability of medical devices throughout the healthcare supply chain and to patients is also a high priority. Following wide public consultation, the TGA will provide advice to the Government on the feasibility of requiring a Unique Device Identifier system to achieve better tracking of devices. This would mean that patients will be able to know much more about the particular device they have implanted or treated with.

After consultation with stakeholders, the TGA will assess options to increase its inspection program of medical device manufacturing sites to confirm ongoing quality in manufacturing medical devices. Increasing the frequency of manufacturer inspections of certain high risk devices and new onsite auditing of their reporting of adverse events will also be explored.

Consumers and consumer organisations will have direct input on how these actions will be implemented.

An Action Plan for Medical Devices
Improving Australia's medical device regulatory framework

Actions

Early 2019: Establish a working group with state and territory health departments and the Australian Commission on Safety and Quality in Health Care.

Mid 2019: Consult publicly on proposed changes to adverse event reporting requirements and systems and strengthened tracking of devices in the healthcare system.

Mid 2019: Consult publicly on proposed changes that potentially incur a change in fees or charges and/or regulatory burden.

Mid-late 2019: Consult with consumer groups, healthcare industry representatives on opportunities for collaboration and proposed changes.

Early 2020: Government to introduce legislation to implement agreed regulatory changes.

STRATEGY 3:
Provide more information to patients about the devices they use

What happens now?

The TGA provides information on its website about a range of regulatory responsibilities. However the information is often not easy to navigate or understand given the technical language that is used. Social media is also used by the TGA and an information enquiries service is in place to answer specific questions from the public, healthcare professionals and industry. Despite this, there is a very low level of consumer awareness about the TGA and the medical device regulatory system.

For many years, Consumer Medicine Information documents have been required to be made available for prescription medicines but there are not corresponding information sources for many medical devices. In addition, while the TGA publishes a document called the "Australian Public Assessment Report" explaining the factors behind the decision to approve or reject each new prescription medicine, there is not currently a similar public document made available for new high risk devices. Consumers

report that it is hard to find information on medical devices, difficult to report adverse events and that the TGA information on medical devices is not in a format that is easily accessible, user friendly or searchable.

Strategy 3

- **Publish more information about decisions made and the medical device products regulated by the TGA**
- **Strengthen consumer awareness of how safety and performance of medical devices are assessed**
- **Find and implement ways to help consumers report adverse events more easily**
- **Establish expert groups with consumer representation**

What is proposed?

Recent media has raised patient concerns about the safety of medical devices and more broadly, the lack of public information available about the regulatory framework for devices in Australia. The TGA will partner with consumer groups to co-design a strategy to raise awareness about the regulatory system as well as about how regulatory decisions were reached about individual products, in particular higher-risk devices. This will include publication of consumer-friendly information on each new higher-risk device.

We will also strengthen consumer awareness of the responsibilities of the TGA, suppliers of medical devices and health professionals through a range of new consumer communication and education programs. For example, the requirements of manufacturers to provide consumer information leaflets and implant cards for implanted medical devices will be widely publicised and monitored for compliance. Healthcare facilities will be encouraged to ensure patients are aware of these materials.

The TGA will seek feedback on options to publish more information on how regulatory decisions are reached for individual higher risk devices, including publishing clinical evidence, searchable incident reports, manufacturers' inspection reports and regulatory actions on individual devices.

To assist in monitoring those medical devices already in use, the TGA will encourage greater reporting of adverse events by patients by working collaboratively with consumer advocacy and support groups to identify mechanisms that consumers find easier to use.

The TGA will also publicly report on assessment timeframes for new products to demonstrate that assessments support timely access by consumers.

In addition to the existing Advisory Committee on Medical Devices, the TGA will establish expert working groups with consumer representation and co-chairing to provide advice and feedback on devices of

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concern. This will include a women's health products working group, and possibly other groups for particular product types or technologies.

Direct input from consumers on these actions will be a core component of how the strategy will be implemented. In addition, the TGA and consumer organisations will co-design a range of consumer friendly documents. These should help translate technical regulatory language into plain English and make documents more accessible to non-expert audiences.

Actions

Mid-late 2019: Consult with consumer advocacy, support groups and industry on proposed changes to transparency.

Mid-late 2019: Publish regulatory assessment timeframes.

Late 2019: Government decision on any changes to regulations required to support publication of additional information on medical devices.

End 2019: Establish new consumer working groups and publish their Terms of Reference.

HALYARD

Education Foundation

IS YOUR CSSD 4187 COMPLIANT? EXPERT ADVICE IS AVAILABLE NOW

UNDERSTANDING THE STANDARDS

Halyard presents an eight-part series focused on understanding how packaging relates to each element of AS/NZS4187:2014 and ISO11607 Parts 1 and 2.

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CELEBRATING YEARS OF CSSD EXPERENICE

On April 10th 2019, The Campbelltown Public Hospital CSSD celebrated with the 'World Federation for Hospital Sterilisation Sciences'. This falls at the same time each year and Sterilising Departments around the world have been invited to participate.

We took advantage of the 'World CSSD Day' to enjoy a well-deserved afternoon tea in recognition of our Sterilising Technicians and the dedication, expertise and service they contribute to patient safety.

Together our CSSD prides itself with an excess of 270 years' experience in the Sterilising Industry from both Public and Private sector.

Our team of Technicians share approximately 220 years of dedication to the Campbelltown Hospital alone. If it weren't for recent retirements, we would have easily reached 300 years.

This celebration was specifically to present 'Years of Service' pins and acknowledge 10 Sterilising Technicians who have provided more than 170 years combined dedication and experience to the Campbelltown Hospital CSSD. The service pins were presented to the team by the Director of Corporate Services.

Over the years the team has shared weddings and babies, birthdays and retirements, laughter and tears – supporting each other along the way. They have seen & survived many changes in instrumentation, equipment and technology.

We are about to experience the biggest redevelopment in the history of the Campbelltown Hospital. With this comes new services to the Campbelltown area and surrounding communities.

It will also provide opportunity for employment of Sterilising Technicians and professional development in the CSSD.

Is your CSSD playing Russian Roulette with patient health?

Site Evaluation

AS4187

water quality compliance assessment

Washing, disinfection and sterilisation efficacy can be compromised by the quality of water used in the reprocessing of RMDs. You may not be aware, but water authorities do not monitor the presence of endotoxins in our mains water supply. If routine sampling and analysis isn't carried out, these contaminants can corrupt water distribution systems and surgical instruments. And once present, they can't reliably be destroyed by disinfection or sterilization processes. If pathogens come into contact with the blood stream it can be fatal.

Did you know:

+ Calcium and Magnesium in water interacts with the disinfection to form insoluble precipitates.
+ Microorganisms can be protected from disinfectants by biofilm.
+ Depyrogenation is not reliably achieved at the temperature used in steam sterilizers
+ Only temperatures in excess of 180°C can effectively destroy endotoxin.

Dr Surani McCaw
Healthcare Consultant

Matthew Cox
Project Consultant

It's critical your RO plant is compliant as disregarding the importance of chemical and microbial water quality puts patient's lives at risk.

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Expression of interest for The Sterilizing Industry

APPLYING FOR A RESEARCH GRANT

Sterilizing Research Advisory Council of Australia

Federation Sterilizing Research Advisory Council of Australia invite all financial members of SRACA to apply for a research grant of up to $1400.00

This package includes;

- Information
- Guidelines
- Application form

You can request your package from your State Secretary, or download from your State or Federal website.

Purpose

To provide financial assistance, to promote research and develop skills to ensure the sterilizing industry is contributing to quality patient care.

Value

Maximum $1,400.00

1. Selection criteria

- Financial assistance will be considered for projects which would be relevant and beneficial to both the applicant and those involved in the field of sterilization.

Expression of interest for The Sterilizing Industry

Applying for a Research Grant

2. Eligibility

- Highly developed written and oral skills
- State SRACA membership number and proof you are a current active member.
- Be a full member of a state SRACA and have been a member of a state SRACA for a minimum of two years immediately prior to submitting an application.
- Be currently employed in the field of sterilization and have been employed in the field of sterilization for a minimum of two years immediately prior to submitting an application
- Has attended SRACA meetings and educational activities during the two years immediately prior to submitting an application.
- Be actively involved in his/her state SRACA. Active involvement is considered to include but is not limited to:
  - Willingness to serve on SRACA committee or sub-committee
  - Promotion of SRACA activities
- Applicants shall submit information about any application for funding from an alternative source/s for the same purpose.
- Only one research grant will be awarded annually.

3. Application Guidelines

- Application forms are available from both FSRACA and SRACA State secretaries
- Applicants should submit a completed type written application form
- Comprehensive Curriculum Vitae, which show details of work and education qualifications.
- Full details of the project, including the objectives, the methodology of the research, the outcome and how the research can enhance sterilization and the estimated or actual budget.
- The proposed project must have commenced within 12 months from receipt of the research grant.
- Within four weeks of completing the research project the recipient will need to submit a type written report outlining the project

- The recipient of a FSRACA grant shall:
  Be prepared to speak on the funded project at FSRACA and/or SRACA meetings, conferences or workshops
- The report may be published in the "Sterilization in Australia" Journal or in an appropriate national professional Journal at the discretion of the editor.
- The recipient will submit progress reports to FSRACA if requested to do so.
- Papers and reports shall not be returned to the grant recipient by FSRACA committee.
- Projects involving human bioethics shall show proof of permission by the people and/or organization's concerned.
- The grant may fund all or part of the project
- The grant will be available only once to any individual.

4. Selection

- Completed application forms together with al l supporting documentation shall be submitted to the Secretary of the state SRACA of which the applicant is a member, by 31 December each year.
- The state SRACA committee will determine whether eligibility requirements (as set out in this document) have been met.
- All applications will be forwarded by SRACA to the FSRACA Secretary together with a State committee recommendation.
- The applications shall be assessed at a meeting of the FSRACA committee.
- The decision of FSRACA committee shall be final and binding on all matters.
- Confidentiality of the selection process shall be upheld by all those involved.
- The names of successful applicants, together with an outline of project and funds granted, will be published in the minutes of FSRACA meeting.

Expression of interest for The Sterilizing Industry

Applying for a Research Grant

5. Publication

- Grant recipients shall retain copyright of all papers/reports submitted to FSRACA

6. Financial Considerations

- Applicant shall submit a statement of proposed expenditure for the proposed project.
- FSRACA committee reserves the right to cancel the grant and request return of any monies granted should the recipient fail to pursue the purpose for which the grant was awarded.

7. Alternative Funding

- FSRACA financial grants are conditioned upon the applicant informing FSRACA at any time should funding received exceed the total cost of the project.
- FSRACA committee reserves the right to request the return of monies over and above full funding.

Expression of interest for The Sterilizing Industry

Applying for a Research Grant

Application form

Title Ms, Miss, Mrs, Mr., Dr (Please circle your title)

Surname _____

Given Names _____

Address _____

_____ **Post code**_____

Email address: _____

Phone number. _____

Current occupation and years of experience _____

_____

Amount of Funding requested $_____

I have/have not made application to alternative sources for funding YES/NO

If YES from whom and what support has been requested/granted: _____

_____

If funding is granted I _____ **agree to abide by the terms and Conditions of FSRACA "Guidelines for Financial Grants"**

SIGNATURE: _____ DATE_____

OFFICE USE ONLY

Received by _____State SRACA Secretary on _____

State SRACA comments regarding eligibility (as per financial grant guidelines)

_____

_____ _____

SIGNED: _____POSITION:_____DATE:_____

Expression of interest for The Sterilizing Industry

Applying for a Research Grant

Received by FSRACA Secretary on _____ DATE:_____

Presented to FSRACA meeting on _____ DATE: _____

FSRACA Action: _____

_____ _____

SIGNED: _____ POSITION:_____ DATE:_____

Attachments

- Current SRACA Membership
- Curriculum Vitae
- 2 x Professional Referees
- Proposed Project
- Budget Plan

Applicant_____

1= Criteria not met

5= Criteria fully met

Criteria Rating Comment

1. Documentary evidence. (Circle correct answer)

- Current membership and active member State group YES/NO
- Two relevant references supplied YES/NO
- Curriculum Vitae supplied YES/NO
- Project details YES/NO
- Budget Plan YES/NO

2. Essential Qualifications supplied YES/NO

3. Communication skills

• Written 1,2, 3,4,5

• Oral 1,2,3,4,5

Summary

_____

_____

_____

_____

_____

_____

Approved/not approved (Circle the correct answer)

Amount granted $_____

Signature_____Date_____

Monitoring Hydrogen Peroxide Sterilization Processes...

gke, The market leaders for the research, development and manufacture of sterilization monitoring products have developed a range of products for monitoring Hydrogen Peroxide (H_2O_2) / Plasma sterilization processes.

Hollow Level Monitoring

The ***gke*** Batch Monitoring System ensures the H_2O_2 gas penetrates into the most difficult areas inside the load.
The air removal and penetration characteristics of H_2O_2 very depending on the sterilizer, program and material characteristics of the load.
gke offer a range of PCDs to suit the requirements of your process.

Package Monitoring

The indicators according to ISO 11140-1 Class 4 are placed onto packages to monitor the variables of H_2O_2 processes for solid instruments or porous goods.

Biological Indicators

The ***gke*** BI's according to EN ISO 11138-1 can be used for validation or routine monitoring of H_2O_2 sterilization processes. For hollow level monitoring the ***gke*** BI's can be placed inside a PCD. The H_2O_2 BI's are available with 4 different carriers: Glass, Tyvek, Stainless Steel and PET.

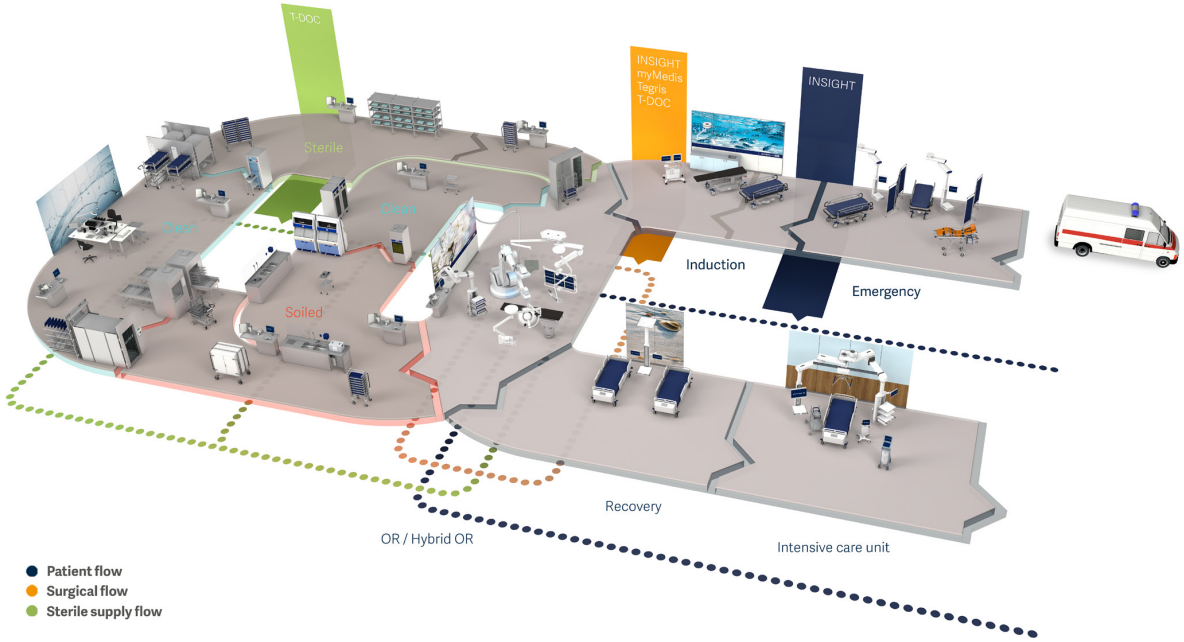
For more information on the ***gke*** products contact ***gke*** **Australia** on **1300 889 201**

gke Australia
"Promoting the Science of Sterilisation"

Sterile Supply Management

Leading the way in traceability, with 1,100 customers in Australia and New Zealand

- Getinge supports a seamless transition from manual to electronic tracking.
- Each of our tracking solutions enable conformance to AS/NZS 4187 standards.
- Modular solutions can be easily upgraded and expanded.
- Subscription model payments create flexibility.



Your traceability partner in the sterile workflow

2019 NSW SRACA Calendar of Events

AGM

- 6th May 2019

General Meeting

- 19th September 2019
- 4th December 2019

State Conference

- 18/19/20 September 2019

Executive Committee Meetings

- 18th February 2019
- 4th March 2019
- 1st April 2019
- 6th May 2019
- 3rd June 2019
- 1st July 2019
- 5th August 2019
- 2nd September 2019
- 14th October 2019
- 4th November 2019

WORLD CSSD DAY

- 10th April 2019

January 2019

S	M	T	W	T	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

February 2019

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28		

March 2019

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

April 2019

S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

May 2019

S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

June 2019

S	M	T	W	T	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30						

July 2019

S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

August 2019

S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

September 2019

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

October 2019

S	M	T	W	T	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

November 2019

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

December 2019

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Please note dates and venues are subject to change due to venue availability

DRAFT

S.R.A.C.A (N.S.W.) INC.

Membership Application/Renewal

Renewals Due 1st July Annually

Sterilizing Research & Advisory Council of Australia (NSW)

ABN: 85 914 815 703

NEW MEMBERSHIP/RENEWALS

MEMBERSHIP COMMENCES: 1st July each year and is valid till 30th June the following year

TITLE_____SURNAME_____GIVEN NAME_____

HOSPITAL/COMPANY_____

POSTAL ADDRESS_____

POSTCODE_____STATE_____PHONE NO_____

EMAIL_____

Please tick Membership Type

FULL Membership renewal includes Electronic Journal **$50.00**	$50	☐
NEW Membership includes Electronic Journal & Joining fee **$55.00**	$50 + $5 Joining fee (Admin)	☐
ASSOCIATE Membership includes Electronic Journal **$50.00**	$50	☐

(NOTE: New Membership MUST be approved at Executive Meeting prior to be accepted after application made)

TOTAL PAYMENT ENCLOSED $_____

TOTAL PAYMENT BANK DEPOSIT $_____

Make cheques payable to:

S.R.A.C.A. (NSW) Inc.

Return with form to

S.R.A.C.A. (NSW) Inc

PO Box M71

MEMBERSHIPS CAN BE DONE VIA EFT or ONLINE

S.R.A.C.A. (NSW) Inc.

BSB: 032096

Account: 871850

Reference: Company/Member Name

Please send or Email Application Form after payment made


STERILIZING RESEARCH & ADVISORY COUNCIL
OF AUSTRALIA