An explanation of the benefits and differences for both 2nd party and 3rd party auditing of Sterile Services within New Zealand

Background

In 2020 after a meeting with the Chief Allied Professions Officer for NZ at the Ministry of Health, the NZSSA Inc. received a letter from the Chief Allied Professions Officer and endorsed by the then Director General of Health-Dr Ashley Bloomfield stating that they will act on an agreed amendment to Part 5: Infection Prevention and Antimicrobial Stewardship of the Health and Disability Services Standard (DZ8134:2021):

- To ensure that checks by the Designated Auditing Authority will be made on Sterile Service Departments (SSDs)
- To ensure that the SSDs have duly completed an internal audit in line with the revised Australian Sterilisation Standard.

In 2021 the NZSSA Inc. received a further letter from the Ministry of Health identifying that the Chief Allied Professions Officers for each DHB had been informed that they had until June 2022 to report back that their SSD's had completed a self-audit against the standard of the time AS/NZS 4187. This was to be completed at that time as there had been a delay to the implementation of the updated Health and Disability Sector Act which would include auditing requirements. In this draft standard the Ministry had recommended that **Clause 5.5.8 - Service providers are able to demonstrate, via evidence of a completed audit across their sterile services in alignment with Standards AS/NZS 4815-2006 and AS/NZS 4187-2014 (or newest version), that equipment has been sterilised prior to use and/or corrective actions have been identified.**

The final wording in the published NZS 8134:2021 Ngā paerewa Health and disability services standard includes audit requirements in clause 5.2.10 "There shall be evidence of audit and corrective actions, if applicable, of the appropriate decontamination of reusable medical devices based on recommendations from the manufacturer and best practice standards. NZS 8134:2021 was required to be implemented by February 2022. The 'best practice standards' for reprocessing in New Zealand is AS 5369:2023 and the associated normative standards.

The Importance of a Quality management System (QMS)

The standard AS 5369:2023 identifies in section two (2), the requirements necessary to maintain quality in a sterile services unit using a risk-based approach. Implementing a QMS based on AS 5369:2023 enables Sterile Service Departments to provide assurance of process by systematically identifying, documenting,

and monitoring risks that could impact patient and staff safety.
A robust QMS supports:

• Risk Management: Proactively addressing risks through documented processes and controls.

• Compliance and Accountability: Ensuring all processes are traceable and meet regulatory requirements.

AS 5369:2023, as endorsed by NZ Ministry of Health and the NZSSA, sets the standard to ensure "…the safe and effective reprocessing, storage, handling, and transportation of reusable medical devices (RMDs) and other devices used in human health care…"

To ensure compliance with AS 5369:2023 audits are the mechanism used to measure conformance. Audits can be 1st party (internal), 2nd party (external) or 3rd party (external certification or regulatory).

The value and benefits of 2nd Party Audits

2nd party audits—conducted by external, knowledgeable consultants offer a unique opportunity for departments to benchmark their practices against best practice and process standards.
These audits provide:

• Objective Assessment: An external auditor brings a fresh perspective, identifying areas for improvement that may be overlooked internally.

• Support for Best Practice: 2nd party audits are supportive, helping services align with current standards and prepare for 3rd party (certification or regulatory) audits.

• Continuous Improvement: Regular audits promote a culture of quality and ongoing improvement. Staff are encouraged and supported to implement innovative ideas that further improve processes.

3rd Party Auditors or Conformity Assessment Bodies (CAB's)

What is a conformity Assessment Body (CAB)?

1. Is an audit agency designated by the Director-General of Health as authorised under the Health and Disability Services (Safety) Act 2001
2. CAB complies with the following International Accreditation Forum (IAF) documents:
    - ISO 17021 - Conformity assessment– requirements for bodies providing audit and certification of management systems
    - AS/NZS ISO 19011 – Guidelines for auditing management systems.
    - IAF MD1 IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization.
    - IAF MD2– International Accreditation Forum Mandatory Document for the Transfer of Accredited Certification of Management Systems.
    - IAF MD5– International Accreditation Forum Mandatory Document for Duration of Quality Management Systems and Environmental Management Systems Audits. Holds third party accreditation with either the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) or the International Society for Quality in Health Care (ISQua) for the Health and Disability Services Standards, and meets all costs associated with this accreditation.

- A CAB that meets the criteria as listed above is " certified CAB"

Auditing by a CAB

At this time a CAB auditing group will only undertake 3rd party certification audit of a Sterile Services Department where they have been requested to do so by that hospital and where the hospital is willing to fund the process. At this time no CAB group has been appointed to do so by the Ministry of Health, although this may occur in the near future as per the original intention in 2020.

NZSSA Involvement

As stated above third party auditing of Sterile Services Department's was raised by the Director General of Health in 2020. The NZSSA Inc. has long considered certification of Sterile Services through 3rd party audit as the gold standard and the way forward for the profession.

To this end the NZSSA Inc. approached a CAB for an initial discussion with a view to identify a way to progress certification of Sterile Service departments. As a result of this discussion an Oversight Committee has been formed to support the ongoing development of this certification scheme. It is made up of:

- The NZ Sterile Science Association Incorporated (two members)
- A designated audit agency representative
- A representative of the NZ Private Surgical Hospitals Association Incorporated
- A representative of Health New Zealand, Te Whatu Ora National Infection Prevention programme.
- A representative of Toi-Ohomai Institute of Technology

When established the NZSSA Inc. will be the owner of the certification scheme.

Summary

The NZSSA Inc. wants Sterile Services departments to understand that 2nd party audit is not replaced by 3rd party audit. They are two different audit mechanisms for the service to demonstrate adherence to AS 5369 and provide assurance to the hospital and clients that the practice of the service is safe.

The NZSSA Inc. acknowledges the benefit of 2nd party auditing as a support mechanism for Sterile Services Departments to achieve quality goals which in turn will support certification through a 3rd party CAB.