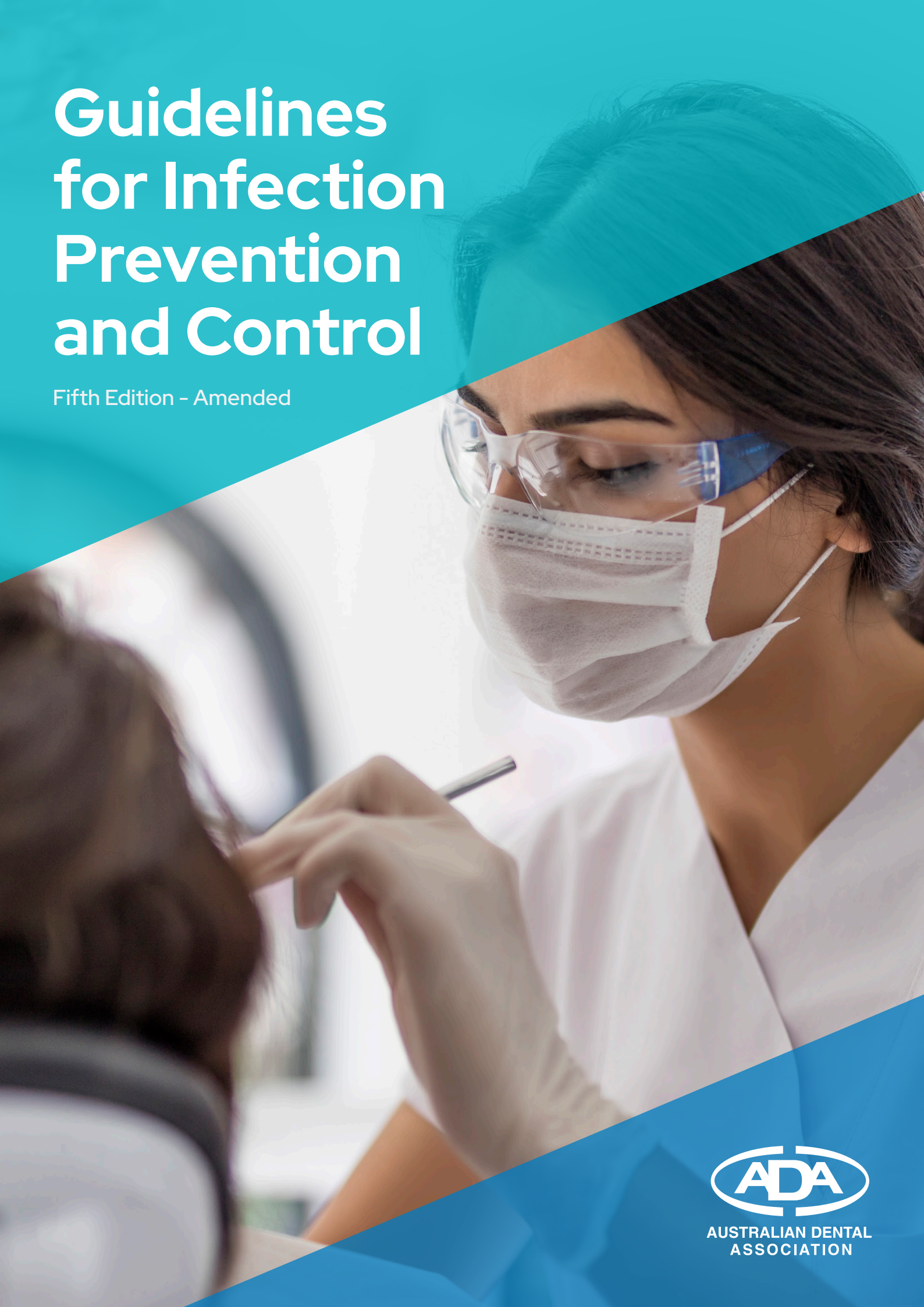
Guidelines for Infection Prevention and Control

Fifth Edition - Amended



AUSTRALIAN DENTAL ASSOCIATION

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Disclaimer: The routine work practices outlined in these Guidelines are designed to reduce the number of infectious agents in the dental practice environment, prevent or reduce the likelihood of transmission of these infectious agents from one person or item/location to another, and make items and areas as free as possible from infectious agents.

Professional judgement is essential in determining the necessary application of these Guidelines to the particular circumstances of each individual dental practice.

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Foreword

This 2026 edition of the Australian Dental Association (ADA) Infection Prevention and Control (IPC) Guidelines incorporates changes to the 2024 5th edition that have arisen since the publication of Amendment 1 of AS/NZS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities.

This ongoing process of revision of the ADA IPC Guidelines follows a commitment by the ADA to follow contemporary Australian guidelines and to align with current international best practice in evidence-based infection prevention and control. These IPC Guidelines will continue to be updated periodically to ensure they remain contemporary, and evidence based.

The IPC Guidelines are the result of more than 36 years of dedicated work by the members of the ADA's Infection Control Committee and input from key stakeholders. The ADA Infection Control Committee is comprised of registered dentists, dental specialists and non-dentists who are experts in IPC in clinical dental practice, and who work in the public sector, private sector and tertiary education settings. They represent the dental profession on national committees developing infection prevention and control standards including the National Health and Medical Research Council (NHMRC), the Communicable Disease Network of Australia (CDNA), subcommittees supporting the National COVID-19 Clinical Evidence Taskforce, the National Clinical Taskforce, and Standards Australia. The ADA's IPC Guidelines have been recognised as a key source of information for the NHMRC Guidelines.

It is important that every registered dental practitioner and all members of the dental team familiarise themselves with each new element of IPC included in this document and incorporate these changes into daily work practices. These changes will also need to be reflected in each practice's IPC manual.

The production of this document has required considerable effort over a long period of time. Special thanks and acknowledgment are due to the current and former members of the ADA's Infection Control Committee (ICC) and in particular Emeritus Professor Laurie Walsh AO, the editor of the IPC guidelines, who has been instrumental in the revision of this document. Other members of the Committee include:

Dr Heidi Munchenberg (ICC Chair)

Dr Kate Amos (Vice Chair)

Associate Professor Sharon Liberali AO

Dr Heidi Munchenberg

Dr Ellen Rogers

Dr Greg Whiteley.

In addition, we acknowledge the significant contribution from the ADA staff and Branches, specialist academies, other dental professional bodies, and national entities (The Australian Commission on Safety and Quality in Healthcare (ACSQHC), The Australasian College for Infection Prevention and Control (ACIPC)), who have contributed their expertise when providing comment during the stakeholder review process for the 2024 5th edition of this document.

The ADA declares that no conflict of interest existed in the development of these IPC Guidelines and that they have been developed independently without any corporate interest or sponsorship.

Chris Sanzaro
Federal President

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Introduction

When applying for or renewing their registration, all dental practitioners undertake to comply with all relevant state and Commonwealth legislation related to their practice. Most notably, they confirm that they will comply with the Dental Board of Australia (DBA) policies, codes, and guidelines, and this includes adhering to the AHPRA and National Boards shared Code of Conduct.

The DBA expects "dental practitioners to practise in a way that maintains and enhances public health and safety by ensuring that the risk of the spread of infection is prevented or minimised." Thus, it is essential that dental practitioners "minimise risks to patients by maintaining professional capability through ongoing professional development and self-reflection, and understanding and applying the principles of clinical governance, risk minimisation and management in practice." Practitioners must "understand the importance of immunisation against communicable diseases, and take appropriate precautions to limit the spread of infectious diseases to themselves and others." The DBA also "expects all practitioners to know how to use infection prevention and control systems to provide safe and effective patient care. In doing so, they should apply a risk-based approach, having regard to their practice setting."

The DBA in July 2022 produced a factsheet, a frequently asked questions document, and a self-reflective tool on Infection Prevention and Control (IPC). The fact sheet was updated on 8 February 2024 to reference AS/NZS 5369:2023. The DBA expects dental practitioners to practise in line with the Board's policies, codes and guidelines by "following the guidance in the Guidelines: Registered health practitioners and students in relation to blood-borne viruses, and completing ongoing continuing professional development (CPD) that contributes to the development, maintenance and enhancement of knowledge, skills and performance."

Dental practitioners must also be aware of and comply with state, territory or federal legal requirements relating to IPC, and maintain knowledge and skills in IPC by being aware of evidence-based practice resources and emerging issues relating to IPC.

In Australia, a combination of guidelines, standards and manuals underpin requirements for IPC practices. In most instances, these documents are formed for broader health or hospital settings rather than for dental practice. The ADA's IPC Guidelines serve to synthesise current requirements into a resource that can be readily applied by dental practitioners and their teams in the dental setting specifically. The ADA's IPC Guidelines is published freely by the ADA for all dental practitioners, in the interest of public safety standards.

The ADA IPC Guidelines is a key resource to guide practitioners in applying complex documentation in a practical way that acknowledges the specific challenges of the dental environment. It reflects a shared interest of regulators and the ADA in ensuring that public safety is at the forefront of our profession through clarity, accessibility, and consensus in our professional practices.

The ADA IPC Guidelines describe the infection prevention and control procedures that dental practitioners and their clinical support staff are expected to follow in a dental practice. The document outlines the primary responsibilities of practitioners and the rationale for those obligations, the routine work practices designed to reduce the number of infectious agents in the dental practice environment, ways to prevent or reduce the likelihood of transmission of these infectious agents from one person or item/location to another, and methods to make items and areas as free as possible from infectious agents. Professional judgement and facility-level risk assessments are essential in determining the application of these IPC Guidelines to the situation of the individual dental practice environment. A summary of risk assessment principles is provided in this document to allow practices to readily apply key elements of this in practice. This is based on ISO 14971:2019 *Medical devices – Application of risk management to medical devices.*

Where no evidence base is available for issues specific to dental practice, these IPC Guidelines draw upon current national and international best practice and expert knowledge and advice in IPC. These IPC Guidelines will be reviewed in the future, and updated when there are changes in the evidence and knowledge base. This version includes changes that flow on from Amendment 1 of AS/NZS 5369:2023.

Responsibility for IPC compliance rests with each registered dental practitioner and cannot be delegated. Failure to comply with the Board's Guidelines may lead to a practitioner's conduct being investigated by the DBA or by a public health regulator in the jurisdiction in which they practice. As regulators are frequently tasked with determining if conduct falls substantially below an appropriate standard, such consensus documents have an important role to play as a clear reflection of professional expectations. Therefore, each dental practitioner must ensure that they fulfil their obligations to practise in a safe and hygienic manner in accordance with the guidelines. This includes a responsibility to ensure that support staff have dedicated IPC procedures in place in alignment with the ADA IPC Guidelines, and ongoing training to ensure consistent implementation.

There is a clear responsibility for owners and operators of dental practices to provide a suitable organisational structure and the necessary human and physical resources to meet the requirements of these IPC Guidelines. This includes suitably trained and competent staff and well-maintained facilities. Practices need to have dated documents which are updated appropriately (usually at least annually) and consider how to best support the ongoing education of staff to maintain their currency of knowledge and IPC competency. Where practices are participating in accreditation, they must also consider the requirements outlined in the relevant ACSQHC standards. These requirements include the implementation of changes that flow on from AS/NZS 5369:2023, including gap analysis and staged implementation of changes.

Supporting and reference documents

The ADA's IPC Guidelines are informed by the following key reference documents:

- Australian Guidelines for the Prevention and Control of Infection in Healthcare (NHMRC 2019) (also referred to as the AICG)
- AS/NZS 5369:2023 Reprocessing of reusable medical devices and other devices in health and non-health related facilities (including Amendment 1)
- The National Hand Hygiene Initiative
- Australian National Guidelines for the Management of Healthcare Workers Living with Blood Borne Viruses Who Perform Exposure Prone Procedures and Healthcare Workers who Perform Exposure Prone Procedures at Risk of Exposure to Blood Borne Viruses (CDNA 2019)

Together with the ADA IPC Guidelines, these documents form the benchmarks for professional practice and describe the level of expectations from regulators and the wider community.

The AICG is a joint publication of the Australian Commission on Safety and Quality in Healthcare (ACSQHC) and the NHMRC. It desribes the the principles of infection prevention and control that apply across all healthcare settings, including dental practice. They also provide specific advice on situations where additional risks exist such that transmission-based precautions are warranted.

AS/NZS 5369:2023 (with Amendment 1) is the uniform national standard for reprocessing of reusable medical devices (RMDs). RMDs refers to any instrument or device (such as a handpiece) where the item is designated or intended by the manufacturer as suitable for processing and reuse. The standard applies to all types of health facilities, including dental practice. It also applies to non-health facilities, such as those doing skin penetrating procedures. The standard stresses the need for quality systems, staff training and competency, and conformance to reprocessing procedures. The standard makes reference to international standards, such as those from the International Organization for Standardization (ISO).

Key compliance points for applying the guidelines to your clinical practice setting

- Maintain access to a copy of the key reference documents listed above.
- Remove any copies of AS/NZS 4815 and AS/NZS 4187 from use as these have been superseded.
- Update your dental practice infection prevention and control (IPC) documents to ensure that they align with the content in this edition of the ADA IPC Guidelines.
- Apply professional judgement when determining how the ADA IPC Guidelines and other key reference documents apply to your individual dental practice environment.

Acronyms, glossary & definitions

The Australian Commission on Safety and Quality in Health Care (ACSQHC): ACSQHC leads and coordinates key improvements in safety and quality in healthcare across Australia. Its purpose is to contribute to better health outcomes and experiences for all patients and consumers, and improved value and sustainability in the health system by leading and coordinating national improvements in the safety and quality of healthcare.

Australian Guidelines for the Prevention and Control of Infection in Health Care (AICG): This is a joint publication of the Australian Commission on Safety and Quality in Healthcare (ACSQHC) and the NHMRC.

Active air removal: Processes for enhancing the removal and air and penetration of steam into load items that are hollow or porous. Examples include positive pressure methods using steam pulses (purge under pressure, assisted air removal) with alternating inflow and outflow of steam, and negative pressure methods using a vacuum pump (single vacuum pulse (pre-vacuum, preliminary vacuum) or multiple vacuum pulse (fractionated vacuum).

Aerosol-generating behaviour (AGB): Normal activities of people that create aerosols, including breathing, speaking, and shouting.

Aerosol-generating procedure (AGP): These include procedures that use any of the following devices: high-speed handpieces, low-speed/prophy handpieces, surgical handpieces, ultrasonic and sonic devices, air polishing devices, and hard tissue lasers. Use of the triplex when air and water are used together or when used with air on a wet surface is considered an AGP.

Air removal and steam penetration test (ARSPT): A test used to assess air removal and steam penetration in a steam steriliser. These tests may come in a variety of form factors. ARSPT for small steam sterilisers are required to conform to ISO 11140.6:2022.

Australian and New Zealand Standards (AS or AS/NZS): Documents produced by Standards Australia that set out specifications, procedures and guidelines that aim to ensure products, services, and systems are safe, consistent, and reliable. These are referred to as either AS or AS/NZS followed by the relevant standard number and the year of publication.

Alcohol-based hand rub (ABHR): An alcohol-containing preparation (liquid, gel, or foam) designed to reduce the number of viable microorganisms on the hands without the use or aid of running water (National Hand Hygiene Initiative, 2023). When hands are visibly clean, the recommended product for hand hygiene in healthcare is ABHR.

Antibacterial hand wash: A detergent-based formulation with proven antibacterial activity, intended to be used with water in a handwashing procedure.

Australian Register of Therapeutic Goods (*ARTG*): The database of the Therapeutic Goods Administration (TGA) that provides information on therapeutic goods that can be supplied in Australia.

Aseptic Non Touch Technique (ANTT®): A method to achieves asepsis by the unique approach of Key-Part and Key-Site Protection, through a combination of standard precautions, non-touch technique and the use of 'critical' and 'general' aseptic fields.

Autoclave: See steam steriliser.

Aseptic technique: Aseptic technique is an element of standard precautions. Aseptic technique is a set of practices that protects patients from healthcare-associated infections and protects healthcare workers from contact with blood, body fluid and body tissue.

Bare below the elbow: All wrist, or nail jewellery (e.g. rings with stones or non-smooth surfaces, bangles, and bracelets), watches, and wearable devices such as 'Fitbits' must be removed by clinical staff, and skin below the elbow not to be covered by clothing, prior to clinical staff engaging in direct patient care or in the reprocessing of RMDs, as their presence impairs correct hand hygiene, compromises the fit and integrity of gloves, and promotes the growth of skin microorganisms. The bare below the elbow concept also includes wearing short sleeves (including for jackets and scrubs), and not wearing clothing with long sleeves unless rolled-up and secured above the elbows.

Batch control identification (BCI): Also referred to as tracking or traceability, is the ability to link a patient procedure involving RMDs back to the records for a specific steriliser cycle. This is done for an individual set, package or cassette of RMDs by transferring batch information from the label into the patient's record for that appointment. This includes the date of processing, cycle or load number and if more than one steam steriliser is in use, its identification number.

Biological indicator (BI): A test system containing viable microorganisms providing a specified resistance to a specified sterilisation process. A common configuration is for a BI to contain the highly heat-resistant spores of Geobacillus stearothermophilus, hence the previous terminology of 'spore test'.

Blood and body fluid exposure (BBFE): An incident involving exposure to blood or other human material. BBFEs include needle stick injuries, cuts with sharp objects or contact of mucous membranes or non-intact skin with blood, tissues or other bodily fluids that are potentially infectious.

Blood-borne viruses (BBVs): A term that includes hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV). These viruses are transmitted primarily by blood-to-blood contact.

Bowie-Dick type test: An air removal and steam penetration test for porous loads in steam sterilisers with pre-vacuum cycles.

Communicable Diseases Network Australia (CDNA): A network comprising government representatives (state, territory, federal and New Zealand) and representatives from relevant organisations that provides national public health co-ordination and leadership and supports best practice for the prevention and control of communicable diseases. The CDNA also provides nationally consistent advice and guidance to public health units in responding to a notifiable disease event such as a pandemic.

Chemical indicator (CI): A device (such as a strip or card) that reveals there has been a change in one or more sterilisation process variables. Chemical indicators may respond to heat, steam, and other factors.

Cleaning: The removal of visible contaminants, including material residues and biological materials, to render an item visibly clean and suitable for further processing (such as steam sterilisation), or for intended use (in the case of non-critical items). For RMDs, mechanical cleaning methods are preferred because of better consistency.

Clinical support staff: Those staff, other than registered dental practitioners, who assist in the provision of dental services – including but not limited to dental assistants, dental laboratory assistants, sterilising/reprocessing assistants, and dental technicians. It is recognised that some individuals may have both clinical and administrative roles.

Competent person: Someone who has acquired, through education, training, qualification, experience, or a combination of these, the knowledge and skill enabling that person to competently perform the task required.

Contaminated zone: That area of work in which direct contamination by patient fluids (blood and body fluids, including saliva) may occur by transfer, splashing, or splatter of material. It includes the operating field in the dental operatory, as well as the area for cleaning RMDs within the reprocessing room.

Dental Board (DBA): The Dental Board of Australia.

Dental Practitioner: An inclusive term for those registered by the DBA to provide clinical dental care to patients. This includes general dentists, dental specialists, dental prosthetists, dental therapists, dental hygienists, and oral health therapists.

Dental Staff: An inclusive term for all those employed in a dental practice setting – namely, dental practitioners, clinical support staff, and clerical or administrative staff.

Disinfectant: A substance:

(a) that is recommended by its manufacturer for application to an inanimate object to kill microorganisms; and

(b) that is not represented by the manufacturer to be suitable for internal use.

Disinfection: Destruction of pathogenic and other kinds of microorganisms by physical or chemical means.

Endodontic file: An instrument used during endodontic therapy (root canal treatment). Includes hand and rotary engine driven instruments. May also be referred to as "root canal instruments". "Endodontic files" is the more common contemporary term, as per the Global Medical Device Nomenclature (GMDN) code.

Exposure incident: Any incident where a contaminated object or substance breaches the integrity of the skin or mucous membranes, or comes into contact with the eyes (i.e. BBFE).

Exposure prone procedures (EPPs): Procedures where there is a risk of injury to dental practitioners resulting in exposure of the patient's open tissues to the blood of the practitioner. EPPs are defined in the 2019 edition of the CDNA *Australian National Guidelines for the Management of Health Care Workers Known to be Infected with Blood-Borne Viruses Procedures and Healthcare Workers who Perform Exposure Prone Procedures at Risk of Exposure to Blood Borne Viruses* as procedures where the fingertips are out of sight for a significant part of the procedure, or during certain critical stages, and in which there is a distinct risk of injury to the healthcare worker's (HCW) gloved hands from sharp instruments, needle tips, and/or sharp tissues, including spicules of bone or teeth.

Fallow time: A period in which an operatory is 'rested' before being used again to allow aerosols suspended in the air to settle, after which any settled particles can then be removed through the environmental cleaning processes.

Failure Mode and Effects Analysis (FMEA): A structured approach used to identify and evaluate potential failures in a product or process, assessing their effects to mitigate risks before they occur. FMEA helps clinics improve reliability and safety by analyzing failure modes and their consequences.

Fit check: A test performed each time a healthcare worker (HCW) puts on a particulate filter respirator (PFR, P2/N95 respirator) to make sure it is properly applied. This ensures the respirator fits the user's face snugly (i.e. creates a seal) to minimise the number of particles that can then bypass the filter through gaps between the user's skin and the respirator seal.

Fit test: A validated method for matching particulate filter respirators (P2/N95 respirators) with an individual HCW's face shape, which is performed by an appropriately trained person.

Fomite: An inanimate object that, when contaminated with or exposed to infectious agents (such as pathogenic bacteria, viruses or fungi), can transfer disease to a new host by serving as a passive vector. Common examples include high-touch surfaces (doorknobs, switches, mobile phones and other personal electronic devices).

Gap analysis: An approach to achieving conformity to a standard that begins with an assessment of what is currently in place and how that compares to the mandatory requirements of a new standard. This identifies the gaps that must be addressed to ensure conformity with the new standard, and informs the development of a staged plan of action that helps to plan resources and timeframes.

Hand hygiene: A general term applying to processes that aim to reduce the number of microorganisms on hands. This includes applying alcohol-based hand rub to hands, or using a soap solution (plain or antimicrobial) and water.

Hand wash: Hand hygiene that uses both liquid soap and water.

Healthcare workers (HCW): All people delivering healthcare services who have contact with patients or body substances. This includes dental practitioners and clinical support staff.

Helix test: A term that was used prior to 2022 for a process challenge device with a coil design for assessing air removal and steam penetration in hollow loads. This term is no longer current and is included here for historical reference only.

Infection prevention and control (IPC): The creation of safe healthcare environments through the implementation of evidence-based practices that minimise the risk of transmission of infectious agents (NHMRC, 2019).

Instructions for use (IFU): Detailed, action-oriented, step-by-step written and visual instructions provided by the manufacturer of equipment to guide the user in the use of and/or reprocessing of that item.

Multidrug-resistant organisms (MRO): Microorganisms that are resistant to one or more classes of antimicrobial agents. Multi-resistant organisms can include bacteria, fungi and viruses.

Negative pressure room: A patient care room used to isolate/treat persons with a suspected or confirmed airborne infectious disease. Environmental factors are controlled in negative pressure rooms to minimise the transmission of infectious agents that are usually transmitted by droplet nuclei associated with coughing or aerosolisation of contaminated fluids. The air handling system operates at a lower pressure with respect to adjacent areas such as the hallway or corridor and is exhausted to the outside (NHMRC 2019, p. 306). The negative pressure room must comply with the Australasian Health Facility Design guidelines.

National Hand Hygiene Initiative (NHHI): The National Hand Hygiene Initiative promotes the use of alcohol-based hand rub at the point of care for all clinical situations where hands are visibly clean.

National Health and Medical Research Council (NHMRC): An expert body supporting the translation of health and medical research into better health outcomes and promotion of the highest standards of ethics and integrity in health and medical research.

Penetrating injury: Any injury from a sharp object such as an injection needle, scalpel blade, dental bur, matrix band, or denture clasp contaminated with a patient's blood or saliva.

Particulate filter respirator (PFR): Particulate filter respirators are designed to reduce the wearer's respiratory exposure to airborne contaminants such as particles, gases, or vapours. P2/N95 respirators are types of PFR.

Process challenge device (PCD): A device that contains a chemical indicator (e.g. Class 2) in a special container that poses a defined resistance to air removal and steam penetration. For small steam sterilisers, such tests must match the level of challenge posed by the reference hollow load described in ISO 1114.6:2022.

Personal protective equipment (PPE): A variety of barriers used alone, or in combination, to protect mucous membranes, skin and clothing from contact with infectious agents. PPE includes gloves, masks or respirators, protective eyewear, face shields and gowns/aprons.

Product family: RMDs that have similar attributes in terms of processing, and present a similar challenge to cleaning and sterilisation processes because of similar shape, size and material of construction, and the presence or absence of lumens. Examples of separate product families include solid metallic dental hand instruments (e.g. excavators, extraction forceps, periodontal probes, Gracey curettes), solid metal hand instruments with polymer grips (e.g. ergonomic scalers), polymer items (e.g. mouth props, dental dam frames), hollow items (piezoelectric scaler barrels, high-speed air turbine handpieces, metal triplex tips, metal suction tips), and sealed sterilisable surgical motors.

Reusable medical device (RMD): This refers to any instrument or device (such as a handpiece) where the item is designated or intended by the manufacturer as suitable for processing and reuse. These items may be separately packaged or formed into sets.

RMD recall: The identification and retrieval of non-conforming RMDs and the identification of patients in which they may have been used. Non-conforming includes a failure to clean or sterilise items.

Single-use item: A device supplied to a dental practice that is specified by the manufacturer as being for use in a single visit of patient care. These will be marked with a specific symbol: ⊗

Standard aseptic technique: IPC strategy applied to routine procedures that involve the use of critical instruments, e.g. extractions. Standard aseptic technique aims to promote asepsis by protecting the critical (active) parts of RMDs and the critical site during the procedure. This includes the Aseptic Non Touch Technique (ANTT®) for critical sites.

Standard precautions: First-line IPC practices that are applied to all patients, regardless of their perceived or confirmed infectious status, to ensure a basic level of IPC. These evidence-based practices are designed to both protect healthcare personnel and prevent the spread of infections among patients.

Steam steriliser: A device that uses moist steam under pressure for sterilising RMDs. Previously referred to as an autoclave. May be categorised in terms of size (based on EN13060, into large (60 litres and above) or small), and by the types of cycles (B, S and N).

Sterilant: An agent which achieves a sterility assurance level of 10^{-6} [1 in 1 million].

Sterile barrier system (SBS): The minimum package that minimises the risk of ingress of microorganisms and allows aseptic presentation of the sterile contents at the point of use. Within the SBS may be a containment device, such as a cassette, to facilitate the organisation of RMDs. A sterile barrier system, such as a pouch, may be supplied in a form that is ready for filling and final closure or sealing. Examples include paper-plastic pouches and non-woven polypropylene wrap for steam sterilisation, and polyethylene pouches for low-temperature hydrogen peroxide gas plasma sterilisation.

Surgical aseptic technique: Techniques applied to all surgical procedures where a sterile field must be maintained to ensure asepsis of the surgical site. Consists of additional measures including the use of sterile gloves, surgical hand hygiene, sterile drapes and equipment covers, sterile irrigation solutions and RMDs (such as surgical instruments) that are sterile at the point of use (with batch control identification).

Therapeutic Goods Administration (TGA): A branch of the Commonwealth government that evaluates, assesses and monitors medicines, medical devices and biological agents.

Traceability: Ability to trace the history, application or location of that which is under consideration.

Transmission-based precautions: Additional IPC practices used in situations where standard precautions alone may be insufficient to prevent infection (e.g. for patients known or suspected to be infected or colonised with infectious agents that may not be contained with standard precautions alone). There are three types of transmission-based precautions: contact, droplet and airborne precautions.

Section A. Infection prevention and control (IPC) principles

1. What is infection prevention and control?

The purpose of IPC in dental practice is to prevent/minimise the transmission of disease-producing microorganisms such as bacteria, viruses and fungi, from one patient to another, from dental practitioners and dental staff to patients and from patients to dental practitioners and/or other dental staff. In addition, IPC also involves measures that limit the spread of infectious agents from staff or patients into the work environment. IPC measures break the chain of infection at one or more points.

Successful IPC involves:

- understanding the basic principles of IPC;
- creating systems that allow IPC procedures to be implemented effectively and to make compliance with them easier to achieve. This includes having clear procedural documentation and comprehensive ongoing training of dental staff, together with a process of regular monitoring of the application of these systems and procedures;
- keeping up to date regarding new or re-emerging infectious diseases, particularly newly evolving strains of human influenza viruses and antimicrobial resistant organisms, and how to take precautions against them; and
- identifying settings and situations that require risk assessment to inform the need for modified IPC procedures (e.g. when performing dental care when mobility is restricted, in a patient's home or at a residential aged care facility).

In dental practice, microorganisms may be inhaled, implanted, ingested, injected or splashed onto the skin or mucosa. They can spread by direct contact from one person to another, and through indirect contact with contaminated environmental surfaces (fomites), equipment and reusable medical devices (RMDs) that are not properly decontaminated between uses, or the hands or clothing of healthcare workers (HCW) that become contaminated.

As an example, direct transmission of a blood-borne virus could occur when an exposure-prone surgical procedure (EPP) is being performed. It is possible that exposure of the patient's open tissues (their surgical site) to the HCW's blood (if an injury occurs) may go unnoticed or would not be noticed immediately. This could occur during certain procedures such as periodontal surgical procedures, endodontic surgical procedures, forceps extraction of teeth, surgical exodontia, implant placement and maxillofacial surgery. It would not be likely to occur during the removal of highly mobile or exfoliating teeth. This principle also applies to other procedures undertaken in dentistry that would not normally be regarded as EPPs because the hands and fingertips of the HCW are usually visible and outside the body most of the time. This makes the possibility of injury to the worker's gloved hands from sharp instruments and/or tissues unlikely. If injury occurs, it is likely to be noticed and acted upon quickly to avoid the HCW's blood contaminating the patient's open tissues.

Microorganisms from the mouth and upper respiratory tract are released into the surrounding air by aerosol-generating behaviours (AGBs) (normal breathing, talking, coughing, sneezing) and by aerosol-generating procedures (AGPs) (e.g. use of the triplex syringe, ultrasonic scaler, particle-jet cleaner, high- or low-speed drills). Ultrasonic scalers, particle-jet cleaners, high-speed drills and triplex syringes can aerosolise coolant water as well as patient oral fluids (such as saliva).

These particles are a variety of sizes. Larger particles (above 5 microns in diameter) are referred to as 'droplets', while those below 5 microns are referred to as 'aerosols'. All sizes of respiratory particles can be inhaled and/or deposited on mucous membranes such as the mouth, nose and eyes. The larger, heavier droplets are not suspended in air for very long and settle on surfaces close to the source. This is because droplets move in a ballistic pattern due to effects of gravity, and they rapidly fall onto surfaces and objects along their path of travel.

Aerosols can remain in the air for longer periods, and may travel several metres from the source, depending on air currents in the room and whether dental suction is being used. Like droplets, aerosols can be inhaled and/or deposited on mucous membranes. Environmental contamination from aerosols also may occur when the particles eventually settle onto surfaces (after several hours).

Both droplet and aerosol spread have implications in terms of how far away to position clean items, such as open boxes of gloves, from the patient's mouth. The risk of contamination or transmission from droplets is limited to close proximity to the patient (e.g. splashes of oral fluids and droplets are typically limited to within 1 metre of the mouth in a forward direction, with a reduced level of material found to the side, and very little behind the head). The extent to which such fluid splashes extend beyond the patient's body to reach the working environment depends on the use, positioning, and performance of dental suction, and use of other control measures (such as dental dam).

Transmission of respiratory viral infections (such as influenza and COVID-19/SARS-CoV-2) can occur via both droplets and aerosols. Several relevant respiratory infections are discussed in Section G of this document.

As both droplets and aerosols can be generated by the normal breathing activities of both staff and patients, wearing surgical masks reduces the expulsion of such particles into the air.

Whether or not the spread of microorganisms results in clinical infection depends in part on the virulence (power to infect) of a particular microorganism and on the susceptibility of the host. Patients and dental staff have varying susceptibilities to infection depending on their age, state of health, underlying illnesses, and immune status (which may be impaired by medication, disease, cancer therapy, and other factors such as malnutrition and hormone deficiency, or assisted through immunisation).

IPC focuses on limiting or controlling factors that influence the transmission of infection or contribute to the spread of microorganisms. The spread of microorganisms can be reduced by:

- limiting surface contamination by microorganisms through effective environmental cleaning and reprocessing of RMDs;
- adhering to good personal hygiene practices, particularly effective hand hygiene and cough etiquette;
- using PPE correctly;
- using disposable products where appropriate (e.g. cleaning wipes, paper towels); and
- following risk minimisation techniques, such as the use of high-volume evacuation, dental dams and pre-procedural mouth rinsing.

2. Standard precautions (see Section B for further details)

Standard precautions are the minimum infection prevention practices that apply to all patient care, regardless of suspected or confirmed infection status.

Standard precautions comprise the following measures:

- Hand hygiene: undertaking regular hand hygiene (The 5 Moments for Hand hygiene: before touching a patient, before a procedure, after a procedure or body fluid exposure, after touching a patient, after touching a patient's surroundings (including their belongings)), before putting on [donning] gloves, after glove removal [doffing], and at other 'moments' or opportunities when transmission of infection may occur;
- Respiratory hygiene (cough etiquette): following respiratory hygiene and cough etiquette (when coughing or sneezing or blowing the nose, use a tissue to cover your nose and mouth, then dispose of the tissue, and perform hand hygiene);
- Personal protective equipment (PPE): using personal protective equipment (PPE) such as gloves, masks, eye protection, and gowns during clinical procedures and when cleaning and reprocessing RMDs;
- Aseptic technique: using standard or surgical aseptic techniques, including the Aseptic Non Touch Technique (ANTT®) where indicated;
- Preventing blood and body fluid exposures (BBFE) such as injuries from needle-sticks and other sharps, by appropriately handling sharp items both in the operatory and during reprocessing;
- Cleaning and disinfection, including effectively undertaking environmental cleaning and RMD reprocessing; and
- Waste disposal, including the segregation and correct handling of clinical (contaminated) waste.

These standard precautions minimise the risk of transmission of infection from person to person and are required for the treatment of all dental patients regardless of whether a particular patient is infected with or is a carrier of an infectious disease. They apply to all situations whenever dental practitioners or their clinical support staff touch the mucous membranes or non-intact skin of a dental patient.

Standard precautions are also essential when cleaning the dental surgery environment, when handling items contaminated with saliva (e.g. radiographic films or sensors, dentures, orthodontic appliances, wax rims and other prosthetic work that has been in a patient's mouth), when handling blood (including dried blood), saliva and other body fluids (excluding sweat), whether containing visible blood or not, and when cleaning and processing RMDs.

3. Risk management

Wherever possible, a risk should be identified and eliminated. If it is not possible to eliminate the risk, the likelihood and consequences should be analysed, evaluated and managed by applying appropriate controls.

Assessment and management of risk remains a key responsibility of dental practitioners. This is articulated in the AHPRA and National Boards shared Code of Conduct (p. 19) in Section 7. *Minimising risk to patients* and Section 7.1 *Risk management*.

One of the key principles underpinning risk management is recognition that some strategies will be more effective than others in controlling risk. This is known as the 'hierarchy of risk controls.'

Examples of the hierarchy of risk controls that are applied **in the context of the risk of transmission of infectious diseases** include the following measures:

- **Screening** (elimination): Screen all patients, workers and visitors for clinical and epidemiological risk factors for infectious diseases. Do not treat patients with suspected or confirmed cases of infectious diseases when considered contagious if dental care can be appropriately deferred.
- **Preparation of facilities** (engineering controls): Environmental cleaning and disinfection processes based on a risk assessment including individual patient risks as well as community risks of disease transmission.

The use of dental dams significantly reduces aerosolisation of saliva. The routine use of high-volume evacuation significantly reduces the number of aerosols present in the environment.

There is some evidence that the following commercially available mouth rinses, when used before dental treatment, reduce the viral load in saliva for enveloped viruses: hydrogen peroxide (0.5–1.0%); essential oils; cetylpyridinium chloride (0.07–0.1%); povidone iodine solutions (0.23%–1%); chlorhexidine (0.12–0.2%); freshly generated ozonated water (ozone concentration at least 0.1 ppm). If patients are unable to undertake a pre-procedural mouth rinse (e.g. young or special needs) consider providing topical mouth cleansing with gauze soaked in mouth rinse, focusing on wiping the buccal mucosa and dorsal tongue surface.

In times of elevated risk, remove all high-touch unnecessary items in communal areas e.g. toys and magazines. Use appropriate measures to remind patients of the need for hand hygiene, cough etiquette and physical distancing. Household members who are normally in close contact can be permitted to sit together, and patients may also be given the option to wait in their vehicle if practical.

Provide facilities to enable hand and respiratory hygiene, such as alcohol-based hand rub (ABHR), hand washing facilities, tissues and rubbish bins. Ensure all patients undertake hand hygiene prior to sitting in the waiting area. Have spare masks on hand, as required, for patients to wear in the waiting room. Display patient information on how to perform hand hygiene and other risk management actions such as social distancing in the waiting area or the need to wear a mask.

Consider how to optimise ventilation within your facility to increase air changes per hour. This may include adjustments to air-conditioning systems and the use of air-purifying devices.

• **Planning, protocols and procedures** (administrative controls)**:** Ensure staff are trained in standard and transmission-based precautions and that the practice's IPC policies and procedures are implemented. Ensure the practice's policy on staff vaccination is consistent with national and local directives and with the Australian Immunisation Handbook.

It has been recommended by the NHMRC in the Australian Infection Control Guidelines (AICG) that a 30-minute fallow time is used for patients with suspected or confirmed infectious disease where airborne precautions are required. Fallow times are not required for AGPs in all other patients. When making decisions regarding fallow time, consider the number of air changes per hour (ACH) for the operatory (a higher ACH reduces the fallow time).

- **PPE:** Ensure a supply of appropriate PPE relevant to the setting is readily available and that health care workers (HCW) are trained and competent in its use.

Special protocols such as contact and droplet precautions may be needed for certain conditions. For information on suitable risk-based measures for human influenza and COVID-19, see Section G in this document, and the AICG. Other acute respiratory infections are also described in the AICG. Bear in mind that not all patients have a definitive diagnosis and several respiratory infections, such as respiratory syncytial virus (RSV) and parainfluenza, spread the same way as human influenza.

Going beyond these measures that follow the hierarchy of risk controls, additional IPC measures can be implemented based on the nature of the risks. A range of resources exist that could inform the development of IPC-related risk management, including in the 2019 AICG.

- 2.3 Overview of risk management in infection prevention and control (p. 30)
- 4.1.4 Risk Management (p. 197)
- Risk Management (glossary definition) (p. 316).

For reprocessing of RMDs, risk management processes are described in AS/NZS 5369:2023 in Appendix B Guidance on a risk-based approach (p. 118) sections B.1. to B.5. In addition, a structured approach to risk management for medical devices is described in ISO 14971:2019 *Medical devices – Application of risk management to medical devices.* The ADA has also produced in 2025 a structured risk assessment tool to identify areas of risk in the reprocessing of reuseable medical devices. This ADA tool uses failure mode effect analysis (FMEA).

In many instances, the safest option is to eliminate the risk by deferring non-urgent treatment for patients presenting with confirmed or suspected infections warranting transmission-based precautions. Where specific risks are identified, this should be escalated to an appropriate person in the practice (such as a senior clinician) to assess whether it is appropriate to defer treatment. If treatment is not deferred, consideration can then be given as to what additional infection prevention and control measures outlined above will be adopted to reduce the risk of transmission.

4. Legislative frameworks

Registered dental practitioners are legally required to comply with the DBA's policies and guidelines. As mentioned earlier, the DBA has produced a fact sheet on infection control and a self-reflective tool.

The fact sheet states that "infection prevention and control refers to the actions you can take to prevent or minimise the spread of infection to patients, practitioners, and the community. The Board expects you to practise safely by ensuring the risk of spreading infection is prevented or minimised. Inadequate infection prevention and control has significant consequences for practitioners, patients, and the community."

The responsibilities around infection prevention and control are also laid out in the AHPRA and National Boards shared Code of Conduct, which states that practitioners have a responsibility to protect and promote the health of individuals and the community; maintain adequate knowledge and skills to provide safe and effective care; practice in accordance with the current and accepted evidence base of the profession; and work in ways that improve the safety of patients.

As mentioned previously, these responsibilities cannot be delegated to dental assistants, practice managers or practice owners. Rather, each registered dental practitioner must ensure that they fulfil their obligations to practise in a safe and hygienic manner.

It is essential for staff members to understand that the IPC policies of a dental practice reflect these legislative requirements, as well as other obligations of law, including work health and safety legislation, which stipulates the need to follow legal directions such as written safety instructions or directives from the employer (a term which includes compliance with written IPC protocols).

Key compliance points for legislative frameworks

- Ensure staff are familiar with the DBA website and know where to find key policies and infection control resources published by the Board.
- Plan to undertake infection prevention and control education regularly (for example, annually) as part of your CPD with a reputable provider
- Document initiatives to maintain and improve CPD including all CPD attended, relevant articles reviewed, meetings relating to IPC, risk assessment processes and quality improvement efforts.
- Review safety instructions and directives from employers in relation to infection prevention and control in the practice and use feedback mechanisms to keep these up to date.

Documentation and duty of care

Dental practitioners have a common law legal duty of care to patients under their care, and this is reinforced in the AHPRA and National Boards shared Code of Conduct. Hence, dental practitioners must ensure that effective IPC measures are in place and are complied with in the practice. Consequently, all dental practitioners and clinical support staff have a responsibility to follow the specific IPC policies that apply in their place of work.

All staff members have duties of care to themselves and to others (in this case, other workers and patients of the practice) whose health and safety would be compromised by the staff member not following correct procedures. Compliance of staff members with workplace protocols should be a key element of the assessment of their performance.

The DBA stipulates that dental practitioners must have regard to the infection risks that relate to their practice setting and the type of care provided, as well as any existing policies or procedures required in the place of practice.

Dental practitioners must:

- ensure the practice is kept in a clean and hygienic state to prevent or minimise the spread of infectious diseases;
- develop and implement work practices to ensure compliance with infection prevention and control standards. The DBA states in its Guidance for registered dental practitioners (8 February 2024) that the following national documents can serve as resources on IPC to help practitioners be informed about accepted IPC approaches:
  - National Health and Medical Research Council – *Preventing infection*
  - National Health and Medical Research Council – *Australian guidelines for the prevention and control of infection in healthcare*
  - Communicable Diseases Network Australia – various publications
  - *Australian Immunisation Handbook*
  - Standards Australia – Australian Standard AS/NZS 5369:2023, including Amendment 1.
  - Australian Commission on Safety and Quality in Healthcare – Standards
  - Australian Commission on Safety and Quality in Healthcare – National Hand Hygiene Initiative
- be aware of and comply with state, territory or federal legal requirements relating to IPC (DBA Fact Sheet 8 February 2024); This includes, for dental practitioners working in NSW, following AS/NZS 5369:2023 and meeting other IPC requirements as stipulated in the Health Practitioner Regulation (New South Wales) Regulation 2025.
- document their infection prevention and control protocols in an infection prevention and control manual that is based on the requirements set out in these Guidelines, in the NHMRC 2019 Guidelines (AICG) and in AS/NZS 5369:2023, the Australian standard for reprocessing of RMDs;
- ensure that all dental staff have read the infection prevention and control manual and have been trained in the IPC protocols (including the correct use of PPE) used in the practice;
- provide their dental staff with access to key resources such as these ADA IPC Guidelines, the current edition of the AICG NHMRC Guidelines, and other resources as listed above;
- have in place a system of reporting, monitoring, and rectifying breaches of IPC protocols (which would involve addressing this topic in staff meetings and recording the outcomes from such discussions);
- ensure an immunisation program for dental staff is in place and is in accordance with the current edition of the Australian Immunisation Handbook;
- maintain an immunisation status record for each member of the dental staff (see Section E for a list of recommended immunisations);
- maintain a record of workplace incidents and accidents (including sharps injuries) as required by national WHS legislation;
- maintain an allergy record for each member of the dental staff;
- implement a hand hygiene program consistent with the current version of the National Hand Hygiene Initiative;
- implement systems for the safe handling and disposal of sharps;
- implement systems to prevent and manage occupational exposure to blood-borne viruses (BBVs) including follow through after potential exposures to BBVs, reporting the incident if it was an occupational exposure, undergoing testing and, if necessary, seeking specialist medical management. Note that it is not necessary for practitioners to stop performing EPPs after an exposure incident unless baseline testing reveals that they are already infected with a BBV;
- implement systems for environmental cleaning;

- implement systems for processing of RMDs as per the relevant standard;
- be aware of their immune status. Dental practitioners have a professional and ethical responsibility to know their status for BBVs. The DBA stipulates that all dental practitioners must be aware of their infectious status for HBV, HCV and HIV. Information on the appropriate frequency of testing is based on the nature of the work being done. The 2019 CDNA Guidelines stipulate that all HCWs who perform EPPs should be tested at least once every 3 years;
- if living with a BBV, not perform EPPs unless the criteria in the CDNA Guidelines are met, i.e. be compliant with their prescribed treatment and have a viral load under the prescribed threshold for HBV, HCV or HIV. There are specific pathways documented in the 2019 CDNA Guidelines for managing practitioners who are positive for HBV, HCV or HIV. Such individuals must seek expert medical advice.

Under WHS legislation in all Australian jurisdictions, practice owners have an obligation to provide and maintain a safe working environment for employees and for members of the public. This means that practice owners must provide their employed dental practitioners and dental staff with the required materials and equipment to allow these employees to fulfil their legal obligations for implementing effective IPC in their workplace.

Key compliance points for documentation

- Your practice has a comprehensive infection prevention and control (IPC) manual that is updated on a regular basis, which staff have read and are following. The ADA makes available to its members an Infection Control Manual template that can be customised to an individual dental practice.
- Your staff have access to these ADA Guidelines, and the 2019 edition of the NHMRC Guidelines.
- Your practice has a vaccination status record and an allergy record for each staff member, and both are updated annually.
- There is a record of workplace injuries.

5. Treating patients living with a BBV

Patients living with a BBV (such as HIV or HBV) require the same IPC precautions as patients without BBV (i.e. standard precautions, unless there is a separate requirement for transmission-based precautions). It is important for dental practitioners and their staff to feel assured that their infection prevention and control procedures are adequate for all patients – whether patients carry BBV infections or not. Patients should not want to hide aspects of their medical status including their history of any infections (not just BBV) status because of the way the staff act in their presence. It is a breach of anti-discrimination laws for dental practitioners to refuse to treat or impose extra conditions on a patient who is living with a BBV.

As explained in the 2019 CDNA Guidelines, hepatitis B virus is highly infectious and the chance that this disease will be transmitted by a contaminated penetrating injury to a non-immune dental staff member is on average approximately 30%, but may range from as low as 1% to as high as 62% depending on the infective status of the source patient. In comparison, the chance of transmission of the hepatitis C virus by similar means is approximately 3% on average (but may range up to 7%), and for HIV the risk of transmission from an infected patient to a HCW is on average 0.3% (1 in 300).

6. Dental practitioners with an infectious disease to declare

When applying for or renewing their registration, all dental practitioners must declare that they are aware of their infection status for BBVs and will comply with the 2019 CDNA Guidelines. This requirement applies irrespective of what local 'workplace' guidelines are in place. It also applies to students studying dentistry, dental prosthetics, oral health therapy and dental hygiene. The CDNA Guidelines detail the requirements for healthcare workers living with a BBV, in terms of medical review, testing and the ability to perform EPPs.

If a dental practitioner or student knows or suspects that they have been infected with a BBV, they must consult an appropriately qualified medical practitioner or infectious disease specialist to seek ongoing medical care, in line with the CDNA Guidelines. They must follow the advice of their treating medical practitioner and any additional stipulations of jurisdictional public health authorities. It is not appropriate for a practitioner to rely on their own assessment of the risk they pose to patients.

Diagnosis with a BBV no longer limits the clinical practice of HCWs who perform EPPs. If infected HCWs under treatment with antiviral medications subsequently meet the criteria for viral suppression or elimination as set out within the CDNA Guidelines, it is possible to return to clinical work undertaking EPPs.

According to the CDNA Guidelines, with regard to hepatitis B virus infection, HCWs who are HBV deoxyribonucleic acid (DNA) positive are permitted to perform EPPs if they have a viral load below 200 international units (IU)/mL and meet the other criteria set out in detail in the CDNA Guidelines. Effective antiviral therapy for HBV infection can reduce clinical progression of liver disease.

With regard to hepatitis C virus infection, HCWs must not perform EPPs while they are HCV ribonucleic acid (RNA) positive, but may be permitted to return to EPPs after successful treatment, or following spontaneous clearance of HCV RNA. There are a number of direct-acting antiviral hepatitis C medications that are associated with very high cure rates.

HCWs who are HIV positive are permitted to perform EPPs if they have a viral load below 200 copies/mL and meet the criteria set out in detail within the CDNA Guidelines. Early identification of HIV (before the onset of symptoms) will allow the early start of combination antiretroviral therapy (cART) which can reduce the risk of clinical progression, viral transmission, and the morbidity and mortality associated with the condition.

EPPs in dentistry increase the risk of BBV transmission from either an infected HCW or an infected patient. While performing EPPs, it is possible that injury to the infected HCW could result in the worker's blood contaminating the patient's open tissue, but there is a very low risk of transmission of a BBV from an infected HCW to a patient in Australian healthcare settings. Worldwide, since widespread availability of antiviral medication, there has not been a published case of transmission of a BBV from an effectively treated healthcare worker to a patient.

The magnitude of the risks is summarised in Table 1 below, which is taken from the 2019 CDNA Guidelines. In general, HCWs are at greater risk of acquiring infections than are dental patients.

Table 1: Risk of BBV transmission per exposure episode from untreated infected HCW to patient and untreated infected patient to HCW (in the absence of additional risk management).

Blood Borne Virus	Risk of infected HCW to patient transmission	Risk of infected patient to HCW transmission
Hepatitis B virus	0.2% - 13.19%	1% - 62%*
Hepatitis C virus	0.04% - 4.35%	0% - 7%
Human immunodeficiency virus	0.0000024% - 0.0000024%	0.3%

*There is a wide variability in infectiousness of people with hepatitis B reported in the literature and this depends on their hepatitis B e-antigen status.

Source: 2019 CDNA Guidelines.

Effective antiviral drug treatment protocols reduce the infectivity of individuals. Once an undetectable viral load has been achieved, there are ongoing requirements, with regular testing for BBVs for the duration of the practitioner's career, to ensure that virus levels remain undetectable.

While the protection of the public's health is paramount, employers of dental practitioners should also consider, and comply with, relevant anti-discrimination, privacy, industrial relations, and equal employment opportunity legislation. Employers must ensure the status and rights of all staff members are protected, including those who have been exposed to a known BBV source by sustaining a blood and body fluid exposure (BBFE) and who are now undergoing testing from an occupational exposure. (Refer to the Appendix for the BBFE protocol.)

Key compliance points for BBV disease status

- Staff in your practice are aware of the 2019 edition of the CDNA *Australian National Guidelines for the Management of Health Care Workers Known to be Infected with Blood-Borne Viruses Procedures and Healthcare Workers who Perform Exposure Prone Procedures at Risk of Exposure to Blood Borne Viruses*.
- Dental practitioners who perform EPPs undergo testing for antibodies to hepatitis B, hepatitis C, and HIV at least once every three years, and after an occupational BBFE.
- When a contaminated sharps injury or other BBFE occurs to a staff member, it is followed up correctly with baseline tests of the injured staff member (see the Appendix).

Section B. Standard precautions for infection prevention and control

The following standard precautions form the basis of IPC and must be carried out routinely for all patients.

1. Hand hygiene

Hand hygiene is a general term that applies to processes that aim to reduce the number of microorganisms on the hands by using either a hand wash or an alcohol-based hand rub (ABHR) that is listed on the Australian Register of Therapeutic Goods (ARTG). The purpose of hand hygiene is to prevent transmission of microorganisms from the hands of dental staff to other staff and patients, or from one patient to another patient, either directly or by touching contaminated surfaces or objects. Microorganisms that are present on the patient's skin can be picked up by direct contact (e.g. by handshaking). They are also shed into the area immediately surrounding the patient, depending on factors such as how long the patient is sitting there. Pathogenic bacteria contained within a biofilm on a contaminated surface can readily be transferred from the surface onto gloved hands or bare hands and will remain on hands or gloves for up to 19 subsequent touches. These microorganisms can spread if hand hygiene is not performed at all, or is inadequate.

An implementation guide to help practices implement and manage their hand hygiene program is available from the National Hand Hygiene Initiative (NHHI).

When to perform hand hygiene

'Moments' or opportunities for hand hygiene are points when there is a perceived or actual risk of pathogen transmission from one surface to another, via the staff member's hands.

The 5 moments for hand hygiene are:

Moment 1: Before touching a patient.

Moment 2: Before a procedure.

Moment 3: After a procedure or body fluid exposure risk.

Moment 4: After touching a patient.

Moment 5: After touching a patient's surroundings.

Note that when auditing compliance, two moments or opportunities may coincide (i.e. overlap fully) for example, moments 1 and 2 may coincide when a clinician commences an intra-oral examination.

For more information on the NHHI, including access to free online educational modules, resources and the Hand Hygiene Compliance application (HHCApp), go to NHHI.

Hand hygiene must be undertaken before and after contact with every patient, and before gloves are put on. It must also always be done before putting on gloves (donning) and after removing gloves (doffing). Hand hygiene must be performed again immediately before donning gloves for the next patient, and if there is any contact made between the bare hands and contaminated items or contaminated environmental surfaces. Note that handshaking (which relates to moments 1 and 4) may increase the risk of transmission of skin-borne pathogens.[4]

Alcohol-based hand rub

The NHHI promotes the use of ABHR at the point of care for all clinical situations where hands are visibly clean. The normal routine in a dental practice when no surgical procedure is being undertaken should be for dental staff to use ABHR between patient appointments and during interruptions within the one appointment, in accordance with the 5 moments of hand hygiene. For regular hand hygiene, ABHR is applied to dry hands and rubbed on to cover all surfaces of hands for 20–30 seconds, after which time the hands will be dry.

For non-surgical dentistry, the advantages of ABHR are that it is efficient (taking approximately 30 seconds), does not require a sink with running water, detergent and paper towels, and is much less irritating and drying to the skin than using soap and water (provided an appropriate moisturiser is also used during the day). Unlike detergents, ABHRs do not remove skin lipids and they do not require paper towel for drying.

How to apply ABHR for regular hand hygiene

When applying ABHR, apply enough product for approximately 20–30 seconds of rubbing (if there is no gel left on the hands after rubbing for only 10 seconds, add additional gel).

Key elements of correct technique are as follows:

- Apply ABHR to visibly clean hands.
- Apply a palmful of ABHR product (usually 1–2 pumps) into a cupped hand.
- Distribute ABHR across both hands to cover all surfaces, including the wrists and fingertips (under nails).
- Rub ABHR into hands until dry (20–30 seconds).

Only apply ABHR to dry hands, as water remaining on the hands dilutes the product, decreasing its effectiveness.

Further information on hand decontamination with ABHR and posters on 'How to Hand Rub' can be downloaded from the NHHI.

How to select an appropriate ABHR product

When selecting an ABHR product, ensure that the product has been listed on the ARTG for use as a hand hygiene product for a healthcare setting. To meet the TGA requirements for hand care in a healthcare setting, the product will have met the EN1500 testing requirements for bactericidal effect. This listing will normally be indicated on the product label, and cost should never dictate the use of a non-compliant product. Approved ABHR products include gels, liquids (solutions) and foams. Follow the manufacturer's advice and local waste management regulations regarding how to handle empty containers of ABHR.

For staff whose selection and use of an ABHR product may be influenced by religious factors, it is important to know that using ABHR does not result in any significant alcohol absorption through the skin, and thus using ABHR in the practice does not breach prohibitions around alcohol (ethanol) consumption. The issue can be avoided by choosing an isopropanol-only ABHR product that has no ethanol at all.

Choose an ABHR product that suits the skin type of the staff. When the correct product is chosen, the emollient agent(s) in the ABHR will prevent the skin from becoming dry or irritated and should not leave a sticky residue on the hands. A poorly chosen ABHR product that has poor acceptance is unlikely to be used. Staff with an existing skin irritation or skin disease may experience a stinging sensation when first using ABHR. Usually, this subsides over several weeks with the ongoing use of an emollient containing ABHR. However, medical advice should be sought if symptoms persist.

Surgical hand preparation

There are specific high-potency alcohol-based surgical scrubs designed for surgical hand decontamination. These should be used as a substitute for antimicrobial soaps in a surgical scrub for hand preparation prior to oral surgery procedures where surgical asepsis will be implemented. Such high potency products are specifically labelled as being for surgical hand preparation, have will have been tested to meet the EN 12791 standard for surgical hand disinfection. They are formulated in a different way to those marketed for regular hand hygiene. They have higher concentrations of ethanol and/or isopropanol and are tested using a more stringent performance test. Such products require a prolonged rubbing time (typically 60–90 seconds) to achieve surgical hand hygiene. When using alcohol-based surgical scrubs, be aware that the extended rubbing time requires use of a clock to ensure that the exposure time is sufficiently long to achieve surgical hand decontamination. These products require a multi-step process or multiple applications to achieve the required level of skin preparation. Following the product instructions is critical for their proper use and storage.

Note that ABHR are flammable at room temperature. They have flashpoints ranging from 21 °C to 24 °C, depending on the type and concentration of alcohol present. All containers of ABHR above 100 mL will be labelled with the Australian Dangerous Goods class 3 flammable diamond on the container. Keep bulk supplies of ABHR well away from any sources of high temperature or ignition, such as open flames, gas burner flames, electrosurgery or diathermy. The maximum total quantity of all flammable liquids allowed for 'minor storage' is no more than 10 litres per 50 square metres of floor space (as per AS 1940:2004 *The storage and handling of flammable and combustible liquids*, Section 2, Table 2.1).

Location of ABHR dispensers

Keep ABHR dispensers away from children to prevent accidental ingestion of ABHR.

Avoid having ABHR dispensers located at handwashing sinks as this might cause confusion for staff who think that they should do both handwashing and ABHR application (in fact, only one is needed). Washing hands with soap and water immediately before or after using an ABHR is not only unnecessary but may lead to occupational irritant dermatitis. For this reason, there is no need to position ABHR dispensers near the handwashing sink. It is both desirable and convenient to position ABHR dispensers close to the clinical working area, provided their location is not prone to splashing from patient fluids.

Bottles of ABHR in the dental operatory should not be 'topped up' with product from a bulk container because of risks of contamination. Never tip or pour ABHR products from one bottle to another, as this may cause contamination of the second bottle and its contents. Empty bottles of ABHR from the operatory are to be discarded and not reused.

Use of moisturiser

ABHR can be used as often as is required. However, a compatible water-based moisturiser should be applied, as required, up to four times per day.

Handwashing

Hands must always be washed under the following situations:

1. after toilet breaks;
2. whenever they are visibly dirty, contaminated with proteinaceous material, or visibly soiled with blood or other body fluids; and
3. when exposure to potential spore-forming organisms is strongly suspected or proven.

Washing hands with liquid soap and water is preferred in each of these situations due to the mechanical removal effect.

Further information on hand washing, and posters on 'How to Handwash' can be downloaded from NHHI.

Handwashing should be undertaken in dedicated sinks located in the clean zone. Preferably, these sinks should not include overflow outlets and should preferably be fitted with non-touch taps (e.g. operated by elbow controls or by sensors); otherwise, handwashing should be carried out using a non-touch technique. If conventional (hand-operated) taps are used, they should be operated with the use of a paper towel, rather than with bare hands. Handwashing must not be undertaken using the sink in the contaminated zone that is used for cleaning or rinsing RMDs.

Thorough handwashing is recommended when dental practitioners work outside the normal clinical environment, e.g. in a nursing home or at a patient's home, where it is more likely that pathogens such as noroviruses or spores of *Clostridium difficile* may be present on high-touch surfaces. Thorough handwashing may also be required when treating patients with pathogens that are not readily inactivated by ABHR. Fortunately, common bacteria and medium and large sized viruses (including respiratory viruses) are readily degraded by ABHR. The challenge is more when small-diameter non-enveloped enteric viruses are present, such as in outbreak situations where contact precautions may be required.

Toilets need proper handwashing facilities, including hand basins to perform hand hygiene and means for drying hands such as disposable paper towel. Some practices use hot air dryers as an alternative. These tend to spread microorganisms from the skin into the environment much more than paper towels, with the worst being jet air dryers.

How to select an appropriate hand washing product

Liquid soap products used for routine handwashing require TGA approval for any special claims that are made regarding antimicrobial actions. The ARTG number for the product will typically be given on the label.

Any products for surgical hand preparation must have their claims for antimicrobial actions approved by the TGA, and they must be listed on the ARTG.

Hand care

Hands must be well cared for because intact skin is a first-line defence mechanism against infection. Damaged skin can lead to infection in the host and can harbour higher numbers of microorganisms than intact skin, increasing the risk of transmission to others. Damaged skin in dental practitioners and clinical support staff is an important issue because of the high frequency of dry, itchy skin among these staff from irritant contact dermatitis. It is caused most often by frequent and repeated use of handwashing products (especially liquid soap) and poor-quality paper towel that abrades the skin. Other factors that may contribute to dermatitis include the fragrances and preservatives found in domestic hand care products (which can cause contact allergies), donning gloves while hands are still wet, use of hot water for handwashing and failing to use appropriate moisturisers.

Lacerated, chafed or cracked skin can allow entry of microorganisms. Any cuts or open wounds need to be covered with a flexible, fluid-proof/waterproof dressing.

It is important to follow the manufacturer's advice regarding the proper use of liquid soap handwashing products. Typically, these are applied to wet hands and at the completion of handwashing are rinsed away with running water and the hands patted dry with single-use linen or disposable paper towels.

Appropriate preparation of the hands and wrists – 'bare below the elbows'

Each dental practice needs a clear policy statement within its IPC manual regarding the need for clinical staff to keep their nails both short and natural. Wearing nail polish, artificial fingernails or fingernail extenders is not permitted, as these cause larger amounts of microorganisms to be retained on the hands, particularly around the nail beds, despite hand hygiene. Keeping nails short also prevents them from puncturing gloves and makes hand hygiene easier to perform.

A dental practice must have a clear policy within its IPC manual regarding the 'bare below the elbows' (BBE) principle. In line with the National Hand Hygiene Initiative, all hand, wrist or nail jewellery (e.g. rings , bangles and bracelets), watches and wearable devices such as 'Fitbits' must be removed by clinical staff when they commence work and before engaging in direct patient care or RMD reprocessing activities, as their presence impairs correct hand hygiene, compromises the fit and integrity of gloves, and promotes the growth of skin microorganisms. Areas of skin beneath rings on the fingers become much more heavily colonised with microorganisms than adjacent areas, and wearing rings increases the carriage rate of gram-negative bacteria on the hands of clinical staff. This is why rings should be removed.

The BBE approach also includes avoiding wearing clothing with sleeves extending below the elbows, including cloth coats with long sleeves, during direct patient care. Long sleeves on clothing that is worn during a clinical session will become contaminated with microorganisms from the working environment, and from patients, and may impede proper hand hygiene between patients. When a long-sleeved gown or coat is used (e.g. for surgical procedures such as placing implants), these should be considered as single-use and removed and disposed of, or appropriately laundered after use.

Some team members may wish to cover their forearms when not engaged in direct patient care due to religious, cultural or safety reasons. Nonetheless, team members must ensure that if they are engaged in direct patient care, proper adherence to hand hygiene standards occurs. This means long-sleeved clothing that can be removed or altered to be above the elbows.

Some team members may have concerns or questions regarding continuing to follow their beliefs while maintaining hygiene standards. If this is the case, they should discuss this with managers/owners and cultural leaders where appropriate.

The requirements for hand hygiene are outlined in the AICG NHMRC 2019 guidelines and the ACSQHC National Hand Hygiene Initiative and are in line with the Dental Board of Australia Code of Conduct *and Guidance for dental practitioners: Infection prevention and control* fact sheet. These guidelines are taken as a genuine occupational requirement given the nature of the role. If any employee has a personal factor that may warrant individual consideration of these circumstances against the occupational requirement, they are free to raise it with their employer, who will consider, on all the circumstances, if an alternative arrangement could be made that meets the clinical needs of patients and maintains required standards.

Key compliance points for 'bare below the elbows'

- Check that gowns, coats and undershirts worn by clinical staff have short sleeves.
- Ensure that fingers, hands and wrists are free of items that retain microorganisms or hinder hand hygiene.
- Ensure that nails are kept short and natural, without coatings.

2. Personal protective equipment (PPE)

Wearing personal protective clothing and equipment where splashes and aerosols are likely to be generated is an important way to reduce the risk of transmission of infectious agents. Dental practitioners and clinical support staff must be provided with all appropriate necessary protective clothing and equipment for the procedure being undertaken, and need to be educated on the correct use of these items.

Items of PPE that form part of standard precautions and that provide barrier protection of the body, including gloves, mask, eyewear and an outer layer of protective clothing (such as a clinical gown or other dedicated outer clothing), must be removed before leaving the work area (e.g. dental operatory, reprocessing areas or laboratory areas) for a meal break. Likewise, contaminated gloves are to be removed when leaving the contaminated zone (e.g. when moving from the treatment room to reception areas).

Gloves

Wearing gloves does not replace the need for hand hygiene, because hands may still become contaminated from manufacturing defects in new gloves that were not obvious to the user, or because of damage (such as tears and pinpricks) that occurs to gloves during use.

For dental clinicians, disposable gloves provide an essential layer of protection to prevent direct contact with patient fluids (including saliva and blood) and from the over 700 species of bacteria normally present in the mouth. This has direct benefits, including the elimination of nailbed infections caused by bacteria, fungi, and viruses (e.g. whitlow caused by Herpes simplex virus).

Dental practitioners and clinical support staff must wear gloves for all clinical procedures and whenever there is a risk of exposure to blood, saliva or other body secretions, as well as when the hands will come into contact with mucous membranes. The IPC manual used in the dental practice should list the protocols for glove-wearing and for hand hygiene before donning gloves and after removing gloves.

The IPC manual should also specify how gloves are used, according to the scheme below:

- Non-sterile gloves: routine clinical procedures, root canal treatment, vital pulp therapy, extraction of teeth not involving raising a flap, minor oral surgery not involving raising a flap, cleaning the dental operatory, handling clinical waste, instrument reprocessing activities, and other activities where contact with saliva, blood and body fluids may occur, in line with standard precautions. When performing extractions and minor oral surgery, apply the principles of the Aseptic Non Touch Technique (ANTT®) for critical devices and RMDs to protect their working surfaces from contamination.
- Sterile gloves: for dentoalveolar surgery and other oral surgical procedures where flaps are raised (e.g. surgical removal of teeth, endodontic surgery, periodontal regenerative surgery), and dental implant surgery, as part of surgical aseptic technique (sterile RMDs, sterile drapes, sterile gown, sterile field).

Gloves are now available in a range of materials, including latex, nitrile, neoprene and polyisoprene, with hypo-allergenic versions having reduced levels of polymerising agents on the gloves because of extensive washing. Because of the frequency of allergic reactions to polymerising agents (also known as cross-linking agents), such hypo-allergenic versions should be considered when staff experience skin reactions that are not due to incorrect hand care (such as failing to apply moisturisers every day).

A new, clean pair of disposable, single-use gloves must be used for each episode of patient care. Such gloves must not be reused in patient care or refitted after removal; a new pair of gloves must be used for each patient. Gloves must be changed as soon as they are cut, torn or punctured. Gloves must be removed, and hand hygiene undertaken, before accessing items in drawers or touching areas in the clean zone.

Gloves must be removed as soon as clinical treatment is complete, and then hand hygiene must be undertaken immediately to prevent the transfer of microorganisms to other patients or environmental surfaces. As mentioned earlier, gloves that are contaminated with bacteria arising from biofilms can re-contaminate surfaces for up to 19 subsequent touches. Dental assistants should put on new disposable gloves for cleaning work surfaces during the changeover between patients, rather than using contaminated gloves from assisting with the previous patient.

Glove selection

To protect the skin of the wearer, the glove must cover the hand and wrist region. As dental clinical staff work in short-sleeved clothing when undertaking non-surgical dentistry in the 'bare below the elbows' approach, gloves must have a sufficient 'cuff length' to cover and protect the skin of the wrist from splashes of material.

Defects present in new gloves potentially expose the skin of the HCW to patient fluids, environmental contaminants, and microorganisms from the patient. Defects can develop as the glove material is stretched during use for example, in the thumb and forefinger regions as a result of grasping items with force, and in the fingertip regions from exposure to sharp items. A higher-quality glove will be more durable and will develop fewer defects over the time it is worn.

Many dental procedures involve the use of sharp instruments and items; thus, the glove material must resist tears and punctures. Glove materials vary in their physical properties such as their tear strength. To achieve suitable resistance to tearing, the glove material must be strong and must also have sufficient thickness to handle the stresses of donning gloves, and the shear forces imparted when items are grasped with force. Nitrile gloves are less likely to develop small tears and leaks during use compared to latex gloves, despite not being thicker.

Gloves also reduce exposure to the many hazardous substances used in everyday clinical dental practice, including strong acids, strong alkalis, organic monomers of various types and solvents such as acetone and ethanol, which are found in the bonding agents used in adhesive dental procedures. Use of high-quality gloves contributes to the long-term health of the hands by limiting contact with other chemicals used in dentistry that can cause irritation or allergy, such as methacrylate resins and aldehydes. Glove materials vary in their resistance to chemical agents. Compared to natural rubber latex, gloves made from nitrile have greater resistance to detergents, acids and common organic solvents (such as ethanol). Latex gloves may impair the setting reaction of certain elastomeric impression materials because they contain zinc diethyldithiocarbamate as a preservative and vulcanising accelerator. This chemical can completely inhibit polymerisation of elastomers. Thus, the type of glove chosen must be appropriate for the procedure being undertaken.

Non-sterile examination gloves are to be worn for routine dental procedures. Non-sterile gloves supplied for use in a dental practice are required to conform to AS/NZS 4011:2014 *Single-use examination gloves* (Parts 1 and 2), and sterile gloves to AS/NZS 4179:2014 *Single-use sterile rubber surgical gloves*. Sterile gloves must be worn when a sterile field is necessary for procedures such as dentoalveolar surgery, periodontal surgery or endodontic surgery, or implant placement. For surgical dental procedures, the surgical gloves need to cover the cuffs of the surgical gown sufficiently well to form an effective seal.

In addition to meeting these two sets of Australian standards for single-use gloves, and relevant ISO standards adopted by Australia (such as ISO 11193-1:2020), clinical staff may also consider other factors such as the acceptable quality level (AQL) (defect rate) and whether the gloves are powder-free, hypo-allergenic or have low levels of latex proteins.

Glove AQL is determined by examining gloves for various nonconformities or imperfections, including physical dimensions (width, length and thickness), watertightness, tensile strength and elongation, and air and water tests to indicate any tears, holes or pinpoint defects. The lower the AQL, the better.

A glove that is labelled as being 'powder-free' will have trace amounts of residual former-release powder (2 mg or less per glove) and no intentionally added donning powder. Powder-free gloves are recommended because they reduce occupational allergy to latex in HCWs via both respiratory and contact routes.

Polymerising agents are used in latex, nitrile, neoprene and polyisoprene gloves and are a common cause of delayed hypersensitivity reactions to disposable gloves. Staff who have suspected or confirmed allergic reactions to polymerising agents in gloves should use hypo-allergenic gloves that have low levels of chemical residues.

Gloves must be worn when cleaning RMDs and environmental surfaces. The type of glove worn must be appropriate to the task. For example, disposable latex or nitrile gloves are appropriate for cleaning the dental operatory during changeover between patient appointments.

Gloves must be used during manual cleaning of RMDs in the designated sinks. Gloves are also necessary when loading washer-disinfectors with contaminated RMDs. Items that have been through a washer-disinfector may be handled during inspection and packaging without gloves. Gloves may be appropriate when loading the chamber of the steam steriliser after items have been through manual or ultrasonic cleaning, since in this case the RMDs have not been disinfected.

Use supplied steriliser tray lifters to unload RMDs after completion of the steriliser cycle, to prevent burns to hands and forearms from hot chamber walls and hot items. In the unlikely event that it is necessary to reach to the deepest part of the chamber to retrieve a sterilised item, heat-resistant gloves should be worn, to prevent burns. These heat-resistant gloves must remain as clean items.

If a dental practitioner, clinical support staff member or patient has a proven or suspected allergy to latex, alternative glove materials must be used, such as neoprene or nitrile gloves. A latex-free protocol must also be followed, including use of a non-latex dental dam and non-latex materials such as prophylaxis cups. Note that patients with multiple food allergies (e.g. banana, chestnut, avocado, kiwi fruit, tomato) have an elevated possibility of latex allergy. It is prudent to use a latex-free approach when treating such patients.

Accessibility and Storage of Gloves

Keeping glove boxes accessible is important since many dental procedures require planned changes of gloves during the procedure for the chairside assistant or the clinical operator. This is in addition to unplanned interruptions, such as the need to replace gloves that show visible tears or other defects during use.

Opened and unopened boxes of gloves must be stored away from where they could be exposed to splashes of fluid from patient care. As mentioned earlier, open glove boxes need to be kept away from the direction where most splash occurs, i.e. heading from the patient's mouth towards their feet. If the glove box is located on a wall or a benchtop that is *to the side* of the patient's head, a suitable separation distance of at least 1 metre sideways from the patient's mouth should be implemented to prevent splashes of material reaching the box.

Key compliance points for gloves

- Ensure that gloves are worn as part of standard precautions during treatment and when cleaning.
- Check that the types of gloves being used by dental team members are suitable for the purpose for which they are being used. Ensure that the use of sterile gloves is accompanied by a comprehensive approach to establishing and maintaining a sterile field.
- Check that the placement of glove boxes in the clinic area prevents contamination prior to use.
- Ensure staff in the practice understand the need for hand hygiene before and after wearing gloves.

Masks (including particulate filter respirators)

Surgical masks are an essential item of PPE and wearing a mask forms part of standard precautions. Masks protect the mucous membranes of the nose and mouth, and they protect the skin of the face from splashes of material. They also provide some protection to patients from respiratory secretions of the wearer.

Masks must be worn wherever there is the possibility of splashing, splattering, or spraying of blood, saliva or body substances, or where there is a probability of inhalation of aerosols with the potential for transmission of airborne pathogens. It is recommended that masks be worn at all times when treating patients, as this also prevents contamination of the working area with the operator's respiratory or nasal secretions/organisms.

Dental practitioners and clinical support staff must wear suitable, well-adapted, close-fitting, fluid-resistant masks that conform to AS 4381:2015. A surgical mask that has been properly adapted to the face can block entry of up to 95% of microorganisms, but this filtration capability falls away quickly when the mask is not fitted tightly against the face.

The efficacy of a surgical mask decreases over time, as the inner and outer surfaces of the mask become wet. The duration of time this takes to occur is variable and depends on the wearer's respiratory rate and the temperature and humidity of the room. It is necessary to change a mask when it becomes wet or soiled.

To provide effective filtration, it is critical that a mask is fitted closely to the user's face by adapting the nose bridge piece and the sides to reduce leakage of air. The design of the mask influences how well it can be adapted to the face of the wearer and how much of the face is protected.

Aerosol-generating procedures (AGP) create particles that are 5 microns or less in size. In the dental surgery environment, the most common causes of airborne aerosols are the ultrasonic scaler, the high-speed air turbine handpiece, particle-jet devices and the triplex syringe. The aerosols produced from the patient's fluids may be contaminated with bacteria, fungi and viruses from the oral cavity. Aerosols from powered dental equipment also contain microorganisms that have originated from dental unit waterlines.

As already noted, masks supplied for use in routine dental practice are required to conform to AS 4381:2015 *Single-use face masks for use in health care*. This standard describes masks according to their resistance to fluid penetration (also referred to as splash protection). The standard describes the requirements for procedural masks (level 1) and surgical masks (with level 2 or level 3 resistance to fluid penetration).

A disposable *procedural* mask with a level 1 rating would *only* be appropriate for those clinical situations where no exposure to fluids or splashing is expected (e.g. dental prosthetics, review appointments in removable prosthodontics, minor orthodontic adjustments where the triplex syringe is not used). Any procedure using a powered dental handpiece, irrigation or a triplex syringe requires the use of a mask with at least a level 2 rating for resistance to fluid penetration.

Disposable *surgical* masks used in routine dentistry must have 98% or greater bacterial filtration efficiency and be splash resistant (equivalent to American Society for Testing and Materials (ASTM) Level 2 splash protection) so that they are resistant to the penetration of fluid. The level of protection should be clearly labelled on the mask box or on the mask itself. Where more than minimal blood droplet exposure is expected, e.g. complex oral surgery procedures such as multiple implant placement, a risk assessment should be undertaken to determine whether the mask type should be upgraded to Level 3 splash protection to cope with greater potential exposure to blood and other body fluids.

Masks must have bacterial filtration capabilities that meet the requirements of AS 4381:2015, namely bacterial filtration efficiency (BFE) value for particles from 1–3 microns that exceeds 95%. The standard for single-use face masks does not specify any requirements for filtration of sub-micron size particles, since the preferred means of proving respiratory protection from sub-micron particles (i.e. airborne-transmissible infectious organisms) is a PFR. Most brands of surgical masks have limited particle filtration efficiency (PFE) for particles ranging from 0.1–0.3 microns in size.

The following are some basic protocols to be observed in relation to masks as items of PPE.

Mask Musts	Mask Must Nots
Be put on after performing hand hygiene. Note that further hand hygiene is then needed before donning gloves.	Be touched by the hands while being worn, other than to remove it completely using the strings / loops.
Be fitted and worn according to the instructions for use – this means using both tie strings where the mask has two ties and adapting the mask to the bridge of the nose.	Be lowered to expose the nose.
Cover both the nose and mouth, and, where possible, be folded out to fully cover the chin and upper neck.	Be worn around the neck.
Be changed when soiled or wet.	Be worn for extended periods of time (e.g. more than the manufacturer's recommended duration).
Be removed by touching the strings and loops only.	Be removed by touching the front of the mask.

As described earlier, for procedures undertaken on patients who have a current active respiratory infection or other disease that can be transmitted via the airborne route, it is important to consider the additional risks to clinical staff from aerosols that are generated during patient treatment. Measures such as pre-procedural rinsing and high-velocity evacuation can greatly reduce the load of microorganisms found in these aerosols. For procedures on patients who have a current airborne transmissible infection and for whom care is unable to be deferred, a surgical (fluid resistant) PFR, rather than a surgical mask, should be worn. A PFR will provide better sub-micron filtration and proper sealing against the facial skin.

Key compliance points for masks

- Masks are worn as part of standard precautions.
- Masks are adapted correctly to the face.
- Masks are removed once treatment is complete, and not left dangling around the neck.
- Masks are changed when they become soiled or wet.
- Masks are never reapplied when they have been removed.
- Staff do not touch the front of a mask while wearing it.
- Check that appropriate masks or respirators for the procedures taking place are available for use and that dental team members are trained on appropriate mask donning and doffing.

Eye protection

Many clinical procedures generate particles that travel towards the face of the clinical operator or their chairside assistant. For this reason, dental practitioners and clinical support staff must wear protective eyewear to protect the mucous membranes of the eyes during procedures where there is the potential for penetrating injury or exposure to aerosols, splattering, or spraying with blood, saliva or body substances.

Eyewear protects the eyes from a broad range of hazards, including projectiles, and should be worn for most clinical procedures. Protection from projectiles is particularly important during scaling, when using rotary instruments (particularly when removing existing restorations), when cutting wires and when cleaning RMDs.

Eyewear must be optically clear, anti-fog, distortion-free and close-fitting. It is essential that eyewear be shielded at the sides. Prescription lenses worn for vision correction are not a substitute for protective eyewear because corrective spectacles in regular frames do not have side protection. Most designs do not cover the orbit fully and thus, will not protect the wearer from splashes of material or projectiles.

Reusable or disposable eyewear supplied for use in dental practice is required to conform to the relevant parts of the AS/NZS 1337 *Personal eye protection series of standards.* Part 6 of that standard, *Prescription eye protectors against low and medium impact*, describes minimum requirements for eye protectors fitted with prescription lenses intended to provide low or medium impact eye protection from flying particles and fragments in occupational situations.

Prescription lenses worn for vision correction can become a sound form of protective eyewear when the lenses are inserted in frames designed to provide a suitable level of protection to the orbital region. A variety of corrective lenses (including bi- and tri-focals or transition lenses) can be put into frames approved as protective safety glasses.

Clinicians need to be aware that eyewear becomes contaminated during the course of clinical treatment and needs to be decontaminated between patients.

Clinicians using protective eyewear with either retractable loupes or with a light attachment which has an integrated curing shield need to avoid cross-contamination by ensuring that the eyewear is decontaminated between patients. This includes cleaning the lenses as well as any parts of the eyewear that may be touched by gloved hands while working. Examples of such parts include orange curing filters on lights mounted onto eyewear, and handles for changing the position of flip-down loupes.

An alternative to protective eyewear is a face shield that conforms to the relevant parts of the AS/NZS 1337 P*ersonal eye protection series of standards.* Corrective glasses or magnifying loupes may be worn beneath a face shield. A face shield may be an independent transparent visor supported in front of the face to shield the face and front of the neck, or it may be attached to a mask as a single unit. Because a face shield does not protect the wearer from inhaled microorganisms, it must always be worn in conjunction with a surgical mask or PFR.

Patients must be provided with protective eyewear to minimise the risk of possible injury from materials or chemicals used during treatment. Tinted lenses may be used to protect patients from the glare of the operating light. Spectacles worn by patients for vision do not typically provide sufficient protection. If patients refuse to wear protective eyewear, the risks should be explained, and refusal noted in their dental records.

Eyewear for patients may be either disposable or designed for reuse after cleaning with detergent and water. Reusable protective eyewear for patients touches their intact skin, which is a non-critical site. In cases where the patient has sustained significant facial trauma and it is likely that blood contamination of the patient's protective eyewear will occur, it is advisable to use disposable eyewear, to remove the need for complex decontamination procedures.

Key compliance points for eyewear

- Both staff and patients use protective eyewear that protects the orbit fully and has side protection.
- Regular corrective spectacles worn by staff are not used as a substitute for protective eyewear.
- Eyewear worn by clinical staff is decontaminated between patients.
- Reusable eyewear for patients is treated as a non-critical item and is cleaned with detergent between uses.

Protective clothing

The most suitable type of protective clothing varies according to the nature of the procedure and IPC practices required, and can be a matter of professional judgement. A key concept is that of layering, so that street clothes worn underneath do not become contaminated with material from patient treatment, then transfer that contamination beyond the dental clinic environment and back to the home of the staff member on their person. Items of protective clothing worn during non-surgical dental procedures must be changed as soon as possible when they become visibly soiled or after repeated exposure to contaminated aerosols (i.e. at the end of the session or the end of the working day).

Protective coats or gowns that have been worn in the clinical area must be removed before taking a meal break or leaving the practice. When scrubs are worn as the everyday practice uniform throughout the clinic, it is necessary to wear a suitable layer of protective clothing *on top* of these. This would normally be a suitable disposable or reusable gown (e.g. short-sleeved for routine dentistry, or long-sleeved and sterile for surgical dental procedures). Alternatively, scrubs may be worn over a uniform or street clothes, and removed prior to moving to clean zones (such as after a clinical session, prior to a meal break).

Protective clothing (e.g. disposable gown or washable gown or coat) should be worn while treating patients whenever splatter or aerosols are likely to be generated. This includes procedures using powered RMDs such as ultrasonic scalers or dental handpieces, or those that involve use of the triple syringe.

At the end of a patient appointment, gowns with long sleeves should be either disposed of (if disposable) or removed and appropriately laundered. Long sleeves become contaminated with microorganisms from the working environment and from patients, and can impede proper hand hygiene.

Disposable sterile surgical gowns are suitable for use for oral surgery as a single patient use item. These gowns typically have long sleeves that extend to the area of the wrist that will be covered by the cuff of sterile gloves. At the end of the procedure, they are to be removed and should be placed into the general waste or if visibly contaminated with blood, disposed of according to local waste management regulations.

Cloth gowns and coats worn by dental practitioners and clinical support staff must be short-sleeved, clean and in good condition. Reusable cloth gowns and coats need to be laundered or reprocessed according to AS/NZS 4146:2000 *Laundry practice*.

A single-use, fluid-impervious gown must be worn if the patient has an infectious disease that requires transmission-based precautions. This gown must be disposed of after the procedure is complete and not used for subsequent patient care.

Footwear

Dental practitioners and clinical support staff should wear enclosed footwear that will protect them from injury or contact with sharp objects (e.g. accidentally dropped sharps or spilt chemicals). Footwear should be non-slip and easy to clean in the event of spills and splashes.

Key compliance points for protective clothing and footwear

- A layering approach is used so that street clothes worn underneath do not become contaminated with material from patient treatment.
- Gowns worn for non-surgical dental treatment have short sleeves.
- Shoes are closed in so they protect the foot from dropped objects.

3. Surgical procedures and surgical aseptic technique

As mentioned previously in the section regarding the use of gloves, the principles of the surgical aseptic technique must be applied to all surgical procedures involving surgical penetration of bone, or elevation of a mucoperiosteal flap. This includes the surgical removal of teeth (including residual root tips, and enucleation of radicular cysts) and placement of dental implants. In these situations, in addition to sterile gloves, requirements include surgical hand hygiene, sterile drapes, sterile irrigation solutions (such as saline), and RMDs that are sterile at the point of use (with batch control identification). Long hair must be tied back and covered (e.g. with a disposable cap or hair net) and beards must also be covered.

The World Health Organization (WHO) recommends the use of alcohol-based formulations for surgical hand antisepsis, given their superior antimicrobial efficacy compared to other methods. Hence, for surgical hand hygiene the preferred method is the application of a surgical waterless scrub solution for an extended (manufacturer) prescribed time (e.g. 60 to 90 seconds). Use of antimicrobial handwashing solutions for surgical scrubbing is no longer recommended as the usual approach, due to concerns of antimicrobial resistance and occupational allergy.

Sterile gloves supplied for use in dental practice are required to conform to AS/NZS 4179:2014 *Single-use sterile rubber surgical gloves.*

It may be most efficient and practical for a dental practice to purchase drapes, gowns, gauze and other sterile supplies, rather than to prepare and sterilise these in-house. If it is not possible to find a supplier for certain items (e.g. pre-sterilised cotton pellets), those can be sterilised in the practice using a suitable validated cycle. Refer to the section on porous loads for more information.

Key compliance points for surgical procedures

- Staff perform surgical hand preparation before donning sterile gloves.
- Staff wear an appropriate gown, and hair is controlled.
- There is a defined working field with sterile drapes.
- Any irrigation solutions used are sterile.
- All RMDs that enter tissue are sterile at the point of use, and have been packaged with the use of batch control identification.
- All staff involved in surgical procedures should be trained regularly in surgical asepsis and their competency assessed and performance reviewed.

4. Management of sharps

Frequently, the practice of dentistry involves the use of sharp items and RMDs. Occasionally, when undertaking high-risk EPPs, conditions of limited access and poor visibility will increase the risk of a penetrating injury to dental staff, potentially exposing the patient to the blood of the dental staff member.

Inappropriate handling of sharps, both during and after treatment, is the major cause of penetrating injuries involving potential exposure of staff to blood-borne diseases. Consequently, it is essential that all sharp instruments are handled and used with care, and appropriate techniques employed to minimise the risk of penetrating injuries to dental staff.

Sharp instruments such as scalpels and scalers must never be passed by hand between dental staff members. They must be placed in a cassette or puncture-resistant tray or bowl after each use. RMDs must be carried from the surgery to the reprocessing area in a lidded puncture-resistant container.

In dentistry, recapping or disassembling sharps may be unavoidable. If so, a risk assessment must be undertaken and safety devices must be used where appropriate (NHMRC, 2019, p. 51). Needles and medical sharps must not be recapped unless (1) there is a requirement to control a risk identified based on an assessment under jurisdictional Work Health and Safety regulations, AND (2) the risk of injury cannot be controlled by other means (e.g. the absence of a needle recapping device or self-sheathing needle system).

Practitioners should consider using devices that are designed to eliminate the risks of sharps injuries associated with common tasks, e.g. devices for removing and disposing of scalpel blades and the use of safety syringes, as appropriate to the nature of the work being undertaken. If a blade remover is used during a procedure, the user must not place the handle back into the operatory field, as it is contaminated by contact with the mechanism of the remover. AS 3825:2020 *Procedures and devices for the removal, containment and disposal of scalpel blades from scalpel handles* specifies the requirements for scalpel blade removal devices. One of the requirements of AS 3825 is that the blade can be removed from the handle with a single-handed operation, which implies that the removal device is fixed to a surface, e.g. by hook-and-loop tape or a bracket. Alternatively, using single-use integrated scalpel blades and handles avoids risks associated with attempting blade removal.

Contaminated needles must never be bent or broken by hand or removed from disposable syringes. Dental practitioners are responsible for their used needles and must develop an appropriate management system to render them safe to ensure that support staff members are not injured during patient changeover.

The dental practice must have an easily accessible, clear set of written instructions on the appropriate action to take in the event of a BBFE such as a sharps injury. These instructions must be understood and followed by all dental staff.

For further information on exposure incident follow-up, see Appendix: *Blood and Body Fluid Exposure Protocol.*

Disposal of sharps

The clinician who has been using a disposable sharp item is responsible for its immediate safe management or disposal after use. In routine (non-surgical) procedures, the operator is to place items into a suitably positioned sharps container located at the chairside as they work, as part of their normal workflow. This eliminates the risk to others when the dental chair is being cleaned or from transferring disposable sharps to the reprocessing area. For oral surgery procedures, suture needles and other disposable sharps can be placed into a suitable puncture-proof dish during the procedure, to prevent the dental practitioner leaving the working field. The items can then be emptied into the sharps bin at the end of the appointment.

Used disposable needle syringe combinations, empty or partially used glass cartridges of local anaesthetic solution, used burs, needles, scalpel blades, orthodontic bands, endodontic (root canal) hand files and all other single-use sharp items must be discarded in an approved, clearly labelled, puncture- and leak-proof sharps container. Any sharp item labelled as single use must be discarded, during or at the end of the patient appointment, into a sharps container. Appropriate sharps containers are those conforming to Australian standards AS 4031:1992 *Non-reusable containers for the collection of sharp medical items used in health care areas* or AS/NZS 4261:1994 *Reusable containers for the collection of sharp items used in human and animal medical applications.* The relevant international standards include ISO 23907:2019 *Sharps injury protection – Requirements and test methods – Part 1: Single-use sharps containers and ISO 23907:2019 Sharps injury protection – Requirements and test methods – Part 2: Reusable containers.*

A separate sharps container should be located in each operatory, close to the operator, to facilitate the timely disposal of sharp items. When choosing the size of a sharps container, take into consideration the size of items that will be placed into it, so that items remain below the fill line of the sharps container. Do not locate sharps bins above sinks or waste bins, as this increases risks of accidentally dropping sharps items into those instead of the sharps bin, posing a work health and safety issue. There is no safe way to retrieve an item that has been inadvertently placed into a sharps container. If this occurs, even if it is a dental prosthesis, it must remain in the sharps container and a new item be used/made.

Position sharps containers so they are readily accessible and so the opening of the container can be seen into. Sharps containers should be wall-mounted at a height of 1100–1300 mm from the floor to enable access from a sitting position, or a minimum of 1300 mm if access is required from the standing position, so as to allow staff to be able to see into the opening of the container. If not mounted into a dedicated bracket (e.g. on a wall or on a trolley), determine another suitable method of achieving a stable, upright and secure position for the sharps container.

Each practice must undertake a risk assessment to identify issues associated with the location of each sharps container. Sharps containers must be placed in a safe position within the treatment room to avoid accidental tipping over and must be out of the reach of small children. If considering mounting sharps containers into joinery (e.g. just under an opening or chute in a benchtop), undertake a risk assessment to ensure that (a) it is still possible to safely deposit sharp items, (b) the fill level of the container can be checked, and (c) it will be possible to safely close the container lid before removing the container.

Sharps containers must be sealed when they have been filled to the line marked on the container (or, in the absence of a fill line, when three-quarters full). The containers should then be collected by licensed waste contractors for disposal, according to local waste management regulations.

Any reusable sharp items, such as multi-use burs or ultrasonic scaler tips, are to be placed into an appropriate stand or container. Dental practitioners should remove burs from handpieces, and tips removed from ultrasonic scalers, as the first step in the changeover process between patients. Burs should be removed from handpieces before disconnecting the handpiece from the dental unit. Dental assistants should be trained to check that sharps such as burs and orthodontic wires have been removed by the operator before commencing the changeover procedure.

Key compliance points for sharps handling and disposal

- Correct sharps handling procedures are in place.
- Sharp items are removed from the working area by the dental practitioner early in the changeover sequence.
- Approved sharps containers are used for disposal, and these are located at appropriate locations.

5. Management of clinical waste

Clinical waste may also be referred to as medical waste, medical and related waste, pathology waste and contaminated waste.

Waste in the dental practice should be separated according to its category, in line with jurisdictional contaminated or clinical waste regulations. This should be done at the point of generation, i.e. at the chairside. All aspects of the management of clinical waste must conform to the relevant local state or territory regulations.

Domestic waste goes into the normal waste stream. Clinical waste must be placed into appropriately colour-coded and labelled waste bags that conform to AS 3816:2018 *Management of clinical and related wastes*. These bags will be leak-proof, thick yellow bags labelled with the biohazard symbol. The bags are then placed into secure storage containers until the waste is collected by licensed waste contractors for final disposal. Small bags can be used to collect waste chairside, which are then placed into clinical waste bags. Filled sharps containers are also to be placed into the clinical waste stream.

Standard precautions (gloves, mask and protective eyewear) must be used when handling clinical waste bags and containers. Clinical waste bags and containers must not be overfilled and must not be compacted by hand. Disposal of clinical waste, hazardous chemical waste and pharmaceutical waste must conform to jurisdictional regulations, e.g. from the Environmental Protection Agency (EPA). These protocols vary between jurisdictions.

Extracted teeth, once cleaned of visible blood, debris, adherent soft tissues, and saliva, may be placed in the general waste, or given to the patient sealed in a suitable container or in a sealed steriliser pouch. In some states and territories it is illegal to incinerate teeth that have been restored with amalgam because of issues with mercury vapour emissions; therefore, these teeth must not be placed in clinical waste or into sharps containers. As different rules apply in each jurisdiction, practices need check their local arrangements.

Key compliance points for waste

- Waste is segregated at the point of generation.
- Staff are aware of the jurisdictional definitions of what constitutes clinical waste, and this is included in the practice's IPC manual.
- Approved bags are used for clinical waste.
- Clinical waste containers outside the practice are kept secure.

6. Environment

A range of environmental controls can be used to reduce the risk of transmission of infectious agents in the dental practice. These should be considered when designing or refurbishing a dental practice.

Design of the practice

The design of the practice and the layout of the patient treatment, reprocessing and storage areas are important factors in implementing successful IPC. Work areas should be well lit and ventilated, with sufficient uncluttered and easily cleaned bench space to accommodate necessary equipment.

Examples of template designs and specifications can be found in Part D (Infection Prevention and Control) of the Australian Health Facility Guidelines (AusHFG).

The clean zones of the dental practice include office areas, staff room (used for meals, meetings etc), waiting and reception areas, as well as areas used for storage of supplies and sterilised RMDs.

The dental operatory and reprocessing rooms have both clean and contaminated zones, which must be clearly defined.

The contaminated zone is the area that may become contaminated with material from patients, both during clinical treatment and during cleaning of RMDs. After donning gloves, staff may move from the clean zone to the contaminated zone but never in the reverse direction. Contact with the clean zone after moving from a contaminated zone will cause potential contamination of the clean zone. If this occurs, the violated clean zone should then be considered part of the contaminated zone and must be treated the same as any other contaminated zone and cleaned before next patient use.

The contaminated zone in the dental operatory is the area which becomes contaminated by splashes of fluid and droplets originating from the patient's mouth (in an oval shape with the long axis of the oval in a direction forward of the patient's mouth). Aerosols generated from patient care may remain in the air until the particles settle onto surfaces or are removed by filters in the air-conditioning system.

In the dental operatory, workflow for RMDs and materials must be from the clean zone to the contaminated zone. Care must be taken to avoid contaminated RMDs, equipment or hands/gloves re-entering clean areas. Dental assistants should put on new gloves for cleaning work surfaces during the changeover between patients, rather than using contaminated gloves from assisting with the previous patient.

Appropriate detailing of joints in joinery will avoid areas that are difficult to clean. Gaps between surfaces should be avoided or properly sealed. Key areas of concern are gaps between benches and walls, between cupboards and floors or walls, and between skirting and floors.

Floor coverings in the dental operatory must be non-slip and impervious with sealed joins. Welded vinyl flooring is widely used as it is long-wearing and easily cleaned. Coved joints between the flooring and the walls are preferred for ease of cleaning. Carpet is acceptable in the waiting room and office areas but must not be used in clinical, laboratory and reprocessing areas as it is not impervious.

Attention should be paid to the location and design of any computer keyboards in the dental operatory, to avoid these becoming contaminated. They should be located away from areas of direct splash and should only be used with clean (ungloved) hands.

Patient notes written by hand or electronically must follow a protocol which prevents environmental contamination of the hard copy notes or computer keyboard. Traditional computer keyboards are not waterproof and are likely to be damaged by repeated application of detergent. Alternatively, if keyboards are operated by contaminated (gloved) hands, they must be specially designed so they can be wiped over with detergent-impregnated wipes between patient appointments.

Meal rooms and other common room areas for dental staff must be separate from patient treatment areas, reprocessing areas and the dental laboratory. They must conform to the relevant requirements of work health and safety regulations. Crockery and cutlery used by staff must not be washed in handwashing

sinks, or in sinks used for washing or rinsing RMDs. Food must not be stored in a refrigerator with dental materials, sealed clinical specimens or medical products such as drugs or blood products, because of the risks of cross-contamination.

Key compliance points for environment

- Ensure that the practice has clearly defined clean and contaminated zones and that clean areas are physically segregated from contaminated areas.
- Verify that working areas are kept free of clutter and are easy to clean.
- Implement procedures to handle retrieval of items and supplies from clean areas, so that these do not become contaminated.

Cleaning the environment

State and territory public health regulations require that the practice be kept clean and hygienic. Cleaning schedules should be developed and should specify the frequency of cleaning for various parts of the dental practice. This schedule should include windowsills, door handles and telephone handsets, as well as parts of dental equipment that do not directly contact patients but are in the zone where contamination may occur (e.g. the arms of an intra-oral x-ray unit, and the support arm of a dental operating light).

Recommended routine cleaning frequencies and methods of cleaning can be found in the 2019 AICG NHMRC *Guidelines for the Prevention and Control of Infection in Healthcare*. Table 2 below provides a summary of some key considerations in higher risk and low risk situations. It should be noted that additional environmental cleaning may be required in higher risk situations, such as when there is the presence of multidrug-resistant organisms (MRO). These microorganisms are resistant to one or more classes of antimicrobial agents.

Table 2. Recommended routine cleaning frequencies (based on NHMRC 2019).

Element	Significant risk	Low risk	Method
ABHR dispenser in treatment rooms	Clean daily	Clean weekly	Detergent
ABHR dispenser not in treatment rooms	Clean daily	N/A	Detergent
Carpet	Clean daily	Clean weekly	Vacuum with high efficiency particulate air filter
Soft floor	Clean annually	Clean annually	Steam clean (or shampoo)
Ceiling	Spot clean weekly and wash yearly	Spot clean monthly and wash every three years	Detergent/damp dust
Chair (non-dental)	Clean daily	Clean weekly	Detergent Detergent + disinfectant for MRO
Parts of dental chair unlikely to be contaminated	N/A	Clean daily and when visibly soiled	Detergent
Cleaning equipment	Clean after use	Clean after use	Detergent Detergent + disinfectant for MRO
Clipboard	Clean daily and between patient use	Clean weekly	Detergent
Computer and keyboard outside treatment area	Clean daily or when visibly soiled	Clean weekly or when visibly soiled	Detergent Detergent + disinfectant for MRO
Computer and keyboard used in close proximity to the patient	Clean daily or when visibly soiled Clean between patients	Clean weekly or when visibly soiled Clean between patients	Manufacturer's recommendations Install keyboard covers or washable keyboards where feasible Detergent

Curtains and blinds	Clean, change or replace bi-annually	Clean, change or replace bi-annually	Replace with laundered curtains or steam clean while in place Follow manufacturer's instructions
Doorknob/handle general	Clean daily	Clean weekly	Detergent
Doorknob/handle patient room	Clean daily	Clean daily	Detergent Detergent + disinfectant for MRO
Floor, non-slip	Damp mop daily	Damp mop daily	Detergent Detergent + disinfectant for MRO
Floor, polished	Dust removal and clean daily	Dust removal and clean weekly	Detergent for routine Consider electrostatic mops Detergent + disinfectant for MRO
Fridges	Monthly and defrost as required Daily spot check – clean when necessary	Monthly and defrost as required Daily spot check – clean when necessary	Detergent
Fridge (drug)	Clean weekly	Clean weekly	Detergent
Glazing or other internal partition	Spot clean daily and full clean weekly	Clean weekly	Detergent
Light switch	Clean weekly	Clean weekly	Detergent
Medical equipment (e.g. pulse oximeter)	Clean daily (when in use) and between patient use	Clean weekly (when in use) and between patient use	Detergent Detergent + disinfectant for MRO
Medical gas equipment	Clean daily	Clean weekly	Detergent Detergent + disinfectant for MRO
Purifier for air	Clean daily as per manufacturer instructions	Clean weekly	Detergent
Sink (hand washing)	Clean daily	Clean daily	Detergent
Telephone	Clean daily	Clean weekly	Detergent
Toilet	Clean daily	Clean weekly	Detergent + disinfectant
Walls	Spot clean weekly and full clean yearly	Spot clean weekly and full clean yearly	Detergent/damp dust
Waste receptacle	Clean weekly and spot clean when visibly soiled/bodily substances	Clean weekly and spot clean when visibly soiled/bodily substances	Detergent

MRO refers to the presence of multi-resistant organisms or resistant pathogens.

Floors and walls pose minimal risk of disease transmission in a dental practice; nevertheless, these surfaces must be maintained in a clean and hygienic condition and kept free of dust. Walls, blinds, and window curtains in patient care areas must be cleaned when they are visibly dusty or soiled as well as at regular routine intervals in accordance with a risk assessment as per Table 2 above.

Inanimate objects such as door handles, toys or tablet devices in the waiting room act as fomites and can spread infections through indirect contact. For this reason, it is prudent to clean these high-touch hard surfaces regularly (based on a risk assessment).

Environmental surfaces such as benchtops in the dental operatory that are outside the contaminated zone must be cleaned at least daily using a product containing detergent. When transmission-based precautions are required in times of increased contamination risk, such as pandemics, further measures may

be needed beyond detergent alone, as determined by a risk assessment. Where transmission-based precautions apply, cleaning with both detergent and a disinfectant is required. This can be performed in two ways:

Option 1. Two separate steps: physically cleaning with a detergent, followed by physically cleaning with a disinfectant (a '2-step clean').

Option 2. One step: physically cleaning with a combined detergent/disinfection wipe or solution (a '2-in-1' clean).

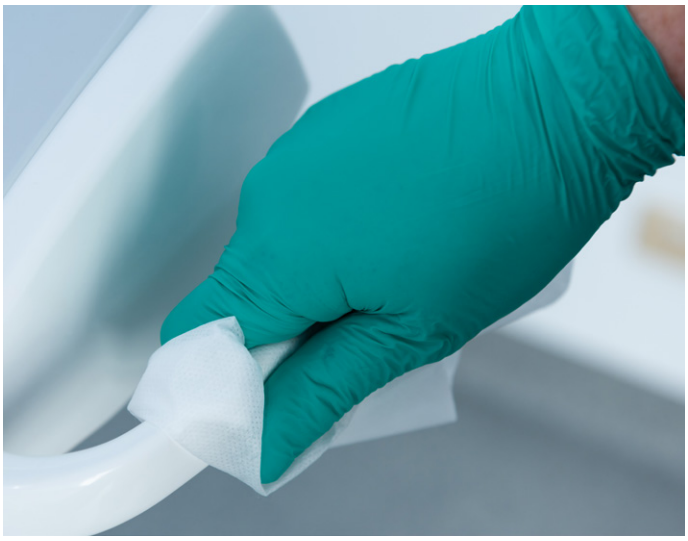
For both methods, contact drying times must be adhered to, to ensure the disinfection biocidal activity is achieved.

Cleaning methods must avoid the generation of aerosols. Damp dusting, dust-retaining mops and vacuum cleaners with HEPA air filtration of the exhaust are recommended. Brooms must not be used in clinical areas as these disperse dust and bacteria into the air. Mops and cloths must be cleaned after use and allowed to dry before reuse. Alternatively, single-use, disposable mop heads or cloths may be used.

The dental operatory (Patient treatment area)

Routine cleaning of the contaminated zone within the dental operatory is necessary to maintain a safe environment because deposits of dust, soil and microbes on environmental surfaces can transmit infection.

Surfaces of dental units must be impervious as they may become contaminated with potentially infective material. Work surfaces and benchtops in treatment areas must be non-porous, impervious to water, smooth without crevices and have sealed joins to facilitate cleaning and prevent the accumulation of contaminated matter.



Working surfaces in the contaminated zone must be cleaned after every patient by wiping the surface with a product based on a pH neutral or mildly alkaline detergent. Neutral or mildly alkaline pH detergents are best for environmental cleaning because they are less likely than acidic or strongly alkaline detergents to damage metals such as stainless steel or to cause skin irritation. Neutral detergents also leave little residue on surfaces. The detergent may be mixed with water and the resulting solution dispensed onto a low lint cleaning cloth. Alternatively, the practice may use pre-moistened wipes.

If preparing detergent solutions in-house, prepare fresh solutions daily (or more often, as needed) and dilute these and replace with fresh solution frequently according to the instructions for use. Discard any unused solution at the end of the day, then rinse the containers and leave them to dry overnight prior to refilling for subsequent use.

Cleaning products may be formulated to contain a disinfectant as well as detergents. The use of cleaning products must follow the manufacturer's instructions and also (as shown in the table above) consider the level of risk and any current public health advice. Environmental cleaning products should be listed on the ARTG as a Class 1 Medical Device.

Standard precautions (including wearing clean gloves and other items of PPE) must be implemented when cleaning working surfaces. Written protocols for cleaning the practice must state the methods used and the frequency of cleaning for the various parts of the operatory.

Spittoons should be cleaned after each patient by wiping with neutral detergent. Special products may be needed for cleaning soft surfaces such as the upholstery of the dental chair and stools used by the clinical operator and dental assistant. The formulation of products designed for use with upholstery may contain additional components, such as conditioners, and lack others, such as alcohols, to prevent degradation of the upholstery over time. It is important to follow the dental chair instructions for use regarding the appropriate surface management protocol and products to be used.

For further guidance on appropriate frequency of cleaning for different items, refer to Section 6.1 Recommended routine cleaning frequencies of the AICG NHMRC Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019).

Key compliance points for environmental cleaning

- Check that the practice has a cleaning schedule that covers all areas of the practice.
- Verify that cleaning methods do not damage surfaces or generate dust or aerosols.
- Ensure the practice uses appropriate products for cleaning both hard and soft (upholstery) surfaces in the dental operatory in accordance with manufacturer's instructions.

Section C. Infection prevention and control (IPC) strategies within the contaminated zone

It is essential that contaminated zone boundaries are clearly defined, since this has implications for surface management (wiping down) and for the location of equipment, to prevent contamination from splashing. The goal during dental treatment is to contain contamination within this zone by determining what is touched and where the spread of droplets, splash and splatter will occur.

Reducing the extent of contamination of the dental operatory can be achieved, in part, by the use of dental dams, pre-procedural antiseptic mouth rinses, proper placement of high-volume evacuation and correct patient positioning. Dental dams minimise spread of the patient's blood or saliva into the operatory when using powered instruments. When a dental dam is not applied during restorative dentistry, high-volume aspiration becomes essential.

All surfaces and items within the contaminated zone must be deemed contaminated by the treatment in progress. The items in the zone must be disposed of, decontaminated or cleaned and sterilised before commencing treatment of the next patient. Clinical contact surfaces in the contaminated zone that are not covered with a barrier must be cleaned after each patient.

Note: RMDs placed into the contaminated zone for a treatment session, but not used during the session, must be regarded as contaminated. For this reason, all bulk supplies such as opened boxes of gloves, cotton rolls or gauze must be stored outside the contaminated zone and protected from contamination from splashes of patient fluids.

For difficult-to-clean equipment, consider the use of a protective barrier. The instructions for use must be followed in terms of how items are managed, both from a regulatory perspective and to ensure they are not damaged by incorrect processing. If the instructions for use stipulate that a barrier must be applied, then these directions must be followed. Likewise, if the instructions for use state that the RMD is to undergo sterilisation using steam, this must be done rather than covering it with a barrier or wiping it over with a detergent-based product.

Depending on age and complexity of design, items that may require barrier protection include:

- operating light handles and hand-operated switches, x-ray heads, tubing for suction, triplex syringe controls, handpiece couplings and tubing, and instrument cradles or hangers;
- polymerising lights, intra-oral cameras, fibre optic illuminators, intra-oral scanners; and
- bracket tables and handles.

Consideration should be given to how to ensure consistent and reliable management of surfaces across different operatories by multiple staff members. There must be a well-documented method for cleaning, and this should specify where barriers are needed on certain items.

1. Clean and contaminated zones

Within the dental surgery, clean and contaminated zones must be clearly demarcated. Clean areas include surfaces and drawers where clean, disinfected or sterilised RMDs are stored. These clean surfaces must never come in contact with contaminated RMDs, equipment or hands. All dental staff must understand the purpose of and requirements within each zone, and must adhere to the outlined protocols. A system of zoning simplifies the decontamination process at the end of a patient appointment.

Dental practitioners and clinical support staff should not bring their personal effects (including telephones, water bottles, changes of clothing, or handbags) into clinical (patient treatment) areas and leave them in locations (such as on benchtops) where cross-contamination is likely to occur.

It is recommended, where possible, that common consumable materials such as cotton rolls, dental floss, gingival retraction cord, and restorative materials are pre-dispensed from bulk supplies. The bulk supplies are then kept in closed drawers or cupboards, or in containers, so that contamination from splashes or aerosols does not occur.

If additional RMDs and materials must be retrieved from outside the contaminated zone during an appointment that is underway, it must be by a method that does not contaminate other RMDs or materials in the drawers or cupboards. The recommended technique is to remove gloves, perform hand hygiene with ABHR, retrieve and dispense the additional materials using clean hands, and then perform hand hygiene again and put on fresh gloves. Based on work health and safety considerations, if the items being retrieved are small (e.g. cotton rolls) or sharp (e.g. burs), use dedicated clean tweezers rather than bare clean hands to move them from the clean zone to the work field. Such tweezers must only be handled by clean hands or when wearing clean gloves.

The same 'clean hands' approach can be used when moving from the contaminated zone to a clean zone when the intention is to touch non-clinical items without a barrier, such as the operating controls of an intra-oral x-ray unit. It is not acceptable to use over-gloves or to open drawers by elbow touch and then retrieve items with tweezers that are being held in contaminated gloves. This is because such retrieval methods have inherent risks of contaminating clean supplies.

Cartridges of local anaesthetic must be stored appropriately to prevent environmental contamination. Cartridges should be kept in their individual bubble packs until use to protect them from contamination. They must never be stored loose, out of their blister packaging in cardboard containers, as these containers absorb water and cannot be cleaned. Likewise, containers of medicaments, including topical anaesthetic tubes or jars and endodontic medicaments, must be kept free of environmental contamination.

Once used, glass local anaesthetic cartridges or carpules are classified as sharp items and must be disposed of as sharps waste. Polymer cartridges must be emptied of all remaining local anaesthetic solution according to jurisdictional waste management regulations (and only into the sink if permitted by local water board regulations), before being disposed of in the regular waste. Polymer carpules can also be placed into the sharps waste, if preferred. Any carpules or cartridges that still contain local anaesthetic solution are considered pharmaceutical waste and must be dealt with as such according to local waste regulations. Typically, pharmaceutical waste requires incineration.

The logical method of decontaminating a dental chair is high to low, clean to dirty. The rationale is that the least contaminated surface is cleaned first, moving towards 'dirtiest' surfaces, thereby reducing the risk of transferring a more heavily contaminated surface load to a less contaminated surface. A dental chair can be divided up into different sections, such as the light handle, the dental chair itself and associated bracket table and attachments, and the associated arms and spittoon. Following this approach, usually a minimum of two impregnated wipes or paper towels moistened with the cleaning product would be needed for the process to be completed.

Key compliance points for clean and contaminated zones

- Perform hand hygiene after touching items in the contaminated zone and before touching any item in the clean zone.
- Ensure all staff are aware of the boundaries of the clean and contaminated zones.
- Document the sequence of cleaning of the dental operatory in the practice's IPC manual.
- Use barriers stipulated by manufacturers for items such as intra-oral cameras and intra-oral scanners.
- Ensure supplies (including medicines and local anaesthetics) are being stored in a way that protects them from environmental contamination.

2. Dental chair waterlines and water quality

The organisms that grow in waterline biofilms are environmental in origin and are found in lakes, rivers and other water sources. They flourish in the waterlines of a dental unit because the lines to the handpieces, triplex syringe and ultrasonic scaler are small in diameter and have very slow flow rates and large surface area to volume ratios. The cup fill and spittoon lines are larger in diameter and pass more water at higher flow rates, and thus tend to show lower levels of biofilm than those lines with small diameter tubing.

Waterlines from any device connected to the dental water system that enters the patient's mouth (e.g. handpieces, ultrasonic scalers, air/water syringes) should be flushed for a minimum of two minutes at the start of the day and for at least 30 seconds between patients, with handpieces in place or as per the manufacturer's instructions. Flushing lines at the start of the day can reduce bacterial levels caused by overnight or weekend biofilm accumulation.

Dental unit waterline biofilms are a reservoir of microbial contamination. Biofilms in dental unit waterlines may be a source of known pathogens (e.g. *Pseudomonas aeruginosa*, non-tuberculous mycobacteria, and Legionella species). Waterlines must be treated with a suitable chemical agent in accordance with the instructions for use. Likewise, those instructions may dictate the use of specific protocols for sanitising waterlines or testing bacterial levels.

An independent (bottled) water supply can help to reduce the accumulation of biofilm as it makes adding chemical agents to the water easy to undertake and facilitates the use of water that has been pre-treated. The instructions for use should be followed with respect to appropriate methods to maintain the recommended quality of dental water and for monitoring water quality.

Biofilm levels in dental equipment can be minimised by using a range of measures, including ozonation, electrochemical activation and chemical dosing of water (e.g. with hydrogen peroxide, oxygen compounds, sodium hypochlorite, chloramines, iodine, silver ions or nanoparticle silver). Special waterline treatment products are made for 'shock treatment' (also called sanitising) of waterlines, and certain products are designed for situations where hibernation is necessary, such as during extended periods of non-use, such as during vacation periods. If the chair is not to be used for an extended period, refer to the dental chair manufacturer's recommendations for waterline management.

As defined in ISO 7494-2:2022 *Dentistry – Stationary dental units and dental patient chairs – Part 2: Air, water, suction and wastewater systems,* retraction is the re-entry of water, air, and/or other medium into the stationary dental unit or the dental handpiece due to flow reversal. It is a requirement for manufacturers of dental units that all waterlines must be fitted with non-return (anti-retraction) valves (also known as check valves) to help prevent retrograde contamination of the lines by fluids from the oral cavity. Flushing waterlines for short periods between patients recognises that the performance of anti-retraction valves in dental chairs can be irregular.

Problems with anti-retraction valves in dental chairs are more common when biofilm control in the waterlines is poor and biofilm builds up on the valve surfaces (or ball bearing surface), preventing them sealing properly against the valve housing or O-ring. Hence, testing the performance of anti-retraction valves becomes more important in cases where levels of bacteria in dental unit waterlines are found to be above the recommended level of 200 CFU/mL. If bacteria levels are regularly found to be low, follow the dental chair manufacturer's instructions regarding how often anti-retraction valves need to be tested.

While some dental chair manufacturers make water retraction testing kits, the extent of retraction can also be tested using transparent small diameter tubing, as explained in section 7.6 of ISO 7494-2, based on the movement of fluid forward and backward in the tubing.

Suction systems are also wet environments and biofilms develop in these, causing odours to be generated. Hence, suction cleaning agents are used to reduce these biofilms in suction tubing and in associated components such as suction traps. The dental chair and suction system manufacturer's instructions will specify proper methods for treating suction lines and filters. Generally, a daily product containing disinfectants and low foaming detergents will be used, in combination with a weekly product that dissolves mineral deposits. Parts of the suction system should not be left overnight in fluids as microbial overgrowth can occur unless a potent antimicrobial agent is present. Clean items that are left dry are less able to support microbial growth.

Key compliance elements for waterlines

- Ensure that the practice has a protocol for testing waterlines and water quality. The protocol should be developed based on the dental chair IFU, prior to purchasing consumables or equipment or performing waterline tests.
- If water samples reveal high loads of bacteria, undertake a sanitising treatment recommended for the chair make and model, then re-test.
- Verify that any chemical treatment of the waterlines is in accordance with the manufacturer's instructions for the dental chair.

Water quality

Sterile irrigant solution, such as sterile saline as a coolant, is required for surgical procedures such as dentoalveolar surgery, endodontic surgery, and dental implant placement.

Water for tooth irrigation during cavity preparation and for ultrasonic scaling should be of no less than potable standard, as specified in the current edition of the Australian Drinking Water Guidelines (updated December 2023). The number of bacteria in water used as a coolant/irrigant for non-surgical dental procedures should be less than 200 CFU/mL since this is a widely used international limit for safe water for medical applications.[6] Bacterial levels can be tested using commercially available test strips, dip slide testers, ATP meters, or through commercial microbiology laboratories. Typical dip slide or dipstick tests for levels of microorganisms in dental unit waterlines are incubated at room temperature for up to seven days, after which time colony counts are made. ATP measurements can also be done to assess the exit water from waterlines, and these provide results in less than 15 minutes, in terms of relative cleanliness. ATP measurements must be interpreted in the context of how these relate to the required target level of below 200 CFU/mL.

It is good practice to test microbial levels in water from dental unit waterlines on a regular basis, for example, six-monthly or annually, when tested levels are found to be below the target level of 200 CFU/mL. When high counts are found, the waterlines will need to undergo shock treatments (also known as sanitising treatments) to reduce biofilms and bring the bacterial levels back to within an acceptable range. Follow the instructions from the supplier of the dental chair. Ensure that any sanitising agent is compatible with the control blocks of the dental chair, and is flushed completely from the waterlines before using the chair. After sanitising, test water levels more frequently (e.g. every three months) to ensure that the biofilm control measures being used are adequate.

Each practice should develop an appropriate routine for hygiene aspects of the water bottle, if present. Water bottles on dental chairs need to be checked visually for the development of biofilm, and cleaned periodically to ensure that the bottle does not become contaminated. Likewise, staff who are handling water bottles or adding chemical treatment agents must perform hand hygiene and wear gloves so that skin bacteria do not contaminate the water in the bottle.

3. Single-use items

Single-use sterile items should be used when indicated by the clinical situation. These items include, but are not limited to, local anaesthetic needles, local anaesthetic cartridges, sutures and scalpel blades. Dental local anaesthetic solution and needles must be sterile at the time of use and are only for single-patient use. Used local anaesthetic cartridges must be discarded after each patient. Similarly, suture materials, suture needles and scalpel blades must be used for one patient and then disposed of immediately into an approved sharps container.

Single-use non-sterile items, including disposable triplex syringe tips, disposable low- and high-velocity evacuator tips, prophylaxis cups, micro-brushes, disposable plastic Dappen dishes and disposable impression trays must not be reprocessed and reused on another patient, but must be discarded after use. It is not acceptable to attempt to clean and then reuse these items. In order to reuse an RMD, it is essential to follow validated manufacturer's instructions; however, such instructions are not provided for single-use items. Note that some consumable single-use items can be made from plastics that are biodegradable. There are also versions of items such as high-velocity evacuator tips that are designed for multiple uses and which can withstand large numbers of steam sterilisation cycles.

Complete sets of dental instruments (including restorative instruments and oral surgery instruments) are now available commercially as single-use items, having been sterilised by the manufacturer. It is not acceptable to attempt to use these items and then reprocess them. They are marked single use, and therefore must be disposed of immediately into a sharps container. The same principles apply to single-use burs.

Single-use consumable items that are not classified as sharps, such as single-use impression trays, disposable suction tips and disposable triplex tips, must be disposed of as these are not able to be reprocessed.

A number of very small and/or sharp instruments are difficult to effectively clean, and should be considered single use, even if not labelled as such. Such instruments must not be reused unless a validated and safe cleaning process is employed. This is why matrix bands, stainless-steel endodontic (root canal) files, reamers and broaches are to be considered single-use items, because there is currently no cleaning method validated as being effective in removing organic material from these items.

Many dental practices now use disposable triple syringe tips to replace the dual lumen ('pipe inside a pipe') metal tips used with DCI or A-dec type triple syringes. Disposable triple syringe tips are often preferred for efficiency reasons (difficulty of cleaning, progressive build-up of inorganic residues within the lumen, and challenges with air removal and steam penetration). Moreover, these dual lumen metal triple syringes need to be sterilised in a pre-vacuum cycle to ensure air removal and steam penetration. Therefore, many practices find using disposable plastic triplex tips a better and more convenient approach.

Key compliance elements for single-use items

- Identify the single-use items at your practice and ensure that these are discarded after use.
- Make sure that no attempts are made to reuse or reprocess single-use items.

4. Matrix bands and other items that contact the gingiva

Matrix bands in contact with the gingiva often become contaminated with blood during use, and if pushed down hard into the tissues, will draw blood. A matrix band is not a surgical blade and it is not necessary to sterilise plain stainless-steel matrix bands before use. A wide range of matrix bands are now available, including some combined with wedges for interdental protection; these are not suitable for sterilisation with steam because of their heat-sensitive components (e.g. combination of a steel plate and a plastic wedge). As noted above, matrix bands are single-use items.

Other items used interdentally, such as plastic wedges, interdental brushes, and dental floss, are not supplied sterile. There is no evidence base around infections arising from these items, so they are not required to be sterilised prior to use. Nevertheless, as none of these items can be cleaned effectively they must be considered single patient use.

Note that stainless-steel and other preformed crowns are not supplied sterile. If exposed to saliva (e.g. when a crown of incorrect size is chosen), before use on another patient follow the manufacturer's IFU regarding reprocessing. Steam sterilisation may affect the colour of some items and their physical integrity.

5. Burs

RMDs must be free of soil, debris and corrosion, and suitable for use, in order to be reprocessed. Stainless-steel burs, which become blunt and corrode after several uses, must be discarded into the sharps waste as soon as any visible signs of corrosion appear. Therefore, staff must look for the tell-tale signs of corrosion when these burs are being reprocessed. Typically, this is seen after the third or fourth cycle of use.

Stainless-steel burs used in restorative dentistry are also difficult to clean. At a minimum these need to be processed through an ultrasonic cleaner. Cleanliness should be inspected with special lighting and magnification. Based on that examination, further ultrasonic cleaning or manual cleaning using a bur brush may be needed, or the bur disposed of. Without special lighting and magnification, it is not possible to properly clean and inspect burs with small cutting heads. For these reasons, some dental practices now opt to use lower-cost stainless-steel burs as single-use items to eliminate the need to clean and inspect them. This ensures that burs, when used, are always sharp. If such burs are to be reused, magnification is essential to check for cleanliness and corrosion.

Most diamond burs are designed for reprocessing. The resin carrier for the diamond does degrade with multiple steriliser cycles. Some brands of diamond burs use chrome-cobalt alloy as a matrix for the diamond particles; these are very long-lasting.

Most surgical burs for dentoalveolar surgery are designed for reprocessing and are made of materials such as tungsten carbide that do not degrade when sterilised using steam. Likewise, silicon nitride burs are also designed for reprocessing.

6. Implant hardware

It is essential to follow the manufacturer's IFU for implant hardware as the materials used in implant drills, impression copings and other components vary, with some being intended for reuse and others intended for single use only. Reuse (where permitted by the IFU) is only possible when an implant drill is undamaged and has been cleaned properly so that it is free of contamination.

Section D. Reprocessing of RMDs

Since contaminated RMDs can transmit infections between patients, it is essential that RMDs are correctly reprocessed between each patient.

Reprocessing is a term which includes all steps necessary to make a contaminated RMD ready for its intended use. These steps may include treatment at the point of use (pre-cleaning), cleaning, inspection, functional testing, packaging, labelling, disinfection and sterilisation.

The type of RMD and its intended use will determine the method of reprocessing. As a general rule, if an RMD cannot be cleaned it cannot be safely reprocessed. Principles for reprocessing RMDs are described in AS/NZS 5369:2023 *Reprocessing of reusable medical devices and other devices in health and non-health related facilities.* Key elements involve following a risk-based approach, identifying where problems could occur in a systematic manner, identifying the associated levels of risk, setting in place processes to manage those risks, and then evaluating if those control measures are working as intended. Examples of risks that will be found in many dental clinic settings include (but are not limited to): limited space and insufficient RMD inventory; insufficient training and supervision of staff; not following correct protocols (including manufacturers' instructions for reprocessing); dropped items; misplaced items; not identifying failed loads that warrant a recall; equipment failures; processing loads of greater size and complexity to those used for validation; missed calibration of steam sterilisers; insufficient water quality for final rinsing; improper storage conditions for sterilised packages; and gaps in maintenance of reprocessing equipment.

Equipment used in reprocessing RMDs needs to be listed on the Australian Register of Therapeutic Goods (ARTG) and conform to relevant standards. Key standards include the following:

- Ultrasonic cleaners: AS 2773:2019 *Ultrasonic cleaners for health service organisations*;
- Washer-disinfectors: ISO 15883 series *Part 1: 2006. General requirements, terms and definitions and tests; Part 2: 2016. Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc; Part 5: 2021. Performance requirements and test method criteria for demonstrating cleaning efficacy*;
- Small steam sterilisers (less than 60 litres chamber capacity): EN 13060:2019 *Small steam sterilisers* and ISO TS 22421:2021 *Sterilization of health care products. Common requirements for sterilizers for terminal sterilization of medical devices in health care facilities)*;
- Large steam sterilisers (more than 60 litres): EN 285:2015 *Sterilization – Steam sterilizers – Large sterilizers* and ISO TS 22421;
- Low temperature hydrogen peroxide gas plasma sterilisers: ISO 22441:2022 *Sterilization of health care products – Low temperature vaporized hydrogen peroxide – Requirements for the development, validation and routine control of a sterilization process for medical devices,* and ISO TS 22421.

1. Categories of RMDs: Infection risk relative to use

Contaminated RMDs can transmit infections to patients during clinical procedures. The risk of this happening is related to the site of use. The intended use of the RMD dictates the minimum level of reprocessing required. The Spaulding classification describes three RMD risk categories (i.e. critical, semi-critical and non-critical), each of which has specific reprocessing requirements described in the 2019 NHMRC *Australian Guidelines for the Prevention and Control of Infection in Healthcare*.

Over a period of time, a practice may want to take on new types of RMDs and devices. As well as the requirements of the manufacturer's instructions for use (IFU), a major question is whether the practice has appropriate equipment and expertise to effectively reprocess such RMDs. Hence, when purchasing new RMDs and equipment, it is important to consider the requirements for reprocessing, and determine before purchasing the RMD whether the practice has the necessary equipment, e.g. some RMDs may require the use of a washer-disinfector for cleaning them or the use of a specific sterilisation cycle. Key aspects to consider are (a) compatibility with cleaning agents and methods; (b) if the device is plastic or metal; (c) if the device is solid or hollow/ cannulated; (d) if the device has moving parts or requires disassembly and reassembly; and (e) tolerance of the device to moisture, steam, and heat. These points relate to how the device is classified into a product family.

The manufacturer's reprocessing instructions for the device can be obtained from the intended supplier, and often are given on the manufacturer's website. Providing reprocessing instructions is a requirement when RMDs are submitted to the TGA for entry onto the Australian Register of Therapeutic Goods (ARTG). Manufacturers are required to conform to ISO 17664.1:2021 *Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices. Part 1: Critical and semi-critical medical devices* for all RMDs that are intended to be sterilised, or to ISO 17664.2:2021 *Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices. Part 2: Non-critical medical devices* for items that are not intended to be sterilised.

Along with this information from the RMD manufacturer, dental practices also need to consider what types of load items their existing cleaning and sterilising equipment can process. This

information will be provided in the operating manual for these systems. An outline of the key areas of information expected in an operating manual for reprocessing an RMD is given in sections 4.2 and 4.3.1 of AS/NZS 5369:2023. These cover installation and routine operation of such equipment. Staff need to be familiar with (a) how the equipment works; (b) what types of load items can be processed, and what types are not compatible; (c) any special requirements to treat load items before the process; (d) how to load the chamber of the system; (e) the appropriate settings or parameters to use (e.g. temperature, exposure time, and pressure for steam sterilisation, and humidity and chemical concentration and time for hydrogen peroxide gas plasma sterilisation) and how to choose between options; (f) how the results of the process are monitored and controlled, including how to detect failures in the process; (g) any special treatments that load items need after the process; (h) safety features of the equipment; and (i) what consumables the system requires to operate (including chemical concentrations, dilution rates etc.).

Given the importance of following the manufacturer's instructions for reprocessing, dental practices must base their local protocols for cleaning, disinfecting, packaging and sterilising RMDs on the manufacturer's advice. If a practice chooses to deviate from the supplied reprocessing instructions, then it is a formal requirement from AS/NZS 5369:2023 that the practice properly test and validate the alternative process(es) in consultation with the manufacturer of the RMD.

Equipment and RMDs used in the treatment of mucosal lesions or diseased soft tissue, and which come in direct contact with mucosa and gingiva or blood, must be single-use disposable or decontaminated and sterilised after each patient. Examples are the tips used with electrosurgery or cryotherapy devices. Follow the manufacturer's instructions regarding the appropriate cleaning and decontamination methods for these tips, to ensure that all tissue residues are completely removed.

Critical RMDs

These enter or penetrate sterile tissue, a sterile cavity or the bloodstream (e.g. surgical dental procedures such surgical removal of teeth where a flap is raised, placing implants, and raising a mucoperiosteal flap as part of periodontal or endodontic surgery). All RMDs that come into contact with sterile body cavities or are used on the critical aseptic field during invasive procedures shall be considered critical medical devices, and reprocessed to the highest level they can tolerate (AS/NZS 5369:2023, p. 38).

Examples of critical RMDs: dental forceps and elevators, flap retractors and surgical burs, instruments used in the placement of implants, implantable items including mini implants, and surgical dental handpieces.

- These RMDs must be sterile at the time of use and must be either 'single-use disposable' or capable of being sterilised.
- Critical RMDs must be cleaned to remove soil and organic material as soon as possible after use, packaged, and then sterilised using moist steam between individual patient uses. Low temperature hydrogen peroxide gas plasma sterilisation may be used to sterilise RMDs that are heat sensitive.
- Careful inspection is needed after cleaning to ensure that critical RMDs are clean, free of corrosion and damage, and fit for reuse.
- Critical RMDs must have batch control identification recorded on the sterile barrier system (SBS) to allow tracking, which is recorded in the patient's treatment notes.
- Any critical RMDs stored in SBS that are found to be damaged or exposed to environmental contamination must be re-sterilised before use.

When used for subgingival debridement, scalers remove the crevicular epithelium and enter the tissue, as is evidenced by bleeding during the procedure from the base of the pocket. This is why scalers (hand scalers, curettes and ultrasonic scaler tips) used for subgingival periodontal debridement are classed as critical RMDs.

There are no alternatives to maintaining critical RMDs in packages with an intact SBS. There is only one clinical situation where a critical RMD that is not in an SBS could arise – the situation of a dropped RMD with no replacement, where 'flash' steam sterilisation is used. The RMD can only be used in patient care immediately after steam sterilisation has occurred. There are multiple risks with this, including contamination from the air and the general environment during transfer from the steriliser chamber to the aseptic field, burns to staff and patients from very hot instruments, and a risk that BCI may not be recorded.

Semi-critical RMDs

These come into contact with intact mucosa, or non-intact skin.

Examples of semi-critical RMDs: mouth mirrors, restorative instruments, dental tweezers and probes, metal impression trays.

- These RMDs must be cleaned to remove soil and organic material as soon as possible after use, following the manufacturer's advice for reprocessing.
- They are to be sterilised using steam or using another approved method (e.g. low-temperature hydrogen peroxide gas plasma sterilisation).
  - As described in section 5.1.1. of AS/NZS 5369:2023, if the RMD is not compatible with sterilisation using either of these two methods, there are two further options. Option 1: The RMD must be subject to a validated thermal disinfection process (e.g. using a washer-disinfector with a thermal disinfection cycle, as per Table 6.1 of AS/NZS 5369:2023) between uses on individual patients. Option 2: For items unable to withstand a thermal disinfection process, they can be subjected to a validated process using high-level instrument-grade disinfection (e.g. with ortho-phthalaldehyde (OPA)). For the latter, BCI is required, as per AS/NZS 5369:2023 section 2.5.3.2 and Table 9.1.

- Careful inspection is needed after cleaning to ensure that these semi-critical RMDs are clean, free of corrosion and damage, and fit for reuse.
- RMDs used in semi-critical procedures do not need batch control identification and are not required to be sterile at the point of use. Therefore, after reprocessing, semi-critical RMDs are, at a minimum, to be stored to prevent environmental contamination, in a dedicated and designated storage space. The storage space must be clean and dry, and not at risk of splash contamination. This can be achieved by keeping them in closed drawers or cupboards.
- Placing semi-critical RMDs in SBS and using batch codes for them is optional. It is recommended that semi-critical items be placed in an SBS before sterilisation, since this assists in preventing environmental contamination during storage, and allows BCI identification in the event a recall of RMDs is required. As well, consideration must be given to practical issues that could arise if some devices are tracked in the practice (critical RMDs), but not others (semi-critical RMDs), should a recall be needed (AS/NZS 5369:2023, p. 85).

In some rare instances, RMDs that may contact mucosa are covered with a disposable barrier (e.g. curing light tip), in line with the manufacturer's instructions. In this event, the RMD still needs to undergo cleaning, followed by disinfection or sterilisation, as appropriate (based on the manufacturer's instructions), between uses, despite having a single-use sheath/sleeve/protective barrier used. In other words, using a protective barrier on an item that enters the mouth is not a substitute for reprocessing.

Non-critical RMD

These come into contact with intact skin (lowest risk).

Examples: protective eyewear, reusable bib chains.

These RMDs must be cleaned to remove soil and organic material as soon as possible after use. Careful inspection is needed after cleaning to ensure that these non-critical RMDs are clean, free of corrosion and damage, and fit for reuse. Generally, cleaning alone with detergent and water is sufficient, but in some cases, thermal disinfection (e.g. using a washer-disinfector with a thermal disinfection cycle) or suitable low-level or intermediate level instrument-grade disinfection will be needed, in line with the manufacturer's instructions. After processing, non-critical RMDs are to be stored in the same way as semi-critical RMDs, i.e. stored in designated areas that are clean and dry, and not prone to splashes of fluids or splatter from clinical procedures, to prevent contamination prior to use.

Key compliance items for the Spaulding classification

- Identify which Spaulding classification category each RMD fits into.
- Ensure that all critical RMDs are packaged, with batch code identification.
- Check that batch codes are recorded for critical RMDs in the patient notes.

Other considerations

The practice must develop procedures for reprocessing RMDs in special circumstances. These may include: (a) having new or loan RMDs processed within the facility in accordance with the device's reprocessing instructions before being used in patient care; and (b) cleaning and sterilising RMDs before they are sent away for maintenance, e.g. air turbine high-speed handpieces being sent for replacement of the turbine capsule. For loaned instrument sets, it is important to know whether these have been cleaned, packaged and processed on site or not.

During clinical procedures, packages of RMDs that have been opened may contain some items that were not used in that procedure. This includes burs in bur sets that were not used. These unused RMDs shall be deemed contaminated if they have entered the zone of contamination, and so they need to be subjected to a full reprocessing cycle.

It is only acceptable to consider reprocessing a single-use instrument that is unused (e.g. past its expiry date, or that has been opened but not used on a patient) if this is **explicitly permitted** by the device's reprocessing instructions. That reprocessing must follow the reprocessing instructions provided with the device. The device is then to be used once, and then discarded. In no other situation can medical or other devices that are labelled as or intended for single use be reprocessed or reused (see clause 5.1.2.(f) of AS/NZS 5369:2023).

2. Reprocessing area and workflow

The reprocessing area must be appropriate in layout and size for the volume of RMDs being reprocessed. Part of the dental facility must be designated as the reprocessing area for RMDs (including cleaning, packaging and sterilising) and must not be used for any other purpose. Ideally, this should be a dedicated room that is physically separate from the treatment room(s).

If that is not possible because of limited space, in line with the principle of segregation, reprocessing should occur well clear of the contaminated zone, in an area that is partitioned off, with good workflow processes established, and where there is minimal risk of aerosol contamination of the reprocessing area. Use of physical segregation (such as dividers or partitions) becomes important in such situations, to ensure proper segregation. Such physical segregation is an important consideration in the design of reprocessing areas. Segregation requirements also mean that where reprocessing work and patient care occur in the same room or physical space where there is no physical separation between them (e.g. in a dental caravan or a mobile facility), reprocessing must only be undertaken at times when no patients are being treated.

To minimise particulate contamination and bioburden (pathogenic bacteria, fungi and viruses), the principles of environmental control need to be observed.

The cleaning process must flow in one direction, from contaminated to clean. To achieve this, the reprocessing area must be divided into distinct areas for:

- receiving, cleaning, and decontamination;
- preparation and packaging;
- sterilisation; and
- storage.

The practice must develop a process map (workflow diagram) showing how RMDs and other items progress through reprocessing. This must be designed to ensure that within the reprocessing area of the practice, the risk of cross-contamination is effectively managed, in accordance with a completed risk assessment (AS/NZS 5369:2023, p. 40).

Processed RMDs must not be stored in an area where contaminated RMDs are held or cleaned or where there is a possibility of contamination from organisms carried in droplets or aerosols.

Design of the reprocessing area

The following are design features for the reprocessing area that will help to facilitate successful IPC:

- Surfaces (floors, benchtops, ceilings, walls) that facilitate cleaning to achieve a high level of general environmental hygiene, as well as control of insects and vermin.
- Control of the traffic flow of people working in the area, and the exclusion of staff who are not required and patients from the area.
- Signage to indicate that entry to the reprocessing areas is restricted to authorised personnel (patients are not permitted). The intention is to restrict traffic to only people working in the area, and exclude other staff and patients from the area.
- Signage to indicate that PPE is required, and reminders that hand creams (lotions) must not be used when performing reprocessing activities.
- A separate basin or sink for handwashing that is fitted with elbow-operated or sensor-operated taps. Handwashing must only occur in this dedicated separate basin for handwashing, and not in the sink(s) used for reprocessing RMDs. Liquid handwash dispensers should be operated by the elbow, knee, or foot.
- Segregation between the reprocessing area and clinical areas and hallways (such as partitions, solid walls or glass walls and non-operable glass windows), unless in clinical areas when reprocessing only occurs when no client care is being performed.
- Use of lighting, signs or features (including different coloured finishes) to indicate the direction of RMD flow, and the contaminated and clean areas. Identification of areas should not include the use of tape on benches as this prevents proper cleaning.
- Segregation partitions between the dirty and clean parts of the reprocessing area, e.g. between packaging and sterilising. These could include solid walls, glass walls, dividers or partitions, dividers made of polycarbonate or Perspex™, the use of pass-through equipment (e.g. washer-disinfectors and steam sterilisers that pass the load through solid walls), or sufficient physical separation (spatial segregation) to prevent clean areas or processed RMDs being compromised.
- Dental practices using large steam sterilisers (with a chamber volume over 60 litres) and large washer-disinfectors should consider, when refurbishing or rebuilding, moving to a design for the reprocessing area that has separate rooms for different functions (cleaning, packaging, sterilising, storage) with the washer-disinfectors and steam sterilisers having a pass-through design (RMDs are fed in from one room, and come out in the next room). Given the scale of the equipment involved (e.g. chamber sizes of 200–300 litres for washer-disinfectors and sterilisers) the pass-through equipment concept is not directly scalable to a small dental practice setting.

Nevertheless, the principles of segregation that underpin this design approach can still be applied in a small dental practice setting, by using unidirectional workflows from dirty to clean activities, and ensuring separation of the cleaning areas from the other parts of the reprocessing area, using distance (spatial separation) or a physical barrier. In a small dental practice or mobile facility where patient care and reprocessing activities are undertaken in the same room they should not take place at the same time, unless a local facility risk assessment indicates that this can be done safely. This includes meeting the above requirements for the effective segregation of clean and dirty activities, and unidirectional workflows, regardless of the size of the practice. This is necessary to minimise the risk of cleaned and sterilised RMDs being cross contaminated.

- Flush ceiling lights (luminaires do not protrude from the ceiling as this allows dust to accumulate).

- Two dedicated decontamination sinks: one for rinsing and manual cleaning, and a second sink for final rinsing. The sinks must be deep enough to avoid frequent splashing onto the bench, and taps provided with aerators or other anti-splash devices. The sink used for initial rinsing or manually cleaning contaminated RMDs should have hot and cold water taps. Taps should ideally be non-touch (e.g. foot- or elbow-operated) in operation. The decontamination sinks may be fitted with a goose-neck type hose for flushing items after cleaning.
- Good task lighting to minimise the risk of sharps injury when handling RMDs. This may be assisted by the installation of strip lighting over the area where RMDs are inspected.
- Magnification to enable proper inspection of cleaned RMDs.
- Efficient ventilation to reduce heat and humidity, with airflow from clean to dirty (i.e. in the opposite direction from the flow of RMDs). Air-conditioning outlets should be positioned over the clean benches of the reprocessing area, rather than above the dirty sink or ultrasonic cleaner. Based on AS 1668.2:2024, there should be a minimum of 10 air changes per hour in the reprocessing area where RMDs are being cleaned. Meeting this requirement may require the installation of local exhaust ventilation, which should be located above the cleaning area. Advice from experts in air-conditioning and ventilation systems should be considered when considering changes to local infrastructure. These individuals may need to conduct on-site assessments of air flows using anemometers or balometers.
- Control of temperature and humidity where RMDs are packaged and where sterilised RMDs are being stored. According to section 5.6.15 of AS/NZS 5369:2023, the ventilation system for inspection, assembly and packaging areas and sterile storerooms shall be continuously operational. The rationale behind this is to prevent degradation of packaging materials from high temperatures and high humidity. If 24/7 air-conditioning is not available or practicable, the stated storage life of sterile packages must be specified as a lower period to deal with this issue and ensure that the stated shorter expiry period does not allow for deterioration of the sterile stock that is generated within the practice by its reprocessing activities. For situations where high temperature and humidity conditions exist in sterile storage areas outside of working periods, setting a shorter interval such as three or six months for reprocessing unused RMDs may be required. See Section 12 for further discussion on this point.
- Non-slip water-impervious flooring that is readily cleanable.
- Smooth work surfaces, without crevices, made of non-porous materials such as stainless steel or laminate to facilitate cleaning. There must be no inaccessible areas where moisture or soil can accumulate.
- Work benches of a standard height and storage cupboards located at heights to minimise bending over or stretching overhead (this should be informed by an ergonomic assessment conducted at the local dental practice level).

Sufficient drawers, cupboards and shelves to keep work benches as clutter-free as possible and to facilitate temporary storage of sterilised packages as well as general items such as labelling guns, logbooks, cleaning agents and self-sealing pouches.

Sufficient bench space for drying and packaging areas to enable efficient work practices, including writing labels on or applying labels to each package.

A sufficient type and capacity of reprocessing equipment (such as steam sterilisers, ultrasonic cleaners, washer-disinfectors etc.) to meet the demands of the practice, taking into account the volume and type of RMDs that must be reprocessed.

A cooling area with a rack for cooling and then releasing sterile RMDs awaiting storage; this is essential to prevent damage to packs and dampness from condensation during cooling.

Where a dental practice outsources parts of its activities, such as steriliser validation and calibration, washer-disinfector validation, or off-site reprocessing of RMDs, the agreements around providing those services should make reference to the need to meet the requirements of these Guidelines and to conforming with the requirements of AS/NZS 5369:2023 for reprocessing RMDs

3. Transfer of contaminated RMDs and sharps within a practice

Pre-cleaning at the chairside

It is important to ensure that appropriate pre-treatment of used RMDs is done at the chairside (point of care) to prevent blood, cements and other materials setting onto RMDs, as drying of contaminants and gross soil onto RMDs makes later cleaning more challenging.

Suitable pre-cleaning methods, such as rinsing the ends of instruments intraorally during use using the triplex and high-volume suction, will remove gross contamination as well as residues of materials, while reducing risks to staff and damage to RMDs. If dry wiping instrument ends with gauze, consider hazardous chemical exposure issues and glove porosity to chemical agents as inherent hazards for this method.

Transfer to the reprocessing area

Contaminated RMDs should be carried to the reprocessing area in a cassette or in a container that is preferably lidded and puncture-proof, to minimise manual handling of RMDs. Use of a lidded container also reduces the chance of deposits drying on the surfaces of RMDs before they are cleaned and lowers the risk of a penetrating injury if the container is dropped during transport. If the container is considered clean externally then gloves are not required while handling the outside of the container.

RMDs should be placed on the bench in the 'contaminated zone' of the reprocessing room.

Procedure for delayed cleaning of RMDs

Cleaning of RMDs should be undertaken as soon as possible, since drying of contaminants onto RMDs makes later cleaning more challenging. The manufacturer's instructions for use must be considered as extended exposure may result in the damage of RMDs, as will 'extended hold times' in detergent and water. Each practice needs to develop a policy position around what is the maximum period of time permitted between the end of a visit and the start of the cleaning process. Such a policy should factor in whether or not holding solutions are used, and what happens to RMDs from the final appointments of the day.

RMDs contaminated with blood, saliva, cements and other contaminants that are not able to be cleaned immediately must be covered with a suitable hydrating solution to prevent the substances drying on them. RMDs must be rinsed well before the next step of the cleaning process is commenced.

4. Cleaning

The presence of organic material left on RMDs may prevent steam penetration during sterilisation. Therefore, it is essential that the surfaces of RMDs are completely decontaminated before being sterilised. Cleaning also dramatically reduces the number of microorganisms remaining on surfaces that need to be killed during sterilisation, which lessens the chance of microorganisms multiplying on RMDs before sterilisation commences.

Following the manufacturer's detailed instructions for reprocessing is essential. These specify the approved methods, and whether disassembly is needed, as well as other requirements such as lubrication, sharpening etc. There must be clear pathways for cleaning particular types of RMDs, such as (a) directly into a washer-disinfector; (b) pre-rinse with warm water to dislodge gross soil then ultrasonic cleaning; or (c) manual cleaning (for especially delicate items, such as glass photographic mirrors).

Note that bur brushes and other accessories used for cleaning are to be cleaned and thermally disinfected or sterilised, at least daily.

PPE requirements during cleaning of RMDs

Staff who are cleaning and reprocessing RMDs must be provided with formal training in the relevant procedures.

For staff members working in the reprocessing room, appropriate PPE should be worn, consistent with standard precautions. This includes eye protection/face shield to protect them from splashes. A mask must also be worn to protect from splashes to the lower face and from aerosols.

Disposable gloves must be worn when handling used RMDs, including loading into an ultrasonic cleaner and/or washer-disinfector. Gloves are also required for manual lubrication of handpieces, for loading automated handpiece lubricators, and for the manual cleaning of delicate or specialised RMDs. Before putting on gloves, hand hygiene must be performed, and again on removal of gloves. If hand hygiene is being performed by handwashing, a dedicated handwashing basin must be used rather than one of the dirty reprocessing sinks.

Based on a risk assessment, a waterproof/fluid-resistant gown/apron may be needed when undertaking large amounts of manual cleaning. Any splashes of water or cleaning agents reaching the skin must be washed quickly with clean water, and the site treated in accordance with the instructions for use.

Wearing a hair net is recommended when packaging RMDs, to prevent any shed hair falling onto the work area or into packages. For the same reason, beards should be covered.

Rinsing RMDs prior to cleaning

Rinsing RMDs prior to cleaning aims to reduce adherent deposits of saliva, blood, and other materials. Only warm water (around 35 °C) should be used for this initial rinsing. Water that is hotter than 60 °C will coagulate proteins and thus entrap microorganisms inside the mass formed, making cleaning more challenging. Use of cold water will precipitate and solidify lipids. Use of warm water prevents such problems.

Potable tap water is suitable for pre-rinsing of RMDs.

Mechanical cleaning of RMDs

Mechanical cleaners used in dental practices may be washer-disinfectors (which also provide thermal disinfection), ultrasonic cleaners or combination units which perform both. Washer-disinfectors are also known as instrument washers and thermal disinfectors. The use of domestic dishwashers to process RMDs is not permitted. Washer-disinfectors must not be used as a substitute for steam sterilisation.

As almost all items can undergo mechanical cleaning, manual cleaning of RMDs in facilities can only be used if the RMD IFU requires manual cleaning, or in the event of mechanical cleaning equipment failure.

Washer-disinfectors are more efficient at cleaning than ultrasonic cleaners. They also generate RMDs that are disinfected, unlike ultrasonic cleaning. As well, an automated cleaning process in a WD is easier to replicate than an ultrasonic or a manual cleaning process, and lowers the risk of penetrating skin injuries from sharp or pointed RMDs.

Washer-disinfectors

Washer-disinfectors specifically designed for use in healthcare settings are regulated as Medical Devices by the TGA. An ARTG reference/inclusion number should be available from the supplier as evidence of the regulatory status.

There are both benchtop and floor-mounted washer-disinfectors designed for use in dental practice. These connect into water supply and drainage systems and must be serviced according to the instructions for use. These systems must conform to the ISO 15883 series (parts 1, 2 and 5) and AS 3836:1998 *Rack conveyor washers for health care facilities.*

These units require daily checks and performance tests in accordance with the manufacturer's instructions for use, AS/NZS 5369:2023 and ISO 15883 Part 5. Washer-disinfectors are required to be validated annually. The release of RMDs from each cycle is based on this validation, daily tests, meeting the cycle parameters, and visual inspection for cleanliness.

Washer-disinfectors must be well maintained and the filters of the chamber cleaned regularly to prevent formation of biofilms that could contaminate the RMDs being processed. As with steam sterilisers, the process record must be checked at the completion of each cycle to verify that the cycle variables are within the specified limits. A suitable performance test (soil test) must be used at least once per day (as per AS/NZS 5369:2023) and the results recorded. A range of soil tests exist that can assess the cleaning performance of washer-disinfectors. Some of these tests have versions designed for use in ultrasonic cleaners. All RMDs must be inspected (with magnification under good lighting) after being cleaned or after being removed from the chamber of the washer-disinfector prior to packing and sterilisation.

Ultrasonic cleaners

Based on the RMD manufacturer's IFU, ultrasonic cleaners complying with AS 2773:2019 *Ultrasonic cleaners for health service organisations* may be used for cleaning RMDs, especially for small items such as nickel-titanium endodontic (root canal) files (following a validated protocol), ultrasonic scaler tips, and dental burs which are designed for reprocessing. Note that there is a specific application for approved enzymatic agents in the ultrasonic cleaning of rotary nickel-titanium endodontic (root canal) files, as part of a validated protocol. Ultrasonic cleaners can be used for cleaning jointed RMDs, such as scissors and stainless-steel syringes, or those with serrated beaks, such as artery and extraction forceps.

RMDs must be rinsed well to make them free of visible soil before being placed in an ultrasonic cleaner. The use of pre-cleaning/rinsing at the point of use to remove gross debris further reduces visible soil. In addition:

- lids, tanks, gaskets, and strainers must be cleaned daily;
- water must have a low hardness (below 150 mg/L) and a low level of chloride ions (below 120 mg/L), as specified in section 8.2.2 of AS/NZS 5369:2023, and be de-gassed before use. Hardness and chloride can be measured using test strips;
- the cleaning fluid must be changed a minimum of twice daily (or whenever it appears visibly cloudy and thus, heavily contaminated), or more frequently in accordance with the manufacturer's instructions for use;
- an aluminium foil test (or another approved performance test recommended by the manufacturer, such as the pencil test, or soil test) must be performed daily and the result recorded;
- lids must be closed during operation (to avoid dispersal of aerosols);
- RMDs must be completely submerged in the fluid; and
- no part of the operator's fingers or hands is permitted to be immersed in the fluid during operation of the ultrasonic cleaner.

The number of foil pieces used in the testing procedure should reflect the volume of the chamber of the ultrasonic cleaner. A large chamber will have several transducers and will require several pieces of foil to check that all transducers are operating correctly. These sheets must be positioned in accordance with the manufacturer's IFU.

Do not leave RMDs overnight in solutions in the chamber of an ultrasonic cleaner. At the end of the day, the chamber must be emptied and rinsed thoroughly, then left to dry overnight.

Manual cleaning of RMDs

As mentioned earlier, manual cleaning of RMDs in facilities can only be used if the RMD IFU require manual cleaning, or in the event of cleaning equipment failure. Very few items require manual cleaning. All routinely used solid stainless-steel dental hand instruments should be processed through a mechanical cleaning device, namely, an ultrasonic cleaner or washer-disinfector (but it is not necessary to send items through both of these).

The use of both pre-cleaning and rinsing to remove gross debris (in line with RMD manufacturer's IFU) assists with later cleaning processes.

If it is necessary to clean a delicate or specialised RMD manually, cleaning techniques used should aim to avoid spraying liquids into the air. The RMD should be held low in a dedicated instrument cleaning sink that has been pre-filled with warm water and instrument-grade detergent (not domestic detergent). To remove debris, a long-handled instrument brush or a non-scratch nylon scourer should be used until the RMD is visibly clean. Abrasive cleaners such as steel wool and abrasive cleaning powders should not be used as they can damage RMDs and may leave residue. A wire bur brush, maintained in good condition, may be used for cleaning tungsten carbide and diamond burs. As mentioned earlier, all cleaning brushes used for manual cleaning must be cleaned and thermally disinfected or sterilised, at least daily.

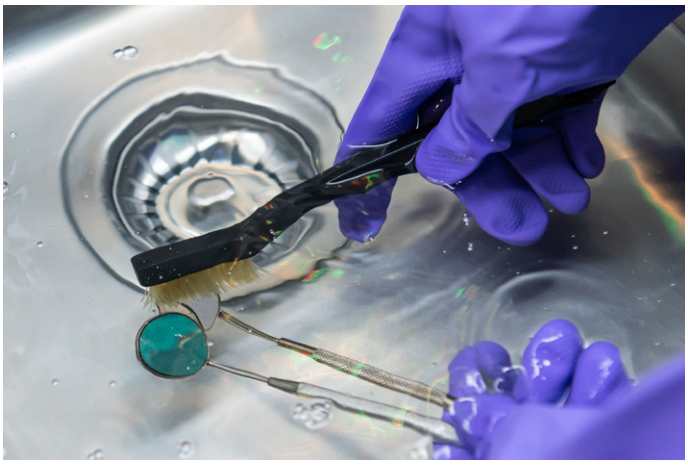
Water for manual cleaning should have a low hardness (below 150 mg/L) and a low level of chloride ions (below 120 mg/L), as specified in section 8.2.2 of AS/NZS 5369:2023. Hardness and chloride can be measured using test strips.

Warm tap water of suitable quality is to be used for manual cleaning of RMDs. As discussed earlier, for the initial rinsing step hot water should not be used as it coagulates proteins, which then increases the difficulty of cleaning, while cold water solidifies lipids.

It is recommended that cleaning agents used in manual cleaning are listed on the ARTG. Such products are designed to be low foaming, and to rinse away freely without leaving residues. Common household domestic detergents must not be used for manual cleaning of RMDs in dental practice as they are high foaming. This characteristic impairs the visibility of RMDs and increases the risk of a penetrating injury during cleaning. They also leave residues on the RMDs after rinsing. Never use a cleaning agent in a way, or for a purpose (such as instrument cleaning) that is not expressly recommended in the manufacturer's IFU.

Instrument detergents will have a neutral or mildly alkaline pH, unlike those used in ultrasonic cleaners (moderately alkaline) or in washer-disinfectors (strongly alkaline). The greater the pH of a detergent, the better it works, but it is more likely to cause skin irritation.

Following manual cleaning, RMDs must be rinsed thoroughly to remove all traces of detergent and must then be visually inspected. The quality of water used for rinsing after manual cleaning is discussed in the following section.



Rinsing after mechanical cleaning or manual cleaning of RMDs

Thorough rinsing is essential after ultrasonic cleaning or manual cleaning of RMDs, to remove residues of microorganisms and their products. This is done using tap water of suitable quality, and then followed by final rinsing using water of a particularly high quality (see below). A local risk assessment needs to be conducted to determine issues around water quality for reprocessing (cleaning and final rinsing).

AS/NZS 5369:2023 in Table 8.1 specifies the test frequency for water hardness and chloride tests for water used with ultrasonic cleaners and supply water for washer-disinfectors. That standard stipulates monthly testing as the norm (which can be done at the local dental practice level using test strips), with the frequency being adjusted (increased or decreased) based on the test results, so that readings remain within the specifications. There is no requirement for measuring total viable count or endotoxin levels for water put into ultrasonic cleaners for a cleaning cycle, so ordinary tap water of suitable quality can be used.

Water for final rinses

Practices must consider the quality of water being used for the final rinse after manual cleaning, ultrasonic cleaning or the final rinse of a washer disinfector. AS/NZS 5369:2023 allows for a risk-based approach to implementation of the standards, and this approach should determine the strategy adopted. The primary risk of using water that does not meet the standard is that the sterilisation process will be compromised, and instruments intended to be free from contamination at the point of use, will not meet that expectation.

The AS/NZS 5369:2023 requirements for final rinse water purity are stated in Table 7.2 of AS/NZS 5369:2023 and are explained in section 7.2.3.1 and in Appendix A.5.6.6.

This includes the following:

- pH (5.5–8.0),
- conductivity at 20 °C (≤ 30 microSiemens per cm),
- hardness (≤ 10 mg/L),
- ions (chloride ≤ 10 mg/L, iron and phosphates ≤ 0.2 mg/L, silicates ≤ 1 mg/L),
- viable bacteria (≤ 100 per 100 mL), and
- endotoxins from Gram-negative bacteria (≤ 0.25 Endotoxin Units per mL).

Bacterial endotoxins associated with gram-negative bacteria are heat-tolerant molecules that are highly inflammatory when introduced into wounds and trigger high fevers in patients. If endotoxins remain on RMDs after cleaning, they may cause intense localised inflammatory reactions, including granulomas, when RMDs enter tissues. This is why there are limits on total viable counts of bacteria and on the allowed levels of endotoxins in water used for the final rinsing of RMDs in washer-disinfectors, as shown in Table 8.1 of AS/NZS 5369:2023.

These requirements for endotoxin levels are based on the risk of high surface area instruments being used in procedures in which the vascular system is accessed. Contact with intact tissues can cause an inflammatory response; however, the tissues of the oral cavity have a lower risk than the vascular system. The risk increases as the surface area of instruments increase and as the duration of contact increases. Based on this, most dental instruments would not pose a significant risk of endotoxins being present at a level that would be likely to cause a host inflammatory response (approximately 2 nanograms per instrument).

When procedures are being performed that pose a risk of accessing the vascular system over an extended period, the risk of adverse reaction to endotoxin exposure is higher and warrants regular (at least annual) testing of endotoxin levels of final rinse water. Other methods to avoid endotoxin exposure concerns can

include the use of new sterile burs when undertaking vital pulp therapy, or surgical procedures, or alternative methods to cut vital tissues such as piezo-surgery or lasers.

Water samples collected on site may be sent to a commercial laboratory for testing. Such testing laboratories are expected to have been accredited, e.g. by the National Association of Testing Authorities (NATA), and to meet international standards for testing laboratories, namely AS ISO/IEC 17025.

A Reverse Osmosis (RO) system that delivers water for instrument rinsing could help to achieve the requirements outlined in AS/NZS 5369:2023. Note that RO water can also be used in a dental practice as feed water for steam sterilisers. RO systems produce purified water by having water pass under pressure through a semipermeable membrane that prevents the passage of ions from dissolved inorganic solids, as well as other impurities.

Drying RMDs

RMDs that will be sterilised using steam must be dried thoroughly prior to sterilisation as residual moisture following cleaning may impede the sterilisation process and may stain or damage the RMD. Suitable methods include use of a drying cabinet, low lint disposable or lint-free cloth, and a short rinse in very hot water.

The drying cycle of washer-disinfectors eliminates the need for a separate drying step.

Inspection

Following either mechanical or manual cleaning, RMDs must be checked visually under good lighting and magnification to ensure all soil/contaminants have been removed. Damaged or rusted RMDs must be repaired or discarded, and those with visible residue soil/contamination must be re-cleaned. If the RMD is not clean, the sterilisation process will be compromised.

5. Packaging of RMDs prior to steam sterilisation

It is recommended that semi-critical RMDs are stored in SBS or in cassettes, since both these methods protect against contamination. Packaging (also known as wrapping or bagging) of all RMDs removes one important variable from the equation and protects the cleanliness of RMDs.

As mentioned earlier, RMDs that must be sterile at the time of use (i.e. critical RMDs penetrating normally sterile tissue), must be packaged prior to sterilisation. Following sterilisation, critical RMDs must remain packaged and must then be stored appropriately until use.

Choice of packaging material

The packaging material (sterile barrier system) and packaging method must be compatible with the sterilisation process. The SBS must allow the removal of air from the packaging and device, and the ingress and egress of the sterilising agent. For example, paper-plastic pouches are suitable for steam sterilisation but not for low-temperature hydrogen peroxide gas plasma sterilisation, as the latter requires polyethylene pouches or non-woven multi-layered polypropylene packaging.

Paper packages and pouches used for steam sterilisation are required to conform to ISO 11607-1:2019 *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems,* and Australian standards AS 1079.5: *Single-use, non-woven wrapping materials – For goods undergoing sterilisation in health care facilities.* Textile linen wraps must conform to AS 3789.2:1991 *Textiles for health care facilities and institutions – Part 2: Theatre linen and pre-packs.* Paper and synthetic packaging for steam sterilisation is designed to be used once and then discarded, as contact with steam alters its properties. Packaging materials must permit the removal of air, the penetration of steam into the pack, and the removal of steam and water vapour after sterilisation. Likewise, cassettes and trays used for packaging instrument sets must be perforated to allow for penetration of steam and efficient drying.

Practical considerations when packaging RMDs

RMDs with hinges or ratchets must remain unlocked. RMDs with sharp edges should be packaged in such a way as to prevent perforation of the package.

Do not place colour-coded tapes (including coloured electrical tape) on individual RMDs for identification, as these can prevent the penetration of steam. The tape may also harbour microorganisms in the adhesive layer, and may detach from the RMD during surgery, compromising patient safety.

There are specifically designed silicone rubber rings that can be used to identify instruments, instrument sets or instrument cassettes; these do not impede cleaning or sterilisation. If used, follow the manufacturer's IFU. Care should be taken to regularly check any colour-coded identification rings, and replace any showing signs of degradation, so they do not detach from the instrument.

It is also possible to chemically etch or laser etch the surface of RMDs for the purpose of identification. Engraving must not be used, as this may disrupt or remove passivated surface layers that resist corrosion. This makes the engraved locations prone to pitting and corrosion, and may weaken the device. The issue of identifying individual RMDs becomes especially important for semi-critical RMDs that are heat-sensitive and are processed by

high-level chemical disinfection only, since AS/NZS 5369:2023 states that these are required to be fully traceable. That involves every RMD or RMD set having a Unique Identifier that is marked on the RMD itself or the container (e.g. instrument cassette), and this being recorded in the patient's history at the time of use.

RMDs organised in cassettes can be easily packaged as a single set; this may be far more convenient than individually packaging every instrument. This approach also greatly simplifies the requirements to record the contents of a steriliser load, since one instrument set contains multiple items in a known fixed configuration, and allows for simpler BCI recording.

As mentioned earlier, in an emergency situation (i.e. a dropped RMD for which there is no sterile replacement) a critical RMD may be steam sterilised without being packaged and then transferred to the operatory in a sterile container for use immediately after sterilisation.

When considering the workflow in the reprocessing area, once RMDs are packaged they must not be placed into the steam steriliser chamber and left there overnight. Likewise, sterilising cycles should not be run overnight when the reprocessing area is unattended. There are several reasons:

- water condensation causing non-conforming wet packages,
- extended exposure to heat causing non-conforming packages,
- dampness enhancing corrosion of RMDs,
- a lack of ability to properly monitor the outcome of the cycle,
- having an unsupervised pressure vessel operating, and
- steriliser manufacturers advise users against doing this in their instruction manuals.

Loads processed overnight are highly represented in sterilising breaches such as the release of unprocessed RMDs. This is why overnight sterilising cycles should be avoided.

RMD packaging decisions

Decisions around packaging and presentation of RMDs to be used in semi-critical sites have implications for RMD inventory and the cost of reprocessing. Each practice will need to examine their work mix to optimise the inventory of RMDs required to support the practice.

In a specialist orthodontic practice where no oral surgery is undertaken, the need for RMDs to be sterilised in packages and presented sterile at the point of use may be zero. On the other hand, in a specialist periodontal or oral surgery practice, RMDs should be routinely packaged and sterilised so they can be used in surgical procedures as well as in non-surgical procedures. A general dental practice performing mostly restorative dentistry sits between these two extremes.

Dental practices must be mindful of accreditation requirements in relation to packaging of semi-critical RMDs. Note that for public sector clinical facilities and hospital-based clinics, the requirements of the *National Safety and Quality Health Service Standards* (2nd edition), published by the Australian Commission on Safety and Quality in Health Care (as updated in 2021), are relevant. This point is discussed below.

For practices that perform periodontal closed debridement, as well as periodontal surgery or implant placement, having the inventory of scalers and curettes packaged allows versatility for use in both surgical and non-surgical patient appointments.

Some private dental practices may choose to delineate RMDs for routine non-surgical dentistry from those used in surgical procedures at critical sites. However, a high level of staff training is essential for this segregated approach, as mistakes can occur when two different systems for handling RMDs are used in parallel. RMD reprocessing mistakes are often the result of poor training and inadequate supervision. In a multi-operator dental facility, it is critical to put in place processes to ensure consistency in reprocessing RMDs, such as assigning one individual to the supervision and oversight of RMD reprocessing.

Sealing of packages

Packages must be sealed prior to processing. This can be done using a heat-sealing machine or with the use of self-sealing pouches. String, domestic adhesive tape, staples and elastic bands are not suitable for sealing packs.

Tests must be undertaken to verify proper operation of heat sealers, and the seal integrity for any self-seal pouches that are used, to demonstrate that these consistently form a robust seal that will withstand the changes in pressure that occur during a vacuum sterilising cycle, without breaks in the integrity of the seal (as per sections 7.4.5.2, 7.4.5.3 and 8.6 of AS/NZS 5369:2023). A typical approach is to check one or more samples of heat-sealed pouches for seal integrity before and then after each steam sterilisation process, checking along the entire length of the seal.

Labelling packages of reuseable medical devices

Packaged RMDs need to be labelled in a way that facilitates appropriate use of the contents. At the same time, the steriliser cycle record (logbook) needs to list the quantity of the names or sets of instruments processed in each load. Hence, grouping instruments into sets, such as restorative, exam or hygiene kits, makes the use of RMDs more efficient, while also making it easier to document in the steriliser cycle records how many respective kits were processed.

With regard to documenting the contents of a load, this aspect is referred to in several parts of AS/NZS 5369:2023, but especially in section 2.5.3.2 which relates to identification and traceability of sterilised RMDs, and again in subsection (b) (iii), which refers to records for the "Identification of the RMD/other device (e.g. device name or name of a set of devices) and the number of these items within the load".

For labelling packages, adhesive stickers, felt-tipped non-toxic marking pens and water-resistant ink stamps may be used. Adhesive stickers may contain information such as the processing date, steriliser identification, batch number and package contents, as well as barcodes or other codes that can be scanned. As mentioned above, combining items into sets may simplify recording of package contents and also facilitate retrieval of information in the event of a recall, especially when suitable software systems are being used.

Labelling should be completed just prior to sterilisation, to identify the date of sterilising, the contents of the pack and provide batch control information. If an adhesive label is used, the label must remain securely attached to the package during sterilisation and subsequent storage, right up to the point of use. Some steam sterilisers print labels that will be applied at the end of a cycle. If using this approach, the label application procedure must not compromise the integrity of the package (e.g. because of rough handling).

The information contained in labels placed on packaged critical RMDs must include the date of processing, the identification of the steam steriliser used and, if relevant, a batch identifier. If a pack is found without labelling, it must not be used and the contents are to be re-packed, properly labelled and sterilised.

Shelf life of packaged reuseable medical devices

Based on a local facility risk assessment of storage conditions (air-conditioning, temperature and humidity), a dental practice may state an expiry date (such as three or six months; see section 12 below) on the labels of packaged sterilised RMDs, since the effective storage life is linked to the storage conditions. The date of processing and an expiry date are also useful for stock rotation purposes.

A special concern with storage arises for dental practices that use back-to-base reprocessing (i.e. when sterilised RMDs are taken off-site for use and then returned to a larger facility for reprocessing). As well as having suitable separate storage environments on site for sterile/clean RMDs and contaminated RMDs, there must be education of staff around proper handling of packaged sterile/clean RMDs. Suitable dedicated labelled clean and contaminated containers must be used for transport. For sterile stock, these dedicated clean containers will prevent damage and environmental contamination, and will protect package integrity until the point of use of the package contents. For contaminated RMDs, the separate dedicated contaminated storage containers prevent damage to RMDs and exposure of staff to contaminated RMDs. When back-to-base reprocessing is done, a local risk assessment is needed. This must specify the conditions for non-conformance of packaged RMDs due to transport issues (e.g. heavy RMDs being dropped or mishandled, causing packages to become breached).

It is recommended that semi-critical RMDs are stored in SBS or in cassettes, since both these methods protect against contamination. Packaging (also known as wrapping or bagging) of all RMDs removes one important variable from the equation and protects the cleanliness of RMDs.

As mentioned earlier, RMDs that must be sterile at the time of use (i.e. critical RMDs penetrating normally sterile tissue), must be packaged prior to sterilisation. Following sterilisation, critical RMDs must remain packaged, and must then be stored appropriately until use.

6. Batch control identification (BCI)

Batch control identification (BCI) assists in risk management. It is essential for critical RMDs, as these may enter or penetrate sterile tissue, or the bloodstream. Critical RMDs include those used during surgical dental procedures such as extractions, periodontal surgery, and endodontic procedures on vital pulp tissue.

At a minimum, the system used for BCI (also known as tracking or tracing) needs to enable the identification of the individual cycle from a specified steriliser where the critical RMDs of a load were sterilised, with documentation of results from the checking that was undertaken prior to release of the load.

AS/NZS 5369:2023 in Appendix A.2.5.3.2 discusses traceability records that connect reprocessing activities to a patient's treatment. Semi-critical RMDs that are packaged and then steam sterilised with an associated BCI will be readily retrievable in the event of needing to recall RMDs (e.g. if a reprocessing error occurs and RMDs are accidentally released into storage). However, semi-critical RMDs do not need to be traced (BCI details entered into the patient's file). Some private dental practices will not need to undertake BCI tracking at all because they do not perform procedures where RMDs are used for critical procedures, or they only use pre-sterilised single-use disposable instruments for such procedures. BCI is not required where sterile single-use instruments are used, since the sterilisation has been undertaken by the manufacturer. Likewise, recording of batch codes or lot numbers for instruments and supplies (e.g. drapes, gauze) that come pre-sterilised from the manufacturer is not required. However, it is necessary to record in the notes the lot number or batch information for all commercially prepared implantable items (e.g. dental implants). Ethylene oxide sterilisation, and sterilisation by gamma irradiation, are commonly used on a commercial scale to produce disposable sterile items for use in dentistry. These processes can be verified.

As a quality assurance or risk reduction measure, a system of BCI must be used for all packages of critical RMDs that have been processed, as a minimum requirement. These batch numbers are to be recorded in the patient's notes at the time of the procedure. The recorded batch information links a critical RMD used on a patient to a specific steam sterilising cycle. This allows dental practitioners to demonstrate that the critical RMDs they have used

on the patient have been through a particular steriliser cycle with verifiable performance data showing satisfactory achievement of the required parameters.

The treating dental practitioner must not delegate responsibility for the accuracy of this information to another person. They must either enter the BCI information for the RMDs themselves or check that the information has been entered accurately by another person.

When using BCI, the batch code put onto a sterilised package of critical RMDs must include the date of processing, cycle or load number, and if more than one steam steriliser is in use, its name or identification number.

Batch information can be recorded on packages manually using non-soluble permanent marker ink, provided that the ink is able to tolerate steam sterilising and does not become unreadable. A manually generated batch code may be a simple incremental sequence of numbers, such as those produced from a labelling gun. Alternatively, it may be a composite of a number sequence with codes for the date and the cycle or load number, and the steam steriliser identifier (if the practice has several steam sterilisers).

If BCI is undertaken using adhesive labels, such as those applied with a labelling gun or printed label, the information on the label and any adhesives used must be able to tolerate steam sterilising without degrading and becoming unreadable or unable to be scanned. Segmented (piggyback) adhesive label systems are available, where one part of the label is peeled off the pack when setting up for the procedure and placed directly under the day's entry on the patient's hard copy chart. In addition, systems also exist whereby batch identification information is printed with barcodes or QR codes, allowing the codes to be scanned for entry into electronic patient records.

All staff (clinicians and dental assistants) should develop a habit of checking external and internal chemical indicators and for the presence of BCI for packages of sterilised RMDs, prior to opening them. RMDs can then be dispensed from the package into the working field. Each practice will need to develop their own workflow around when to record BCI. This could be done at the start or at the end of an appointment, and the choice may depend on what BCI system is in use. Provided that all batches used are recorded, the workflow around when the recording is done is not important. One approach is that during setting up, empty packages are placed onto a separate clean area rather than immediately into the waste, so the batch number information can later be recorded into the patient's treatment records (or checked) by the clinician responsible as part of writing up procedure notes at the end of the visit. Once this is done, the empty packages can be discarded. Another approach is to scan in packages using a barcode scanner when setting up at the start of the visit, and then put aside empty packages for any extra instruments used during the procedure so these can be scanned in later.

Batch lots for dental implants must also be recorded into the patient's notes.

Including batch code data within steriliser cycle records

The steriliser cycle record book is an important legal written record and will be a key piece of evidence if claims are made about inadequate reprocessing practices. Typically, a hard copy cycle record book is used together with signed hard copy printouts to record the key characteristics of each cycle, as follows.

Prior to activating the steriliser cycle, the loading operator will enter the following information into the cycle record book:

- date and time,
- cycle number,
- load type/description (including the numbers/types of RMD sets, individually packaged RMDs or unpackaged RMDs),
- cycle program selected, and
- identification of the loading operator. For the latter, the full name, initials, or an operator code may be used.

At the end of the steam steriliser cycle, the unloading operator then checks the sterilised load and enters the remaining information:

- whether physical parameters were satisfactory (based on checking the printout or checking the data display in cases where the data is stored on a memory card),
- that the chemical indicators included in the load show a pass result,
- whether the sterilised packages are conforming (i.e. they have intact seals and are dry), and
- identification of the unloading operator, who is signing off that RMDs in this load are suitable for use.

Not all sterilisers have software that captures and records all components of information in a secure manner. The capability of a steriliser to capture records of sterilising parameters varies greatly depending on the type and age of the steriliser, as well as the software in use. Where the required information is not captured by the steriliser software, practices should continue to use hard copy cycle record books.

To prevent cross-contamination, it is important that the steriliser operator does not complete a hard copy record book while still wearing contaminated gloves. Gloves should be removed, and hand hygiene performed before completing documentation of the steriliser cycle that is about to start. They should not push the cycle start button until the recording of the loading data is complete.

Items must not be released from the reprocessing area for return to the operatory until they have been released for use. The process for releasing items for use requires a sequence of events designed to eliminate the situation in which items are used that have not been sterilised. The release process includes holding items in a separate area following sterilisation that is clearly signed until they are released, checking the sterilisation parameters have been met, checking the SBS indicators demonstrate sterilisation has occurred, and recording the release in the cycle record book.

Items should then be placed in an area that indicates items are released for use. This sequence is designed to eliminate the situation in which a load is returned for use when it has not been properly sterilised.

By completing the record, the unloading operator is stating that the sterilised load is suitable for use, which is a tangible contribution to quality and safety in the practice. If the unloading operator identifies issues such as an incorrect cycle, an overloaded chamber, or wrongly positioned RMDs when the chamber is opened, the cycle record book identifies who the loading operator is for follow-up with regard to these problems.

Key compliance items for reprocessing stages prior to sterilisation

- Ensure there is a method to safely transfer RMDs from the operatory to the reprocessing area (e.g. puncture-proof, lidded container).
- Determine how each RMD used in the practice will be appropriately reprocessed (each stage required) and include this in the infection control manual.
- Determine how RMDs will be managed if they cannot be immediately reprocessed.
- Review the layout of the reprocessing area to ensure it allows effective and efficient flow of RMDs throughout reprocessing.
- Ensure the practice Infection Control Manual contains up-to-date information on the use and maintenance of reprocessing equipment.

7. Sterilisation using steam

Effective cleaning is the first step in the sterilisation of any RMD. Once RMDs are cleaned, packaging and sterilisation follow. Sterilisation is the process of rendering an item free of all forms of viable microorganisms, including spores. In office-based dental practice, the most efficient and simplest means of sterilising dental RMDs is steam under pressure (commonly called steam sterilising or autoclaving). It involves the combination of heat and moisture maintained at the correct temperature and pressure for a sufficient length of time to kill all microorganisms, with the probability of survival being less than 1 in 1 million. This is also known as the sterility assurance level (SAL). For effective sterilisation using steam, all air in the steriliser chamber must be removed and replaced by steam.

Low-temperature sterilisation using hydrogen peroxide gas plasma is an alternative method that can process a range of heat-sensitive RMDs and has fast throughput. It uses several vacuum phases and can sterilise hollow objects as well as solid objects. The RMDs can be used immediately, since they exit the chamber at the end of the cycle just above room temperature and hence are safe to hold without the risk of burns. This method is not suitable for absorbent textiles such as cotton rolls or gauze.

Dry heat sterilisation is not recommended for routine sterilising of dental RMDs. Ultraviolet light and boiling water do not sterilise RMDs and must not be used for sterilisation. As a result, proper workflow is needed to eliminate the need to decontaminate heat-sensitive items in a dental practice that would degrade readily if exposed to heat or steam. As an example, appropriate decontamination of prostheses at the chairside prior to polishing prevents contamination of polishing buffs.

Benchtop steam sterilisers (also called autoclaves) are widely used for sterilising RMDs in office-based dental practice. Most RMDs (including rotary handpieces and some piezoelectric ultrasonic scalers, as well as some surgical motors and low-speed electric motors) are designed to withstand steam sterilisation. If an RMD is specified as being suitable for steam sterilisation by the manufacturer, and the instructions from the manufacturer are to undertake sterilisation using steam, then that is what must be done. The RMD cannot be processed using thermal disinfection or high-level (instrument-level) disinfection.

All sterilisers, regardless of their type, that are used in dental practice must be approved by the TGA and listed on the ARTG. They must be operated according to the requirements listed in AS/NZS 5369:2023, and in line with the manufacturer's instructions for use.

There are three types of sterilisation cycles:

N cycles – (N indicates 'none packaged, none hollow'). These cycles can only be used for non-packaged, solid RMDs. Steam pushes the air downwards using gravity and forces it out a port in the bottom of the chamber in a passive way. Such sterilisers would only be suitable for a dental practice that does not do exposure-prone procedures and does not sterilise any hollow items.

S cycles – (S indicates 'specified'). These cycles are intended for processing certain load types and load configurations specified by the manufacturer. They are not 'general purpose' sterilisers and can only be used for specific loads which the manufacturer has verified as being suitable. A range of dedicated S cycle units have been developed, including units for sterilising certain brands of dental handpieces and cassette-type compact sterilisers that use induction heating for rapid processing. It is essential that staff carefully read the instructions for these sterilisers so that load types and load item positioning in the chamber match those specified as being suitable. S cycles use various processes for active air removal to overcome the limitations experienced in N cycles which employ gravity displacement. These include positive pulses of steam to purge air from the chamber. This is why sterilisers running only S cycles can sterilise certain brands of restorative dental handpieces.

B cycles – These are used for hollow objects where the removal of air and entry of steam is more challenging. Air is exhausted from the chamber by a mechanical vacuum pump to create negative pressure (a vacuum) before steam is introduced into the chamber. Sterilisers that run B cycles require specific performance tests, including vacuum/air leak tests and air removal tests.

With regard to positioning non-packaged RMDs and packages of RMDs in the chamber of a steam steriliser, when a B cycle is run, the superior efficiency of air removal from paper-plastic pouches by multiple vacuum cycles is such that the arrangement of these (plastic facing up, facing down, or on the side) does not greatly affect air removal. The main considerations are that, for items laying horizontally, paper down is preferred, to avoid water condensation droplets dampening the paper. Most steam sterilisers have angled or vertical racks. These racks are ideal for small pouches as they prevent droplet pooling, and also improve loading efficiency and steam penetration through the load. Hence, the manufacturer's loading instructions should be followed, and where not specified, the preference is for plastic side up/paper side down.

8. Maintenance and testing

AAll sterilisers must be commissioned on installation.

Verification of the sterilisation process

To ensure appropriate sterilisation, validation of the sterilisation process is undertaken, to ensure the desired performance is being achieved. This validation process involves the following steps:

1. Commissioning-installation qualification (IQ) and operational qualification (OQ).
2. A commissioning report includes installation documents and operation verification. This work is performed by the service technician when a new or repaired steriliser (e.g. after a major or critical component has been replaced/repaired) is installed in the practice.
3. Performance qualification (PQ):
   a) Physical qualification (by a qualified instrument technician, service engineer or manufacturer's technician)
      - Calibration report – this addresses the accuracy of thermocouples and data loggers used to measure temperature inside the chamber of the steriliser (undertaken annually).
      - Penetration report – this checks the physical attributes of the steriliser. This record is obtained after major repairs or when pack contents, packaging materials, or loading methods change significantly.

   b) Microbiological report to confirm functioning of the steriliser using a biological indicator (also known as a spore test). AS/NZS 5369:2023 requires PQ and microbiological PQ (MPQ) be performed concurrently. For dental practices, this means that the technician will be required to complete all three cycles using biological indicators. Staff can no longer perform these cycles and ship the indicators to an external laboratory for incubation.

   c) The validation report summarises satisfactory completion of commissioning, operational and performance qualification.
   It provides validation of the total process.
4. Validation is required annually as a minimum. If there are changes in the load, packaging or cycle profiles that are assessed as exceeding what had been previously validated, validation needs to be repeated.

Monitoring of cycles

Sterilisation cannot be assumed to have been achieved without appropriate testing and load checking. For steam sterilisation, time, temperature and pressure must be measured with continuous, automatic, permanent monitoring (e.g. use of a process recorder, data printer or data logger). Where an older steam steriliser with no recording device is used, it must, where possible, be fitted with mechanisms to electronically record sterilising parameters. Otherwise, the parameters must be read from the relevant gauges and then documented at intervals of 10 seconds. Alternatively, a biological indicator or chemical indicator (Class 4 or greater) can be used for each load. The processed chemical indicator must achieve all sterilisation parameters applicable to the indicator used, and that information must be recorded. Hard copy printouts that are checked and signed off provide a valuable record of the cycle parameters.

Given the importance of steriliser cycle records, for sterilisers that use hard copy printers rather than electronic data capture, the practice should develop a protocol around handling the situation where the printer has malfunctioned or supplies of printer paper are exhausted (e.g. including Class 6 chemical indicators inside each pouch or package). If data from the steriliser is recorded onto a memory card or sent to a file server, there must be a process for reviewing this data. The full parameters are to be checked at completion of each cycle. In addition, it is good practice to back up data from memory cards every day.

The everyday performance of a steam steriliser must be monitored by periodic testing, including daily and weekly tests. The details of these tests are given in Table 8.2 of AS/NZS 5369:2023, which was updated in Amendment 1. The sections below discuss the use of chemical indicators and the process of validation.

Operating the steam steriliser

Staff working in the reprocessing area must be trained in the correct operation of a steam steriliser. An operator's manual must be available for each steam steriliser, and the unit must be used according to the manufacturer's instructions.

Before sterilising an RMD, the operator must verify the item is suitable for the process. For example, some items are made of low melting point plastic and cannot withstand steam sterilisation. Likewise, there must not be any attempt to sterilise disposable single-use items. Information on compatibility for steam sterilisation will come from the manufacturer. RMDs may also be marked with symbols indicating the need for sterilisation at 134 °C. Few if any items will require sterilisation at the lower temperature of 121 °C.

Only steam sterilisers with a drying cycle can process packaged RMDs. If the steam steriliser does not have a drying cycle, it can only be used to sterilise non-packaged RMDs.

9. Steam steriliser performance tests

Steam sterilisers are complex pieces of equipment and may be affected by mechanical faults; they are also prone to errors from incorrect use by operators. It is necessary to regularly monitor the sterilisation process to ensure the process has met all parameters and that the reprocessed RMDs have been sterilised.

For a small pre-vacuum steriliser which runs B cycles, a range of tests must be carried out. These tests are shown in the flow diagram below, which is a suggested workflow. In summary, after the vacuum/leak rate test is performed, an appropriate air removal and steam penetration test (ARSPT) that is compliant with ISO 11140-6 is run. Guidance on choosing an appropriate ARPST for small steam sterilisers (either a hollow device (previously known as a helix test) or a porous device (such as a Bowie-Dick type test)) is provided in the following sections.

On the other hand, for a large pre-vacuum steriliser which runs B cycles, with a chamber size above 60 litres, the required daily tests include an ARSPT of the porous type, namely a Bowie-Dick type test. As well, a large steam steriliser requires a warmup cycle is needed prior to commencing vacuum leak rate tests. This warmup is not needed when doing the vacuum/leak rate test for small steam sterilisers.

Leak rate test (vacuum test)

This tests the integrity of the entire system under vacuum, including the door seals and the vacuum pump, and the pipes and components between them. This test must be performed prior to commencing the first sterilising cycle of the day. A high leak rate means there is a damaged door seal or a leak in the pipes or chamber, or in the vacuum pump.

If the steriliser incorporates automatic air leak detection, then this leak rate test is only performed weekly. In the absence of automatic air leak detection, this test is run every working day. It is important that each dental practice checks whether their steam steriliser has an air detection capability, since most small steam sterilisers do not have air detectors. For this reason, daily vacuum leak rate tests are the norm.

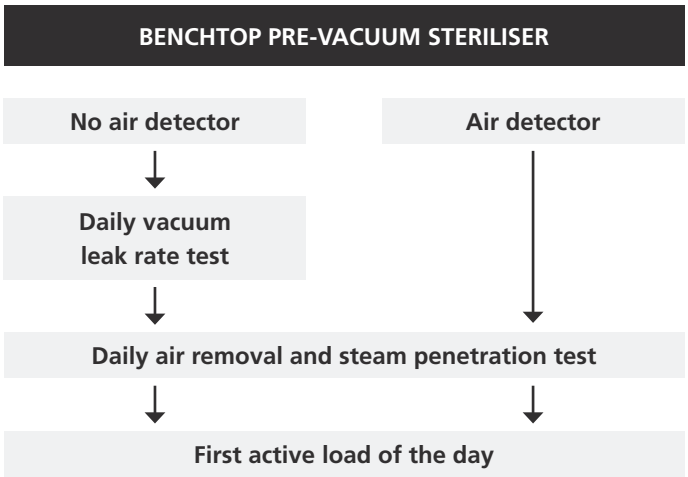
For those brands of steam sterilisers that have air detectors, it is important that its proper functioning is checked. The required interval for testing the air detector should be stated in the manufacturer's IFU. Manufacturers make special devices to check proper performance of air detectors. In the absence of documented information (e.g. from the service engineer who conducts annual calibration) that the air detector system is working properly, users should perform vacuum leak rate tests daily instead of weekly.

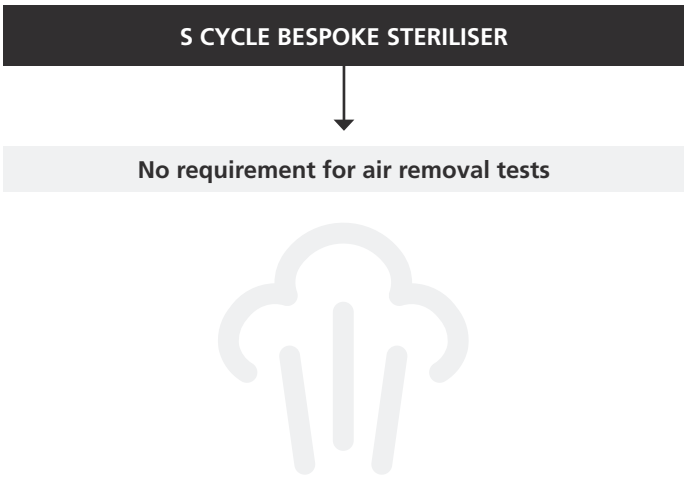
Tests for air removal and steam penetration for small steam sterilisers

Air removal and steam penetration tests (ARSPT) come in a range of form factors (sizes and shapes). As explained in ISO 15882 section 6.4, the performance of an ARSPT is the combined effect of the chemical indicator within it, the dimensions and materials of manufacture. This is why different types of load challenges can be represented by different ARSPTs.

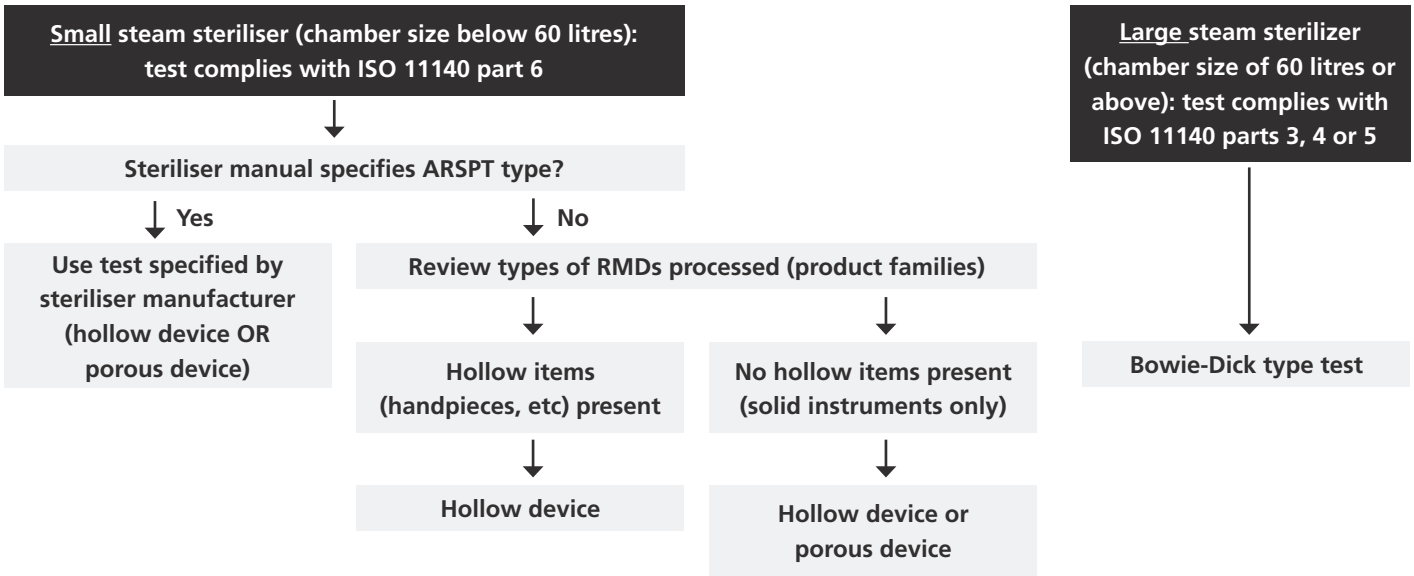
Table 8.2 of AS/NZS 5369:2023 requires an air removal and steam penetration test (ARSPT) to be performed daily. For small steam sterilisers, the test must be compliant with ISO 11140.6:2022 *Sterilization of health care products – Chemical indicators – Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers.* This ISO standard includes specifications for both:

- A reference porous device.
- A reference hollow device.





Choosing air removal and steam penetration tests (ARSPT) for mandatory daily tests for pre-vacuum sterilisers



Amendment 1 of AS/NZS 5369:2023, removed all specific references to Bowie-Dick type tests for small steam sterilisers from Table 8.2 and section 8.7.4 and does not specify which (porous device or hollow device) should be used to meet the daily ARSPT requirement.

There are several sources for guidance on the choice of ARSPT for small steam sterilisers. Users should initially refer to manufacturer advice (e.g. instruction manual) for guidance on what type of daily ARSPT (hollow device or porous device) is advised for that particular steam steriliser. In the absence of specific manufacturer advice, the type of ISO 11140-6 compliant test required daily should be determined based on the types of RMDs being processed, i.e. if hollow loads (lumens) are commonly included in loads, then a daily reference hollow device ARSPT should be performed. The rationale behind this is explained further in the following discussion.

Air removal is most challenging from devices that are lumened (hollow). Hollow devices could have a closed end or be doubled open ended. Devices with a closed end pose the greatest challenge to air removal and steam penetration.

Based on EN13060:2014, the difficulty of air removal increases when the ratio of length of cavity to diameter is greater than 5. This ratio can be calculated, as shown in the table below. For double open ended lumens (i.e. both ends open to the environment) the functional length is taken from the midway point, since air can be removed in both directions.

Examples of dental RMDs with a narrow lumen, internal tubes or pipes include (but are not limited to) the following:

RMD	Length	Midway length	Diameter	Ratio
High speed handpiece	150 mm	75 mm	0.8 mm	93.8:1
Slow speed handpiece	100 mm	50 mm	0.8 mm	62.5:1
Metal triplex syringe tip	83 mm	41.5 mm	0.8 mm	51.9:1
HVE Suction tip	130 mm	65 mm	6 mm	10.8:1
	160 mm	80 mm	6 mm	13.4:1
	160 mm	80 mm	8 mm	10:1

Other examples of devices with a narrow lumen include surgical handpieces, piezoelectric ultrasonic scaler bodies, and piezo-surgery handpieces.

As RMDs with a hollow lumen could be present in most dental sterilisation cycles, the recommendation for small sterilisers therefore is that the daily ARSPT should be a hollow device that conforms to ISO 11140 part 6.

When choosing a hollow device from the wide range available on the market, check the description for conformity with ISO 11140 part 6 (2022), as this means that the test has equivalent difficulty or challenge to the reference hollow device in that ISO standard.

It is important to follow the ARSPT manufacturer's IFU regarding the correct method of using a test. The instructions for use will describe where to place the test device in the steriliser chamber. When a hollow device contains tubing made of plastic polymers rather than metal, the test device will have a restricted number of uses, and they must not be used beyond that point.

Users should check their steam steriliser instruction manual for specific advice on how to select and run the appropriate test cycle. This may be called a "helix test" cycle or a "helix/Bowie-Dick test" cycle. This cycle is shorter than a normal pre-vacuum cycle because the drying stage is much shorter.

An ARSPT is read by assessing colour change in the Class 2 chemical indicator positioned inside the device. A uniform colour change with no residual original colour remaining indicates that steam has penetrated. The results of the test are then recorded in the steriliser cycle records (as a pass or fail). There is no need to retain the chemical indicator strip.

Tests for air removal and steam penetration for large steam sterilisers

Large steam sterilisers have chamber sizes above 60 litres, and their use is based on EN 285. In AS/NZS 5369:2023 Amendment 1, in clause 8.7.4 and Table 8.2, Bowie-Dick type tests are required as the daily ARSPT for large steam sterilisers. Such tests will conform to ISO 11140-3 *Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test,* ISO 11140-4 *Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration,* or ISO 11140-5 *Class 2 indicators for Bowie and Dick type air removal tests,* as appropriate.

A test pack for the Bowie-Dick type test consists of two components: a small standardised test load and a chemical indicator system to detect the presence of steam. The test load is typically presented with the indicator system already incorporated and intended for single use.

The Bowie-Dick type test must be run using an otherwise empty chamber, and with a special cycle. Staff need to check their steam steriliser IFU for specific advice on how to select and run the special Bowie-Dick type test cycle. The steam steriliser instructions for use will also describe where to place the Bowie-Dick type test device in the chamber.

At the end of the test, the indicator sheet or strip must show a uniform colour change under the exposure conditions used (134–135.5 °C at 3.15 mins with a tolerance of 5 seconds), with no residual original colour remaining. The results of the test are to be recorded in the steriliser cycle records (as a pass or fail), but the chemical indicator sheet itself does not need to be retained.

A 'fail' result could be due to problems with air removal (including failure of the vacuum pump or vacuum system) resulting in air and other gases remaining in the chamber, and causing insufficient steam penetration onto the indicator surface.

In addition to the Bowie-Dick type test, a clinic with a large steam steriliser can also consider the additional use of a hollow ARSPT based on the nature of their load items, specifically the volume of items that have a narrow lumen. This would be an addition to, and NOT a replacement of, the daily Bowie and Dick type test.

Batch monitoring of cycles using PCDs

As well as the use of a hollow device in an empty chamber as the daily ARSPT before a live load, another use for a hollow device is for batch monitoring. Their use in this way is optional and is based on a local risk assessment, as outlined in Amendment 1 of AS/NZS 5369:2023.

Batch monitoring devices do not replace the mandatory requirement to use an ARSPT in an empty chamber every day. Different types of load challenges can be represented by different process challenge devices (PCD). For example, a special PCD could be made that copies the internal design of an air turbine handpiece, for the explicit purpose of assessing air removal from dental handpieces. This would confirm the absence of residual air that could affect the attainment of sterilising conditions in the load (as per section 8.7.7. of AS/NZS 5369:2023).

Key compliance items for tests for air removal and steam penetration

- Check the steriliser IFU for which cycle to select for running ARSPT tests.
- Check the steriliser IFU for advice on how to select the type of daily ARSPT to use. If not specified, choose the ARSPT based on the types of RMDs processed &/or chamber size of the steriliser.
- Run ARSPT tests immediately after the vacuum leak rate test.
- Ensure that the daily ARSPT complies with the correct ISO standard. For small steam sterilisers, choose products that comply with ISO 11140-6 (check the product labelling). For large sterilisers choose products that comply with ISO 11140-3, 11140-4 or 11140-5.
- Base any use of hollow PCDs for batch monitoring on local risk assessments.

Loading

A steam steriliser can only work effectively if steam can circulate freely and touch every surface of every RMD. Steam steriliser trays should not be crowded; items must not be densely packed, must not touch each other or the chamber walls and must not be layered on top of one another. Correct loading reduces damage to packs and their contents and maximises the efficient use of the steam steriliser by reducing the chance of failed loads.

To ensure correct air removal, items should be loaded into the chamber according to the IFU for that steam steriliser and the configuration that has been validated. Some sterilisers have angled racks to ensure proper loading of items in pouches.

To reduce the risk of RMDs awaiting sterilisation being mistaken as having been sterilised, and thus being recirculated back to the operatory, packaged RMDs awaiting sterilisation must be stored in a dedicated 'pre-sterilisation' area, not in the chamber of the steam steriliser.

If non-packaged RMDs are loaded, a Class 1 chemical indicator must be placed in each loading tray being processed.

For every packaged RMD, a Class 1 chemical indicator must be included on the outside of the package as a visual check that the package has been through the sterilising process.

Drying

Items at the end of the steam sterilising process should be dry, not damp or wet. Damp items are indicative of a faulty drying cycle. It is not acceptable to use a fan to dry items that are damp, nor is it acceptable to boost the local air-conditioning to forcibly cool items.

Packaged or unpackaged RMDs must never be dried by opening the door of the steam steriliser before the drying cycle is completed.

A cycle must not be interrupted before the drying phase is complete. If a cycle is interrupted before the drying phase is completed, all RMDs, whether packaged or non-packaged, must not be used. Instead, all these instruments must be reprocessed.

Only steam sterilisers with a drying cycle can sterilise packaged RMDs using moist steam. At the end of a cycle, to avoid contamination and thermal injury, these items should be allowed to cool in the chamber before being handled.

RMDs sterilised by steam must be allowed to cool prior to handling. Packages of RMDs and trays of non-packaged instruments removed from the steam steriliser should be placed on racks, and not directly on the bench. This prevents water condensation occurring either around or inside the cooling packages, affecting the pack or load integrity.

Checking the completed load

Several variables influence the process of sterilisation:

4. quality of cleaning (residual bioburden);
5. choice of packaging materials;
6. packaging technique;
7. steriliser chamber loading technique;
8. sterilant quality (levels of ions and lubricants in the water); and
9. cycle parameters (time, temperature, steam wetness).

Once the sterilising process (including the drying cycle) is complete, multiple checks must be made and the results recorded.

The operator must check whether the physical parameters were satisfactory by checking the printout or data display for readings of pressure, temperature, and time. For non-packaged loads of dental RMDs, steam sterilisers must reach a holding temperature of 134–137 °C and must maintain this for at least three minutes. For readings outside the specified limits, the sterilisation cycle must be regarded as unsatisfactory, and all RMDs must be re-packaged and re-sterilised. If a second cycle is unsatisfactory in the same manner, the steam steriliser has a significant fault and must not be used until the problem has been rectified by a technician.

Reprocessing records (including electronic data and any hard copy printouts) must be retained for inspection and monitoring for a period of at least seven years (and up to age 25 for children below the age of 18, depending on jurisdictional regulations). Modern steam sterilisers have an integral or external printer or data logger for routine monitoring.

Visual inspection of sterilised packaged RMDs

When unloading the chamber, the unloading operator must visually check each package of RMDs, as follows:

- Check the package for damage. There cannot be any items penetrating through the packaging.
- Check that the seals are intact along their length, with no interruptions.
- Check that the package is dry.
- Check that the external (Class 1) chemical indicator has made the required colour change.

If a paper-laminate pouch has been used and internal chemical indicators have been included (Class 4, 5 or 6), check that these chemical indicators have made the required colour change; this shows the required parameters have been achieved. Remove from circulation and quarantine any packs where the internal chemical indicators reflect insufficient exposure to steam, as this identifies a flaw in the steam sterilising process. Defective packages must NOT be used in the operatory. Pay particular attention to a situation where most packages are satisfactory, but one package shows inadequate colour change; this may indicate issues with air trapping from incorrect loading.

Quarantine from circulation any damp or wet packages, and any packages that have been dropped on the floor or show loss of integrity. In all these cases, the affected RMDs are to be considered contaminated and must be cleaned again and then reprocessed in full, from cleaning through to packaging and sterilising.

Record the identification of the unloading operator who is signing off that RMDs in this load are suitable for use.

The chamber of a steam steriliser requires daily inspection for any debris, and to check the integrity of the door seal. Follow the manufacturer's IFU for daily maintenance checks that are needed. The chamber itself must not be wiped with a detergent-impregnated wipe, as products from the wipe will introduce contaminants into the chamber. Manufacturer's instructions will specify proper methods to remove scale or deposits from the chamber (usually weekly or every 100 cycles). Only use products designed for maintaining the chamber that are recommended by the steriliser manufacturer.

Retention of cycle data from steam sterilisers

Practices must retain data from steam steriliser cycles for a minimum of seven years, and as mentioned earlier, they may be longer based on jurisdictional regulations for RMDs used on children (e.g. until they reach 25 years of age). This requirement is the same for hard copy printouts and electronic data downloaded from a memory card. Printouts generated by thermal printers

tend to fade with time and become illegible, so these need to be transferred into digital format (photographed or scanned) or photocopied to give a stable record. Printouts from ink printers do not fade and can be stored over the long term. Hard copy printouts should be signed off by the unloading operator who has checked them, as part of the normal process for releasing a load of sterilised RMDs.

Some modern steam sterilisers offer cycle data capture onto a memory card. This data must be periodically downloaded from the flash memory card and regularly backed up. It is good practice to use two memory cards and fully back up the contents of each card every week. The longevity of memory cards used in sterilisers is likely to be less than those used in other devices because of higher ambient temperatures. Some sterilisers can connect to a computer network for uploading cycle data onto a server. This approach overcomes functional issues with memory cards.

The following IPC records should be maintained, and then kept in a safe manner for at least seven years (unless a longer period is stated in the facility's local policy).

- **Steriliser records:**
  - Daily performance tests, including vacuum/air leakage tests and air removal and steam penetration tests for pre-vacuum steam sterilisers.
  - Reprocessing cycle records for sterilisers (in electronic or hardcopy format).
  - Results from any PCDs used for (optional) batch monitoring
  - Steriliser servicing and repairs (see below for more details).
  - Annual calibration.
  - Performance tests and records for the validation of sterilisers (IQ, OQ and PQ), including results of biological indicator tests for verification of cycle parameters, and the certification of validation issued by the service engineer (see below for more details).
- **BCI records:**
  - Batch control identification (in patient records) when critical RMDs are used that have been through a sterilising process.
  - BCI and RMD details for semi-critical RMDs released from high-level disinfection.
- **Equipment-related records:**
  - Daily performance tests for washer-disinfectors and ultrasonic cleaners (such as the results of foil, soil or pencil test for the ultrasonic cleaner, soil tests for the washer-disinfector).
  - Annual validation for washer-disinfectors.
  - Records of performance tests done to verify proper operation of heat sealers, and any self-seal pouches that are used (e.g. proper sealing of test samples by heat sealers).
  - Records of servicing any other items of reprocessing equipment.
- **Personnel-related records:**
  - Induction and training processes (including staff meetings) used to update infection control knowledge and skills, and employee training records including competency assessments.
  - Vaccination and allergy status for each staff member, and staff immune status declarations (reviewed annually).
  - Incident reports, e.g. non-conforming products or workplace health and safety incidents, workplace injuries and incidents (such as breaches in infection control protocols and how these are managed).
- **Documentation of procedures:**
  - Instructions for use and operating manuals.
  - Loading diagrams for sterilisers and washer-disinfectors.
  - Quality and procedure manuals, which cover the cleaning, inspection and assembly steps prior to packaging and sterilisation of RMDs.
  - Procedure manuals for cleaning of the operatory (patient treatment area) and the reprocessing area.
  - Procedures to follow at the beginning and end of the day, and special procedures for closing the practice down for longer breaks when equipment such as the dental chair will need to be placed into hibernation status.
  - Procedures to recall failed or missed loads of RMDs, such as lookbacks and investigations around non-conforming sterilised RMDs.
- **External interactions of the practice:**
  - Records for purchasing RMDs and single-use sterile consumables.
  - Records of any outsourcing of reprocessing activities off-site.
  - Records of any loaned sterilisers or loaned sets of RMDs (for loaned sterilisers: the dates of transfer in and out, whether a full validation was undertaken for the loaned unit and details of that validation, whether internal chemical indicators in packages were introduced for RMDs sterilised in the loaned steam steriliser; for loaned instrument sets: whether these were cleaned, packaged and processed on site, or not).
- **Risk management:**
  - Any IPC risk assessments or audits undertaken, and the results of these.
  - Records from internal audits and the corrective actions that were implemented to rectify deficiencies. These actions need to be reviewed to check that they have been effective in addressing the deficiencies that were identified.
  - Business continuity plans in the event of major events affecting IPC (such as steriliser failure).

Validation records

These describe the validation protocol, which consists of three components: Installation qualification (IQ) Operational qualification (OQ) and Performance qualification (PQ). These three elements apply to steam sterilisers, low-temperature sterilisers (HPGPS) and washer-disinfectors.

For a steam steriliser, there are two components to PQ, i.e. physical performance qualification (PPQ) and microbiological performance qualification (MPQ). These are performed concurrently.

When documenting PQ for sterilisers using biological indicators (spore tests), the following details are required: what was used as the largest and most challenging load, and where items of the load were positioned in the chamber; the location of the biological indicators and other sensors within the load (the positions within the load where sterilising conditions will be the most difficult to achieve); the heat distribution data for packaged items in the chamber; the parameters used for the test cycles; who performed this test and when; and the date when the requalification is due (a maximum of one year).

Part of the annual validation process is to review local reprocessing protocols and training manuals to ensure that information regarding routine procedures is comprehensive and accurate. The validation report details are given in section 7.5.2. of AS/NZS 5369:2023. The completed report must be reviewed and signed off by a competent person (staff member), and the report retained on file (electronically or in hard copy).

Servicing records

Each dental practice should arrange for regular servicing of their equipment, e.g. through written service agreements, to cover planned preventive maintenance, calibration, performance assessments and annual requalification for all reprocessing equipment. This will include checking the calibration of timers and gauges, as specified by the equipment manufacturer. For small steam sterilisers, calibration of thermocouples and an assessment of thermal penetration is required each year. Mains powered electrical devices also require periodic (e.g. annual) electrical safety checks, in line with jurisdictional electrical safety regulations. Note that testing intervals vary depending on what safety switches are fitted to the practice. Records must be kept of all such activities.

Records must be kept for both routine scheduled maintenance and unscheduled major servicing and repairs of reprocessing equipment (e.g. ultrasonic cleaner, washer-disinfector, heat sealer, handpiece lubrication system, steam steriliser). Those records will include what was done (including parts replaced), who did the work, and what was done when the equipment was returned to service to verify correct operation. Where steam steriliser equipment failures have led to non-conforming items, the steriliser that has undergone a major repair needs to have full PQ performed to verify it is suitable to be returned to service.

The recommended frequency of recalibration, preventive maintenance and testing of cleaning, disinfection and packaging equipment and associated equipment is given in Tables 10.1 and 10.2 of AS/NZS 5369:2023. For most items, the frequency of planned preventive maintenance/recalibration will be based on the manufacturer's instructions and the maintenance/calibration history of the system, with a maximum duration of 12 months between instances

Key compliance items for sterilisation

- Ensure all team members involved in reprocessing are familiar with the proper use, packing and maintenance of sterilisers.
- Check that the daily, weekly and annual processes that are used to ensure sterilisation processes are effective for the specific steriliser and indicators in use have been documented.
- Check that all dental team members involved with inspecting sterilised RMDs are aware of the requirements for passing a load and what to do when this is not the case.
- Verify that steriliser cycle data is stored and accessible for a period of at least seven years. Note that longer periods of data retention are applicable in some jurisdictions when patients are treated as minors.

10. Steam steriliser monitoring tests

Chemical indicators

Regular monitoring of the steam sterilisation cycle is necessary to ensure the sterility of reprocessed RMDs. This is done using physical indicators (e.g. printouts of cycle parameters) in combination with chemical indicators to show that certain temperatures, times, and steam exposure conditions have been reached during the sterilising process.

Physical and chemical indicators are designed to show whether the correct sterilisation parameters have been achieved. As part of the formal validation process, the exposure parameters have been determined using a 'most difficult, worst case' scenario with the most challenging load configuration. Provided that cycle parameters have been followed and the load has been correctly sterilised (as shown by the results of the physical and chemical indicators), packaged sterilised RMDs can be released for use in the operatory. Release of RMDs must be recorded and signed off by the person performing the task. Table 9.1 of AS/NZS 5369:2023 gives the criteria for release of a packaged device from reprocessing.

It is essential that the staff member undertaking load checking for sterilisers is competent. They must have acquired, through education, training, qualification or experience or a combination of these, the knowledge and skill enabling them to perform this task. That requires following all the steps of load checking, and being vigilant for non-conforming items. In a large practice, their

work in this regard may be supervised and audited by another more senior staff member. Practices must have a risk management process in place to ensure the parametric release of RMDs can be confirmed, particularly if there is no cycle printout or detailed screen that enables staff to check all three parameters (time, temperature, pressure).

Chemical indicators provide information about conditions in the steam steriliser at the specific locations where they have been placed, whether sitting loose in the chamber, included within packs, or inside a process challenge device.

Some indicators, such as Class 1 types, are only sensitive to changes in temperature, while others, such as Classes 5 and 6, are sensitive to variables such as temperature, time and water (as delivered by saturated steam). Key characteristics are summarised in the following table.

Chemical indicators

Class	Where used	Features
1	Indicator tape, external surface of the paper side of a pouch	Changes colour in response to heat.
2	Inside a hollow PCD and inside a Bowie-Dick type test	Used to assess air removal and steam penetration. Responds to steam.
3	Only with dry heat steriliser containers	Changes colour in response to heat.
4	Inside packages of RMDs (e.g. mandatory when non-validated sterilising conditions)	Lowest precision.
5	Inside packages of RMDs	Moderate precision. Responds to time, temperature, and steam.
6	Inside packages of RMDs	High precision. Responds to time, temperature, and steam.

Class 3 is unique to dry heat sterilisers.

Class 1

A Class 1 indicator must be used on the outer surface of every individual pack of packaged RMDs to show exposure to reprocessing. These indicators are only sensitive to changes in heat; they do not measure exposure to steam. These indicators may be built into the package as dyes which change colour, or applied as tape which undergoes a colour change. Class 1 indicators do not provide any insight into the conditions inside a package or pouch.

A **Class 1** indicator should be used in each load of non-packaged, semi-critical or non-critical RMDs. The indicator will show a fail result if the load has not been processed at all, or when there has been a gross malfunction of the steam steriliser. Best practice would be to include one Class 1 indicator on each tray in such a situation.

Class 2

A Class 2 indicator is a specific test used within a test for air removal and steam penetration (ARSPT) for a steam steriliser with pre-vacuum cycles. This could be either a hollow PCD test or a Bowie-Dick (B-D) type test.

For steam sterilisers running only S cycles that do not use a vacuum pump for air removal, no ARSPT is needed, unless the use of a specific test is stated in the steriliser IFU.

With any test that uses Class 2 chemical indicators, a pass result requires a uniform colour change across the entire surface of the indicator, with no residual original colour remaining.

Class 3

A **Class 3** indicator responds to only one critical variable (i.e. temperature). These indicators have relatively poor accuracy and are only used with dry heat sterilisers. They have limited value in general dentistry where sterilisation is undertaken using steam rather than dry heat.

Class 4, 5, and 6 chemical indicators

These indicators are designed to be used either loose in the chamber (for a non-packaged load) or included within packages or pouches of RMDs. Their purpose is to provide evidence of steam exposure. Use of these indicators is described in Table 8.2 of AS/NZS 5369:2023.

For packaged RMDs, these chemical indicators demonstrate that steam exposure within the package has met the stipulated conditions. Each class of chemical indicator has a different level of precision for measuring temperature and exposure time, with Class 4 being the least precise and Class 6 being the most precise. The tolerance for measuring temperature is 2 °C for Class 4, but only 1 °C for both Class 5 and Class 6. The tolerance for measuring exposure time is 25% for Class 4, 15% for Class 5 and 5% for Class 6.

The terminology used with these indicators can be confusing. Typically, Class 4 indicators respond to two variables (hence may be called 'multi-variable' indicators), while Class 5 and 6 indicators respond to time, temperature, and steam wetness (hence may be called 'integrating indicators') and surpass the exposure parameters for biological indicators (spore tests) (hence may be called 'biological emulators'). This terminology should be avoided. Instead, indicators are to be recognised and referred to by their class, since this indicates their tolerance. Class 5 and Class 6 indicators are routinely labelled with their class descriptor; however, this is not the case for Class 4 indicators. Unless there is documented evidence to the contrary, users should regard any unknown and unlabelled internal chemical indicator that has been included inside a packaged RMD as a Class 4 indicator.

Under AS/NZS 5369:2023, a Class 4 chemical indicator is the minimum that must be included inside every package of a packaged load when the reprocessing conditions have not (or not yet) been verified by a full qualification process involving biological indicators used in three replicate cycles. This situation may occur when a brand new or loaned steriliser is being used, when the

printer associated with a steriliser has failed, or when a new brand of packaging material is being used. In these situations, there is a lack of formal evidence of effectiveness; thus, the use of internal chemical indicators inside every package is mandatory. This requirement applies to all non-validated loads, regardless of whether the RMDs in the pouches are intended for use in routine dental procedures in a semi-critical site, or whether the RMDs are intended for use in a critical site where they must be sterile at the point of use. Higher classes of indicator (Class 5 or 6) are desirable for this situation because of their higher precision.

This requirement for internal chemical indicators applies to all non-validated loads, regardless of whether the RMDs in the pouches are intended for use in routine dental procedures in semi-critical sites, or whether intended for use in critical sites and required to be sterile at point of use. Once a full validation test has been done, the inclusion of a chemical indicator inside every package for every cycle is optional.

When interpreting Class 4, 5 or 6 chemical indicators, ensure that the colour change meets the stipulated requirement. If the colour change is incomplete, do not use the RMDs in the operatory; instead, re-clean, re-package and re-sterilise them (i.e. repeat the full reprocessing sequence).

When the internal chemical indicators inside a package or pouch show a fail result, this could be due to insufficient air removal causing persisting cool air pockets; this may be caused by an overcrowded chamber, incorrect loading, or incorrect packaging. Air pockets occur less often in pre-vacuum steam sterilisers than in sterilisers that use other methods of air removal.

Storage and use of chemical indicators

Chemical indicators are designed to be read at the end of a cycle, and the result obtained is compared with the reference colour change chart provided by the manufacturer. Once checked, chemical indicators must be discarded. There is no requirement to keep and store these indicators. The colour change chemistry used within chemical indicators is not intended to provide results of archival quality if these indicators are stored for several years.

This is particularly relevant to Class 5 and 6 indicators, which use sophisticated multi-step chemical reactions. When indicators are stored in record books, acid released from the paper of the record book can permeate into the indicator and cause colour changes. Thus, do not keep ANY chemical indicators (Classes 1 through to 6) as part of the records of the practice.

Key compliance items for chemical indicators

- Ensure all dental team members involved with reprocessing know which chemical indicators are being used and their purpose.
- Consider protocols for the use of additional chemical indicators when the reprocessing conditions have not (or not yet) been verified by a full qualification process (such as when a loan unit is being used or a temporary printer failure).

Biological indicators

Whenever RMDs are packaged, it is essential to determine what steam steriliser cycle parameters are required for successful air removal and steam penetration. Validation of the conditions is necessary when there is a change in the type of packaging material used. Validation must also be repeated annually, even when there has been no change in the type or method of packaging RMDs. This test is typically undertaken by a service engineer or steriliser technician.

Qualification and validation

When there is a change in the brand of packaging, and annually (regardless of consistent processes being used), it is necessary to undertake the process described below to establish what steam steriliser cycle parameters are required for successful air removal and steam penetration (validation).

Validation of cycle parameters involves using multiple biological (spore) tests. Biological indicators contain highly heat-resistant bacterial endospores. Killing these demonstrates that sterility has been achieved. For steam sterilisers, the spores of *Geobacillus stearothermophilus* are used. These spores are heat resistant (and thus, difficult to kill) and do not cause human disease.

For long thin pouches, the recommended approach is to use at least two biological indicators in each test pack, for example, with a small pouch two indicators would be used, while with a large pouch there would be one placed at each end and one in the middle of the pouch, giving three in total. With larger packs, one indicator is placed in each corner and one in the centre of the pack. The intention is to select the largest and most difficult pouch or package for this performance test. A test pack with multiple indicators must be prepared in triplicate so that one can be processed on each of three consecutive cycles. A further indicator is not sterilised but, rather, is used as a positive control. This control will show growth (colour change), demonstrating that activation and incubation of the biological indicators have been undertaken correctly.

AS/NZS 5369:2023 requires that PQ and microbiological PQ (MPQ) to be performed concurrently. The technician is required to complete this for all three loads. Based on AS/NZS 5369:2023 A.7.4 performance qualification, at least two BIs should be used in a steriliser chamber not exceeding 0.3 cubic metres, and additional BIs should be used where loads are complex. This is why the dental setting uses at least two BIs.

The packages containing the biological indicators are placed into location within the steam steriliser chamber; they are to be placed in either the known (from manufacturer information) or shown (from a heat distribution test run using thermocouple probes) 'cold spot' where the chamber temperature is the lowest. Typically, this location is towards the bottom of the chamber. The rest of the chamber is loaded with packages as per normal.

After completion of three cycles, 10 biological indicators, nine of which have been processed and the tenth as a control, are activated (by crushing the end of the vial to release the liquid growth medium) and incubated at 55–56 °C for 24–48 hours, then checked for growth. When spores survive and germinate, there is a colour change in the liquid medium, indicating a failure of sterilisation. Correct steam reprocessing parameters will cause inactivation of ALL biological indicators in test items in the three successive loads. Growth should only be seen in the positive control. If there is no growth in the control, this indicates a failure to activate or incubate the spores, and thus, all results are invalid; in this case, the test sequence must be repeated in full. The results from the biological indicators must be recorded in the steriliser cycle book. The used biological indicators (including any that show growth) are discarded into the sharps waste.

The results of performance qualification (PQ) tests must be recorded with sufficient detail that can inform future tests of the same type. The data to be recorded includes:

- date of the test;
- brand and type/description of the packaging system used
- how the test packs were assembled, and where they were placed in the chamber (this could be done using photographs);
- type of biological indicator used and the batch number. It is important to check that the biological indicators used are within their expiry dates;
- location and identification number of the steam steriliser (if there are multiple steam sterilisers in the practice);
- name of the operator running the performance qualification;
- the cycle parameters that were tested and shown to be suitable;
- that the service engineer conducting the tests is familiar with AS/NZS 5369:2023 and these ADA IPC Guidelines.

Key compliance items for biological indicators

- Determine when validation of steam sterilisers will occur.
- Ensure service engineers and technicians using biological indicators for validation are familiar with the protocols in these Guidelines and AS/NZS 5369:2023, and that the data to be recorded is maintained.

Low-temperature hydrogen peroxide gas plasma sterilisation (HPGPS)

HPGPS systems for use in healthcare settings have been on the global market since the late 1980s and are now being used in some dental practices and mobile dental services. HPGPS can be used for heat-sensitive plastic, rubber and other polymer-based RMDs that if subjected to steam sterilisation would melt. HPGPS can be used with non-packaged RMDs as well as with packaged RMDs. These systems also suit dental practices that require a very fast turnaround (e.g. because of a limited inventory of RMDs, or to recover from 'dropped item' situations). As well as a short cycle time (as little as seven minutes), RMDs leave the chamber at body temperature, and so can be used immediately.

HPGPS systems have a vacuum pump, and so can sterilise hollow RMDs, solid RMDs and packaged RMDs. A daily ARSPT test is not required with HPGPS unless the use of a specific test is stated in the steriliser IFU. However, a leak rate test is to be done at the interval recommended by the manufacturer.

In HPGPS, concentrated hydrogen peroxide (e.g. 60–65% w/v) is released from special sealed cartridges. This is first vaporised into a gaseous state by heating it up. The chamber remains at a low temperature when plasma is generated – less than 50 °C and typically 37–44 °C – which is sufficient to prevent condensation. There are two consecutive cycles, each with a separate injection of hydrogen peroxide followed by plasma generation. The cycle concludes by venting the chamber of all the gases and restoring the chamber to normal atmospheric pressure.

HPGPS can process items made from acrylic resin and 3D printed plastics as well as most plastic polymers and metals. It cannot process items with cellulose (e.g. cotton or paper), nor copper or brass. Special packaging is needed (e.g. polyethylene or polypropylene pouches that need low-temperature settings for heat sealing). Special chemical and biological indicators are made for HPGPS. Chemical and biological indicators are not interchangeable between HPGPS and steam sterilisation.

As with other sterilising technologies, HPGPS performance requirements are addressed in ISO 14937:2009 *Sterilization of health care products – General requirements for characterisation of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices. Systems are required to conform to* ISO 22441:2022 *Sterilization of health care products – Low temperature vaporized hydrogen peroxide –*

Requirements for the development, validation and routine control of a sterilization process for medical devices, as well as ISO TS 22421:2021 *Sterilization of health care products – Common requirements for sterilizers for terminal sterilization of medical devices in health care facilities.*

Like other steriliser types, annual maintenance and recalibration is mandatory. At more frequent intervals, as specified by the manufacturer, various user interventions may be needed, e.g. checking and replacing the cartridges that scavenge ozone and other oxygen compounds, or replacing the oil in the vacuum pump.

As with steam sterilisers, at the end of a cycle, product release must only occur after checking process parameters (cycle data, external chemical indicators, any internal chemical indicators, and package integrity). Each packaged item must be completely intact and there must not be any visible moisture or fluid present. Packages appear 'vacuum shrink wrapped' after sterilisation, with no large air spaces within the pack.

11. Disinfection

Disinfection does not ensure the same degree of safety to patients as achieved with sterilisation because it does not always destroy all microbial life forms – some resistant forms, such as bacterial endospores, may survive.

Disinfection is a process that uses either thermal (moist or dry heat) or chemical means.

- Thermal disinfection uses heat and water at high-temperatures to destroy infectious materials. It is appropriate for items that are heat- and moisture-resistant. It can be achieved in a thermal washer-disinfector (WD).
- Chemical disinfection can be achieved with a TGA-approved sterilant to medical device disinfectant. Chemical disinfectants include (but are not limited to) alcohols, chlorine, hydrogen peroxide and quaternary ammonium compounds.

There are three levels of disinfection, depending on the intended use of the instrument.

- **High-level disinfection** – a disinfectant that kills all microbial pathogens (except large numbers of bacterial endospores).
- **Intermediate level disinfection** – a disinfectant that kills all microbial pathogens (except bacterial endospores – it is bactericidal, tuberculocidal, fungicidal and virucidal).
- **Low-level disinfection** – a disinfectant that rapidly kills most vegetative bacteria and lipid containing viruses (it cannot be relied on to destroy bacterial endospores, mycobacteria and fungi).

Disinfection is not a sterilising process; wherever possible, sterilise items to be used in semi-critical sites or use single-use items.

Disinfectants are regulated by the TGA in several categories. The requirements of disinfectant manufacturers have recently been changed by the TGA, and these changes will force greater discretion onto clinical use applications.

Instrument disinfectants:

Two categories of chemical instrument-grade disinfectants are used to reprocess an RMD.

- A high-level instrument-grade disinfectant. This the minimum grade disinfectant that can be used for disinfection of a semi-critical RMD or other device.
- An intermediate or low-level instrument-grade disinfectant. This the minimum grade disinfectant used for disinfection of a non-critical RMD or other device where required.

Other classes of chemical disinfectants, e.g. hospital-grade disinfectants, must not be used to reprocess an RMD.

Any instrument-level disinfectants used must be TGA-registered and must be used according to the manufacturer's specific directions.

Surface disinfectants:

Surface disinfectants include two regulated categories, and one exempted category, as follows:

(a) hospital-grade disinfectants (with or without additional claims);

(b) commercial grade disinfectants (with or without additional claims);

(c) sanitisers (exempt from regulatory supervision).

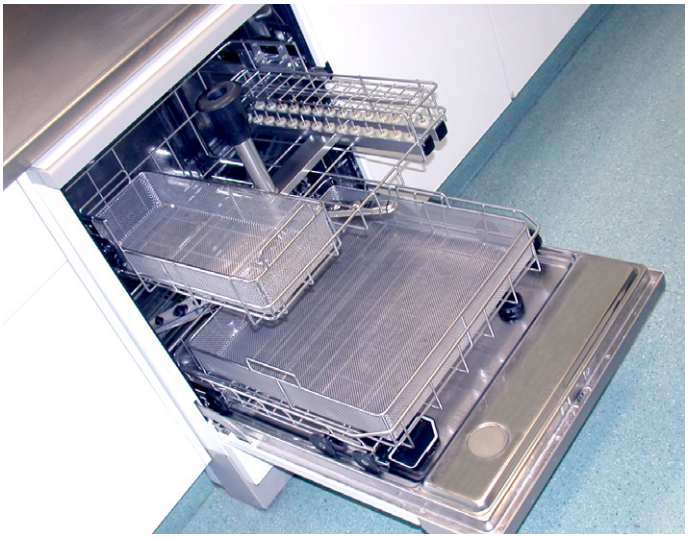
Hospital-grade hard-surface disinfectants with no specific claims are not required to have an ARTG entry.

Thermal disinfection:

Thermal disinfection undertaken with a washer-disinfector is not a sterilising process and must not be used as a substitute for steam reprocessing and sterilisation where the RMD can withstand steam sterilisation.

Thermal disinfection using washer-disinfectors

To achieve disinfection, a washer-disinfector (WD) must employ a cycle that holds RMDs at a high temperature for a sufficient time. Only WDs that are regulated by the TGA and which conform to the requirements of AS/NZS 5369:2023 shall be used for this purpose. The applied heat destroys pathogenic non-sporing vegetative organisms. Thermal disinfection can be used for some prosthetic instruments, polishing buffs, and brushes since instruments used in dental prosthetics are semi-critical and buffs are non-critical. An alternative approach is to use single-use disposable instruments for dental prosthetics, as this eliminates the need to reprocess instruments.



RMDs to be thermally disinfected must be cleaned prior to disinfection. If an RMD is not clean, it cannot be disinfected. The required cleaning steps are undertaken within a WD. RMDs and other items can be placed into a WD without prior cleaning or while still wet (if previously rinsed). Individual RMDs require inspection at the end of a WD cycle.

WD performance tests (known as soil tests) must be undertaken to document the performance of the WD, as a check of the efficacy of the process. AS/NZS 5369:2023 in Table 10.1 requires this to be done at least once per day. As well, the chamber floor filters and door gaskets of the WD must be checked and cleaned regularly as per the manufacturer's instructions.

Most WDs connect directly to mains (reticulated) water and mix this water with highly alkaline detergents for washing RMDs. Incoming water must not be too 'hard' or this will reduce the WD performance in the cleaning phase of the cycle. In some locations, the reticulated water is too 'hard' and needs to be treated using a water softener to make the water suitable for use with detergents in the WD. It is important that the quality and pressure of the feed water used for washing and rinsing matches the manufacturer's specifications. Note that the same water hardness problems affect manual cleaning of RMDs.

WDs have specific requirements for the quality of the final rinse water. It is common to use reverse osmosis to generate the required quality of final rinse water.

It is not appropriate to use small electric ovens (portable cooktops) or domestic microwaves as a means of thermal disinfection of RMDs in dental practice.

Chemical disinfection using instrument disinfectants – high-level (instrument-level)

All instrument disinfectants are fully regulated by the TGA and are registered on the ARTG. According to AS/NZS 5369:2023 (section 3.3.1), a high-level instrument-grade disinfectant is the minimum grade of disinfectant that can be used with a semi-critical device or instrument. On the other hand, an intermediate or low-level instrument-grade disinfectant is the minimum grade that can be used for disinfection of a non-critical device. Lower classes of chemical disinfectants, such as hospital-grade disinfectants, must not be used in reprocessing RMDs. High-level instrument-grade disinfectants should only be used for RMDs that are not compatible with sterilisation or thermal disinfection, in accordance with the RMD manufacturer's IFU.

For practical purposes, there is no place in dentistry for the routine, everyday use of high-level chemical disinfection for devices, dental impressions or RMDs (e.g. use of glutaraldehyde or ortho-phthalaldehyde). Instrument disinfectant products should never be used on surfaces. This is due to concerns about safety and effectiveness of glutaraldehyde and other aldehydes.

High-level (instrument-level) chemical disinfectants should only be used when thermal disinfection or steam sterilisation is unsuitable (e.g. some prosthetic or laboratory items – surgical guides or surgical templates). In many cases, low-temperature hydrogen peroxide gas plasma sterilisation can be used with such items, and provides a solution to the need to have these items packaged and delivered so that they are sterile at the point of use.

When high-level (instrument-level) chemical disinfectants are used, the manufacturer's directions must be followed precisely. This includes whether the agent is used undiluted or whether it needs to be diluted or mixed with an activator, and how RMDs and other items are to be rinsed and then handled after disinfection. As with thermal disinfection, items must be cleaned thoroughly prior to using high-level disinfection.

Instrument disinfectants cannot be mixed with other disinfectants. RMDs must not be stored in these disinfectant solutions for any time extended beyond the intended soaking time required to achieve the specified sterilisation or high-level disinfection outlined in the specific product label conditions.

The use of an instrument chemical disinfectant must be undertaken with all due caution, including full training of staff with respect to both the intended purpose and the safety requirements set out in the product Safety Data Sheet. This includes proper storage, handling and decanting methods, access to a chemical spill kit, the use of appropriate PPE, suitable ventilation conditions, and the use of potency test strips as recommended by the instrument disinfectant product manufacturer. It is important to consider the potential impacts on the environment of instrument disinfectants, and to follow the disposal requirements stated by the manufacturer.

Ultraviolet cabinets must not be used for disinfection of RMDs.

Surface disinfectants and disinfectant wipes

Such products are intended for use on environmental surfaces and patient equipment only and not on RMDs such as dental instruments and dental handpieces. Changed requirements from the TGA have altered the level of oversight for disinfectants. Dental practitioners should take great care in reading and understanding the efficacy claims of surface disinfectants, particularly claims around inactivation of SARS-CoV-2 (the virus responsible for COVID-19) or other viral or bacterial pathogens.

Any compliance concerns over product potency, use conditions, or safety and efficacy should be addressed to the manufacturer in the first instance. For any complaints or concerns over product performance, potency, safety or efficacy, a complaint should be lodged directly with the TGA via the TGA website under the Medical Device section.

Key compliance items for disinfection

- Ensure disinfectants are being used according to the manufacturer's instructions for their intended purpose, and safely stored.

12. Storage of processed RMDs

The shelf life of a packaged sterilised RMD is not fixed in time but reflects the conditions of storage, particularly temperature, ventilation and humidity control (as described in AS 1668.2:2012 *The use of ventilation and airconditioning in buildings Part 2: Mechanical ventilation in buildings*). This is called an 'event-related' shelf life. Therefore, where 24-hour air-conditioning control of temperature and humidity of the sterile stock storage area does not occur, the permitted use life of packaged RMDs needs to be set at an appropriate interval, due to degradation of the packaging material, such as at 12 months. For situations where high temperature and humidity conditions exist in sterile storage areas outside of working periods, setting a shorter interval such as three or six months is appropriate.

During storage, packs also can be contaminated by:

- over-handling – this can happen through excessive transferring from one place to another or during rotation of stock, from over-stocking of storage areas, or from bundling packs together using rubber bands;
- moisture – if the pack is placed on a wet benchtop or splashed with water or other liquids; or
- penetration – if RMDs break through the packaging and breach the surface.

A package is deemed to be non-sterile when it:

- is damaged or open;
- comes out of the steam steriliser wet or is placed on a wet surface; or
- is dropped onto the floor or placed on a contaminated surface.

It is essential to store packaged RMDs away from the contaminated zone, to avoid them being exposed to splashes of fluid and aerosols produced during clinical treatment or from reprocessing of RMDs. The correct storage of processed RMDs will protect them from environmental contamination. In dental practice, the major source of environmental contamination of processed RMDs is splashes of fluids and aerosols of airborne bacteria and viruses which settle over time.

For this reason, non-packaged RMDs and RMDs in packages must be stored in such a way that contamination from splashes and aerosols does not occur. Keeping sterilised RMDs in closed drawers, closed cupboards or sealed containers achieves this. Locating the stored packages of RMDs at an appropriate height, or using cupboards with transparent doors, allows the contents to be seen easily.

Care is necessary when moving packages of RMDs within drawers, to reduce the chance of a surface breach caused by RMDs with sharp edges perforating the paper or textile of the package. Staff must also ensure proper rotation of sterile stock, using the older processed RMDs first.

Storage areas for packaged sterilised RMDs must be dedicated to this purpose only and must be kept free of dust, insects and vermin. Ideally, packaged sterilised RMDs will be stored in enclosures (such as drawers or cupboards) that prevent the occurrence of environmental contamination. Special requirements are necessary if open shelves or racks are used for storage of packaged sterilised RMDs. For open shelving, a useful guide is to have items at least 250 mm above floor level and 400 mm away from ceiling fixtures, away from any open windows and protected from direct sunlight, to prevent packaging being degraded by sunlight. Note that windows in reprocessing areas should not be opened. Ideally reprocessing areas need all windows to be fixed in place (non-operable) and unable to be opened. This avoids packages becoming contaminated by dust and facilitates environmental cleaning.

The area used for storage must be of sufficient size that packages are not packed densely on top of each other. If it is too small, too high, crowded or awkward, access may be difficult, and this increases the likelihood of the integrity of the packaging being compromised. The storage area must not have high humidity, as this increases problems due to dampness.

Non-packaged semi-critical and non-critical RMDs must be stored dry and in a way that will prevent contamination from dust or splashes prior to use. This can be achieved by storing items in:

- cassettes, which are then placed into drawers or cupboards;
- trays in closed drawers; or
- trays or cassettes kept in sealable plastic containers with lids.

Cardboard boxes must not be used as storage containers for packaged RMDs as these are porous, cannot be adequately cleaned and may harbour organisms.

The condition of the area used for storage of sterilised RMDs needs careful review. Continuous (24-hour, seven day) air-conditioning is ideal in that it ensures low humidity and constant temperature, which gives a longer life for SBS. In many situations, 24/7 air-conditioning will not be available or possible. In such situations, it is appropriate to place a fixed expiry state on sterilised packages of RMDs, such as three, six or 12 months. A shorter time is suited to the situation when both temperature and humidity levels are high, or otherwise impossible to control (e.g. with mobile dental facilities).

As part of environmental cleaning, areas that are used for storage of RMDs (whether packaged or not) require periodic cleaning, e.g. monthly or three monthly, according to the local cleaning policy. At this time, drawers or containers are cleaned with detergent and water.

As discussed earlier, before opening any package of sterilised RMDs, it is essential for the dental practitioner to check the package to ensure it has been sterilised and the barrier function of the SBS has not been compromised during storage. If there is any doubt about the sterility of the package, or if the package has been compromised, the RMDs cannot be used in patient treatment. Packages showing evidence of damage must not be used. Instead, the RMDs must be put through the cleaning, packaging, and sterilising process once again.

Key compliance items for storage of processed RMDs

- Note any circumstances in which items may become contaminated or non-sterile prior to use and determine what changes may be required to storage arrangements to avoid this.
- Verify that any non-packaged semi-critical or non-critical items are stored in a way that prevents contamination prior to use.
- Assess environmental storage conditions and determine an appropriate shelf life for sterilised items.

Non-conforming RMDs

RMDs can fail to meet requirements at different parts of the reprocessing journey, because of both human error and equipment malfunction. Examples (not an exhaustive list) of non-conforming RMDs include the following:

Cleaning:

- RMDs that have visible soil or corrosion present after cleaning.
- RMDs that are non-functional (missing parts, broken edges, or blunt cutting edges).
- Broken RMDs due to incorrect handling during cleaning or during transport from the chairside to the reprocessing area (e.g. due to not following the correct procedures for the transportation of used RMDs, and not protecting RMDs from harm during transport and cleaning).

Packaging:

- Incorrect packaging – too few or too many layers.
- RMDs with handles packed away from the opening edge (i.e. not presented to allow aseptic presentation).
- Hinged RMDs reprocessed closed or ratcheted RMDs reprocessed closed.
- Too many RMDs placed in the one pouch.
- RMDs with sharp edges that have pierced through the packaging before or after sterilisation.
- SBS not sealed correctly.
- Lack of a suitable contents description for a package.
- Packaging is soiled with lubricants.

Sterilisation:

- Packages after sterilisation are wet, perforated, torn, or broken.
- Seals are not intact.
- Class1 chemical indicator on the package exterior has not made the appropriate colour change.
- Class 4–6 internal chemical indicators have not made the appropriate colour change.
- Sterilised package has been dropped on the floor or onto a dirty benchtop surface.
- RMDs sterilised using an inappropriate cycle.
- RMS sterilised using an incomplete cycle.
- Sterilising cycle parameters not met.

Storage:

- Sterilised packages in storage have been splashed with water, patient fluids, or other contaminants.
- Missing batch control label information.
- Defective batch control label where the information is not legible or able to be scanned.
- Compression resulting from large or heavy packages being stored directly on top of small packages.
- RMDs stored in less-than-ideal conditions, e.g. exposure to excessive heat or humidity.
- Packages that are past their shelf life, or expiry date, or have been stored in non-ideal conditions, and the packaging material has been degraded or damaged and the SBS is no longer intact.
- Packages that have been damaged because of the actions of insects and vermin.

Deterioration of paper-plastic pouches occurs more rapidly under high temperatures and under high levels of humidity. Likewise, paper-based packages that are old become brittle, and the contents can pierce through more easily. This is why sterile storage temperature and humidity conditions (and hours of operation of air-conditioning) affect the stated expiry time for packaged stock in a particular facility.

Further information on non-conforming RMDs, devices and packages is found in sections 2.6.2 and 2.6.3 of AS/NZS 5369:2023, and in Appendix A.2.6.2.

When a non-conforming package or RMD is found, an investigation is needed to identify the causes, in line with the local risk assessment policy, so that appropriate corrective action can be taken. This may need to include going beyond just removing the non-conforming RMD from regular use. A 'root cause analysis' (RCA) may need to be undertaken to identify human, system and equipment factors. Faulty equipment that is found must be removed from service until repaired or replaced.

Recall procedures

AS/NZS 5369:2023 (section 2.3.6.2) requires services to have policy/procedure to recall RMDs in the event of identification of a failure in the reprocessing process such as the release of non-conforming RMDs (breach). Breaches have the potential to pose an infection risk to patients. A breach can involve anything from a single packet of RMD/s to a complete steriliser load(s) of RMDs.

The level of risk, and therefore the required response, depends on:

- what the reprocessing failure/non-conformity is;
- the likelihood that affected RMDs may have been used on patients;
- the type(s) and numbers of RMDs involved;
- the procedure that affected RMDs were used in;
- whether the problem is ongoing.

Ideally, all conformance criteria should be checked for and identified before any RMD is released from the reprocessing area for use. However, some non-conforming issues may arise due to improper storage of reprocessed RMDs, or poor handling of RMDs, such as soiling or tearing of the SBS. Any actual or suspected breach must be assessed as soon as it has been identified to minimise risk to patients and allow for corrective actions to be initiated as soon as possible.

If the breach has been identified as a reprocessing failure and the load(s) have been released from the reprocessing area, a practice-wide recall of affected RMDs must occur. Washer-disinfector and steam steriliser cycle records form a key part of the recall process, and so must be accessible (readable) and of sufficient detail to allow identification of the RMDs needing to be recalled. Affected RMDs must be held back or quarantined, and not placed into service, while determining if all RMDs in a load have been recalled, or if unable to be located, have been used on patients. Where applicable, the practice will need to identify, using BCI records, any patients possibly impacted by the recall, and appropriate follow-up action taken.

An investigation into the cause of a reprocessing breach must then occur to identify the root causes of the incident (e.g. lack of training, not following correct procedures) and determine suitable corrective actions.

Only once the recall has concluded can the affected quarantined load be fully reprocessed before being returned to service.

Further detail regarding the RMD recall process can be found in separate ADA resources on this topic.

A final concern with recalls is the open disclosure requirements of the DBA Code of Conduct (June 2022), and the need to inform affected patients and in appropriate cases to also contact public health regulators. Staff should refer to the guidance provided in AS/NZS 5369:2023. ADA branches can provide support and advice to ADA members in such situations, to assist decision making. Note that if the recall involves RMD that were sterilised in another facility and supplied to the practice, the issues become more complex, and may involve the TGA. The TGA has a Uniform Recall Procedure for Therapeutic Goods (URPTG) that provides a consistent approach for undertaking recall and non-recall actions of therapeutic goods in Australia.

Root cause analysis

The purpose of root cause analysis is to: (1) identify the cause(s) of the incident (why did it occur?) – this will involve talking to people involved in the incident and reviewing any associated documentation, equipment, etc.; and (2) identify the preventive measures that address the cause(s) (what can be done to prevent a similar incident in the future). This could be changes to procedures, documentation, education of staff, equipment repairs, bringing in new equipment etc. When the incident is discussed, causes and preventive measures will be identified and the necessary changes can then be introduced to staff and reviewed for their effectiveness. Root cause analysis will often identify gaps in training, or in compliance with approved procedures or manufacturer instructions. It may also identify impacts arising from work related pressure and the adoption of suboptimal procedures to manage an insufficient inventory of RMDs.

Section E. Documentation and practice protocols for infection prevention and control (IPC)

This section summarises key aspects of record keeping with a focus on not just meeting minimum requirements but using the process of creating and updating those records to contribute to broader quality management and improved processes. In so doing, some information found in earlier sections will be repeated but with a different emphasis and context.

1. Maintaining records of RMD reprocessing

Dental practitioners must maintain records relating to reprocessing activities; these records must include the results of annual calibration, annual performance qualification using biological indicators (spore tests), and daily cycle data from air removal tests, as well as the records of individual steriliser cycles. The temperature measurement system used by the service engineer to calibrate the thermocouple sensors in a steam steriliser is expected to itself have been calibrated periodically against a relevant national or international standard. AS/NZS 5369:2023 states this requirement, and recommends that individuals performing such tests should meet the requirements of *AS ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories* as this is scalable to any organisation that performs testing, sampling or calibration and wants reliable results. A calibration report for a steam steriliser should show the certification number of the calibration device used for temperature measurement.

Maintenance of this portfolio of records provides evidence of quality management processes and supports BCI of critical RMDs. The length of time that documentation must be kept varies and depends on the state or territory where the practice is located, but typically it is a minimum of seven years. Steriliser cycle records must be readable over this period of time. This will be an issue if the printout from the steam steriliser uses thermal paper, as the printout fades with time and becomes unreadable. As discussed earlier, solutions include scanning or photocopying thermal printouts.

For every steam sterilising cycle (including those that do not have packs of critical RMDs), the recorded entry for the cycle in the steriliser log must include:

At the time of loading the chamber:

- the steam steriliser number or code (if there is more than one steriliser in the practice, to identify the machine the RMD was sterilised in);
- the date and time;
- the cycle or load number on that date;
- the contents of the load;
- which cycle parameters were used (time and temperature) – ensuring these are appropriate for the load type being processed – whether packaged or non-packaged;
- batch numbers of packs included in the load (if any); and
- identification of the loading operator.

At the time of unloading the chamber:

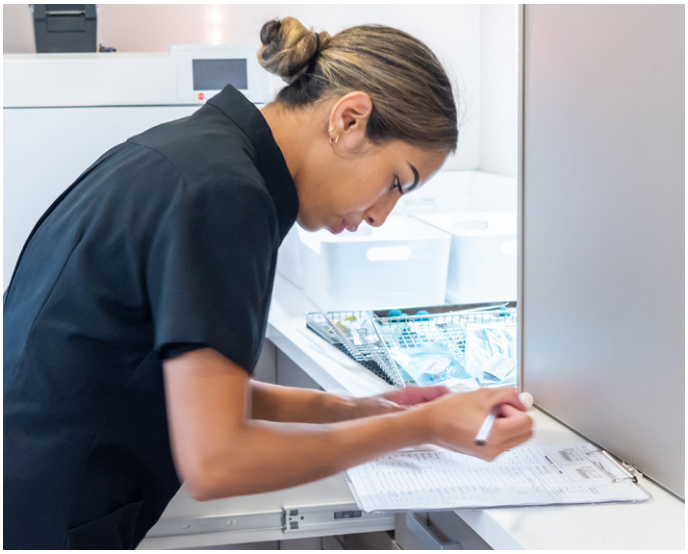
- check for the correct physical readout data (on the digital display or on the printout) for the cycle;
- check of the chemical indicators used in the cycle (this includes checking all external Class 1 chemical indicators as well as any visible internal chemical indicators);
- check of packages (if present) for the integrity of the seals and that packages are intact;
- check of packages for dampness and a lack of environmental contamination; and
- identification of the unloading operator.

After the last dot point has been completed, the unloading operator has now authorised release of the load for use in the operatory.

Other documentation for the steam steriliser

Following installation of a new steam steriliser, a certificate of calibration, installation qualification (IQ) and operational qualification (OQ) should be issued by the technician carrying out the process. This must be kept as part of the documentation for the dental practice.

It is also necessary to keep a record of servicing and repairs to the steriliser, as well as records of any upgrades to its hardware or software.



Key compliance items for documentation of sterilisation processes

- Ensure calibration and performance qualification for steam sterilisers are scheduled with a trained technician.
- Verify that installation and maintenance records as well as daily, weekly and annual test results are being maintained, as well as cycle records.

2. IPC for dental practitioners and clinical support staff

Immunisation

As discussed in the introduction, dental practitioners and clinical support staff are at risk of exposure to many common vaccine preventable diseases (VPDs) through contact with patients and the general community. Immunisations substantially reduce the potential for acquisition of disease, thereby limiting further transmission to other dental staff and patients.

The list of immunisations recommended for HCWs is provided in the current edition of the *Australian Immunisation Handbook* and is summarised below.

- A history of successful immunisation against HBV. This is shown by having developed antibodies to hepatitis B surface antigen in a blood test taken after the initial course of three injections.
- Varicella (if seronegative).
- Measles, mumps, and rubella (MMR) (if non-immune).
- Pertussis (whooping cough) – every 10 years.
- Viral influenza (required every year to cover new circulating strains of these viruses).

Note that there may be local jurisdictional requirements for COVID-19 immunisation for those working in certain environments, e.g. residential aged care facilities.

Those working with remote Indigenous communities should also undergo vaccination for hepatitis A, while those at increased risk of exposure to drug-resistant cases of tuberculosis (TB) should consider vaccination with bacille Calmette-Guérin (BCG), once their immune response to tuberculosis has been tested using an appropriate challenge test. As the efficacy of the BCG vaccination in adults is more limited compared to children, tuberculosis prevention and control strategies should focus on pre-employment screening and infection control measures, including treatment for latent tuberculosis.

All dental practitioners and clinical support staff require immunisation against HBV, unless they have documented evidence of pre-existing immunity (from natural infection or prior vaccination) prior to commencing work. Any staff who are new to dental practice must be assessed for their HBV status. It is essential that staff who are undergoing vaccination for HBV are tested for antibody levels after the full course of three injections has been completed. This will demonstrate immunity and identify poor responders who require additional vaccinations. The follow-up protocols for this are in the Australian Immunisation Handbook.

Dental practices should have education programs to support their immunisation strategy, and all dental staff must be advised of the potential consequences of non-immunisation. Consequences include an increased likelihood of acquiring infections in the workplace, increased probability of spreading infections to family members and close contacts, and restrictions on being able to work chairside when patients have active infections. While a staff member has the right to refuse vaccination, this refusal must be documented with their reason for refusal noted and signed by the employee.

Immunisation records

The practice must develop and maintain regularly updated immunisation status and allergy records for dental staff. It is recommended that dental staff also maintain their own personal immunisation and screening records.

Staff should be asked to declare their vaccination status for hepatitis B, influenza and other infections of relevance to the healthcare setting when commencing employment. This information needs to be updated when staff receive further vaccinations (e.g. for viral influenza) or when they receive booster injections. The rationale for asking for hepatitis B vaccination status is that past successful vaccination confers lifelong immunity, even if/when serum antibody levels wane, since there is lifelong immunological memory in lymphocytes, something not easily tested for using commercial tests.

It is highly recommended that when employing new staff, they are asked to complete a statement of their immunisation status and vaccination history. It is not appropriate to ask them for details of their immune status (i.e. actual levels of antibodies for all the listed conditions above); however, a statement from their medical GP regarding immunisation status can provide a practical way of determining immune status. Staff who are using the national health record system can produce of list of some vaccines by using the myGov database.

For further information on immunisation requirements, consult the current edition of the *Australian Immunisation Handbook*.

Key compliance items for immunisation

- Ensure all dental team members are aware of immunisation required for HCWs, and have an opportunity to declare and update their immunisation and allergy status regularly.

Education

Dental staff must be provided with comprehensive training in the full range of IPC procedures they are expected to know about and follow in their day-to-day work. Regular refresher training is also appropriate to ensure IPC measures are being complied with and understood.

New clinical dental staff should complete an induction program. This pre-service training should include the practical implementation of workplace health and safety and IPC measures used in the practice.

This induction program should contain the following:

- general orientation to the physical environment of the practice, including the clean and contaminated zones, as well as the flow of RMDs in the operatory and reprocessing room and the associated documentation and record keeping. (This should be followed by periodic assessments to confirm that staff are trained and competent to undertake reprocessing activities, at intervals defined by the practice's local policy);
- discussion of key topics for IPC, including modes of transmission of infection; infection control principles, including standard precautions and transmission-based precautions; hand hygiene training (including techniques); and the importance of removing jewellery, nail polish and artificial nails;
- work health and safety issues, including the use of PPE (e.g. protective gowns, eye protection, surgical masks and N95/P2 particulate filter respirators (PFR), closed footwear and gloves);
- practice expectations in terms of IPC and safe working procedures, as laid out in the practice's IPC Manual;
- practice policy on wearing and cleaning uniforms, shoes, and clothing;
- practice expectations and recommendations for vaccination prior to commencing work;
- reporting requirements for sharps injuries and workplace incidents;
- emergency procedures for fire and medical emergencies;
- first aid procedures;
- management of waste streams and hazardous substances, and the locations of containers for various types of waste;
- safe handling, use and storage of cleaning agents and disinfectants (including the use of PPE), and procedures for spills and exposure management;
- confidentiality of patient information;
- hand hygiene procedures;
- policies in terms of hair, footwear, and jewellery (such as 'bare below the elbows');
- surgical aseptic technique, including surgical hand hygiene, gowning and donning gloves;
- procedures for changeover between patients; and
- procedures for cleaning and sterilisation of RMDs.

To supplement and update the information provided during the initial induction, regular staff meetings should be held to discuss IPC matters. There should be a short summary record kept of these discussions. Likewise, staff attendance should be recorded for external (including online) infection prevention and control training. A summary of a formal induction/orientation and training program for new staff is provided in Appendix A.2.4.3. of AS/NZS 5369:2023

Key compliance items for education

- Review how members of the dental team are equipped with skills and knowledge in infection control topics, and what strategies are being used to maintain and document this.

3. Exposure incident protocol

In the healthcare environment, the term 'exposure incident' refers to any BBFE incident where a contaminated object or substance breaches the integrity of the skin or mucous membranes, or comes into contact with the eyes. This includes:

- penetrating injuries of the skin caused by a sharp item (e.g. a sharps injury caused by dental instruments, burs, needles, scaler tips, wires or scalpel blades);
- an injury involving direct skin contact with blood or saliva visibly contaminated with blood and where there is compromised skin integrity, such as a cut, open wound, abrasion or dermatitis;
- bites or scratches inflicted by patients; and
- direct contact between blood or body fluids and the mucous membrane of the mouth, nose or eyes.

While the site of a penetrating injury can become infected with microorganisms, the major concern to dental practitioners and

clinical support staff is the risk of transmission of HIV, HBV, and HCV by contaminated blood from a patient. For exposures involving the skin, the larger the area of skin exposed and the longer the time of contact, the more important it is to verify that all of the relevant skin area is intact.

To comply with work health and safety legislation, all exposure incidents must be recorded and followed up. The required post-injury counselling may be undertaken by a designated medical practitioner or infection control practitioner. Services such as sharps injury telephone hotlines may also be of value. Public health units will be able to provide assistance or arrange referral to emergency departments or medical GPs.

Injured staff must be encouraged to undergo follow-up tests after a contaminated sharps injury or other significant BBFE, and blood samples for serological testing for BBV status testing should be obtained from the source wherever practicable. The same principle applies if the patient is the injured party. These tests include HBV surface and envelope antigens, HCV antibody and HIV antibody (and in some cases, viral load). Where the source is positive, follow-up tests of the injured person will need to be repeated at intervals to assess whether seroconversion has occurred. Refer to the appendix for a detailed protocol. The source (e.g. patient) should be encouraged to undergo testing as this facilitates the management of the exposed person. This testing will need to be facilitated by the practice or by referrals from public health units, as noted above,

Post-exposure prophylaxis for HIV and guidance in the use of antiviral agents in the early management of HIV and hepatitis C infection may be available from public hospitals. The use of prophylactic antiviral agents is restricted according to a formal risk assessment that would normally be overseen by a specialist in infectious diseases.

For further information see Appendix: *Blood and Body Fluid Exposure Protocol.*

4. IPC manual and other practice management issues

Many obligations of dental practitioners are stated in the DBA Code of Conduct. Others arise under nationally harmonised work health and safety legislation, since this takes a risk reduction approach and applies a hierarchy of risk controls. Likewise, a similar approach has been taken in national health safety and quality standards (including primary care standards). This section focuses on aspects relevant to IPC.

Each practice owner has a duty to:

- facilitate the collection of a detailed medical history to establish if a patient may be more susceptible to infection, and therefore, may require special measures to prevent infection (e.g. patients on immunosuppressants, patients with poorly controlled diabetes mellitus, leukaemia or neutropenia or other conditions that impair host immune defences that may require antibiotic prophylaxis); and
- ensure adequate physical facilities are maintained and conduct regular quality checks to ensure all equipment is always in sound working order.

Employers and practice owners should:

- maintain awareness of new vaccine preventable diseases (such as new forms of viral influenza) and ensure dental staff at risk are encouraged to be fully immunised when these vaccines become available (including annual influenza immunisation);
- offer testing following occupational exposure such as a sharps injury;
- ensure dental staff are adequately informed of the rights and responsibilities of patients, especially those related to their right to refuse to provide information on their infection status or to be tested for a BBV;
- develop a comprehensive IPC manual for the practice, and keep this up to date;
- provide measures that protect staff from infections, including PPE and immunisation, and implement effective reporting systems for breaches of protocols and safe work practices;
- inform dental staff of the health screening policies of the practice at the time of their employment;
- inform employees of local work health and safety policies, including the use of PPE;
- allow patients to access the practice's IPC strategies and provide information about procedures for dealing with concerns about IPC procedures; and
- provide all dental staff with a specific program of education and training in IPC principles, policies, and procedures.

5. Infection control manual

Each practice must develop a comprehensive IPC manual that outlines pertinent information for the daily routines of the practice. It must describe the infection prevention and control procedures of the practice in sufficient detail such that it can be used as the foundation for training new staff who join the

practice. The ADA has developed a suitable IPC manual for ADA members that serves as a template and can be adapted to the specific requirements of an individual dental practice.

All staff in the practice must know who is responsible for ensuring certain activities are carried out and to whom they should report any accidents or incidents.

The content for this manual must include:

- methods of hand hygiene (both routine and surgical, where relevant);
- PPE requirements;
- setting up the treatment area between patients;
- environmental cleaning protocols;
- surface management, including barrier protection and cleaning between patients;
- the protocol to be followed after an exposure incident (BBFE), such as a sharps injury;
- handling and disposal of sharps;
- waste disposal;
- reprocessing of RMDs (e.g. cleaning, disinfection, packaging, sterilisation, storage);
- processing of radiographs in a manner that avoids cross-contamination;
- quality control mechanisms, including documentation for the maintenance and monitoring of equipment;
- immunisation requirements;
- use of single-use items;
- recording of information during patient treatment in a manner that avoids cross-contamination;
- use of computers and computer-run equipment during patient treatment in a way that avoids cross-contamination;
- management of waterlines used in direct patient contact; and
- handling allergies to latex and glove materials in dental patients and dental staff.

Practice IPC manuals must be regularly updated as new guidelines are produced by the DBA, the ADA or the NHMRC, new standards are released by the ACSQHC and Standards Australia, and when there are changes in jurisdictional regulations (public health directives, clinical waste management).

Key compliance items for infection control manual

- Ensure the practice IPC Manual is up to date and consistent with these Guidelines.
- Implement systems that facilitate ongoing review and compliance with the protocols documented in the infection control manual.

Section F. Special areas and their dental IPC requirements

Several aspects of dental care, or particular settings in which dental care is provided, present specific challenges in implementing effective IPC measures.

1. Dental radiology and photography

RMDs and materials placed in a patient's mouth and subsequently removed for processing must be considered biologically contaminated and must be handled in a safe manner. Gloves must be worn when taking radiographs and handling contaminated film packets or sensors. Other PPE (e.g. masks, protective eyewear) must also be used in case of spattering of blood or other body fluids. It is recommended that heat-tolerant or disposable intra-oral radiograph devices are used (unless using digital radiography) wherever possible. Semi-critical RMDs (e.g. film-holding and positioning devices) must be cleaned and either heat sterilised, or barrier protected before use on subsequent patients.

Exposed radiographs need to be transported and handled carefully to avoid contamination of the developing equipment. Following exposure of the radiograph, dry the film packet with a paper towel to remove blood or excess saliva before placing it in a container (such as a disposable cup) for transport to the developing area, where it will be decontaminated. Use protective barriers on developing equipment where possible. When these surfaces become contaminated, they must be cleaned.

When handling intra-oral radiography, methods to prevent contamination of equipment must be implemented; for example:

- remove gloves and perform hand hygiene (moment 3) to ensure clean hands are used to position the tube and operate the x-ray controls; or
- use gloved hands to position the tube and operate the controls, then clean all the contaminated surfaces of radiography equipment (e.g. x-ray tube head and control panel) at the end of the appointment; or
- use gloved hands but operate the x-ray controls through a barrier that is changed at the end of each appointment. These controls then need cleaning before the barrier is replaced.

Digital radiography sensors come into contact with mucous membranes and are considered semi-critical devices. They must be cleaned and then covered with a barrier before use on subsequent patients. Follow the instructions for use, in terms of appropriate products and methods to be used for this cleaning, to ensure that the sensor is not damaged. Perform hand hygiene and don clean gloves prior to touching sensors or intra-oral films.

Most state regulations accept radiographic film packets and barrier envelopes contaminated with saliva or blood for disposal as general waste. However, some jurisdictions require these to be treated as contaminated medical waste – this means they must be placed in yellow containers or plastic bags appropriately marked with the international biohazard symbol and collected and disposed of by a licensed waste contractor.

For dental photographic mirrors, contrasters and retractors, it is important to refer to the manufacturer's IFU when reprocessing. Photographic mirrors vary in their substrate materials (stainless steel, glass etc.) and in their reflective coatings (e.g. rhodium, silver, chrome-cobalt alloy). Incorrect cleaning procedures will damage these coatings. Manufacturers give specific advice regarding suitability for manual cleaning and/or ultrasonic cleaning and/or cleaning in a washer-disinfector, e.g. some stainless-steel mirrors with chrome-cobalt alloy coatings can be cleaned using a washer-disinfector. If able to use an ultrasonic cleaner, it is essential to prevent the mirror from touching any other product or a metal cassette tray as this could damage the surface coating. Some manufacturers warn against the use of paper towels for drying afterwards because of the risk of damaging the surface coating. At the end of cleaning, it is important to make sure no drops of water remain on the mirrors before they are packaged, otherwise mineral spots can form. For packaging, again follow the manufacturer's instructions, as some mirror manufacturers recommend placing each mirror in a separate pouch while others discuss using gauze to separate them or wrapping mirrors in microfibre cloth or a lint-free surgical towel to protect the surface and separate it from the plastic of the pouch.

2. Specialised intra-oral equipment and devices

Specialised intra-oral equipment and devices include:

- handle and tip of the curing light used for photo-polymerisation of dental materials;
- intra-oral scanners used for digital impressions and CAD/CAM;
- keyboards, mice, touchpads and other computer peripherals associated with CAD/CAM systems and other electronic devices;
- air abrasion units;
- intra-oral cameras and image capture devices;
- lasers;
- apex locators;
- electronic periodontal probes;
- occlusal analysers; and
- electrosurgery units.

Several factors need to be considered when determining whether a barrier is needed (or not) on a piece of dental equipment.

The first point relates to the responsibilities of importers/suppliers, who must comply with the legislation covering the sale of these items of equipment. These responsibilities include providing accurate, evidence-based advice on reprocessing, as per the Essential Principles under the Therapeutic Goods (Medical Devices) Regulations 2002 (Commonwealth) adopted by the TGA. These reprocessing considerations form a central part of the directions for use, as will any advice to clinicians regarding the Spaulding classification. Generally, if the item is considered critical (contacts sterile tissue or the blood stream) – then sterilise using steam or low temperature hydrogen peroxide gas plasma sterilisation. If the item is semi-critical (makes contact with mucous membranes or non-intact skin) – sterilise, or if not compatible, then high-level instrument disinfection. If the item is non-critical (contacts intact skin) – then cleaning or low-level instrument disinfection. In other words, the importer/sponsor will already have addressed this topic with the TGA during the registration of the device.

The need for any one dental practitioner to determine if a barrier is needed, or whether the RMD can be cleaned, disinfected, or sterilised, should be small, since all TGA-approved specialised devices used in clinical practice are required to come with instructions from the manufacturer on how to ensure appropriate control of cross-infection. Some devices will have parts that can be steam sterilised and other parts that need to be covered (e.g. sheaths for intra-oral cameras and digital imaging sensors). If the manufacturer recommends and supplies a dedicated barrier that covers the parts of the device that may come into contact with saliva, then failure of that barrier during operation is unlikely to occur.

When a manufacturer or supplier is unable to provide suitable advice regarding routine reprocessing and maintenance of an RMD, a complaint should be made directly with the TGA as the regulator, via the TGA website (www.tga.gov.au then search 'medical devices' and then 'lodge a complaint').

A range of options exist for surface management of specialised devices such as intra-oral cameras used in patient examination and intra-oral scanners used to record digital impressions. A common approach used for intra-oral cameras and scanners which cannot tolerate heat sterilisation is protection with a single-use barrier (such as a disposable sheath); this is important due to their exposure to saliva and potentially blood. Options such as steam sterilisation, thermal disinfection or cleaning with detergent followed by immersion disinfection are likely to damage the specialised optical and electronic components. Follow the instructions for use as to the appropriate barrier and/or cleaning/sterilisation procedures required for these devices. Some devices can be sterilised using hydrogen peroxide gas plasma sterilisation, which does not use heat.

Likewise, follow the instructions for use for how to manage equipment with touch panels. Some lasers and surgical motor controllers have touch panels for operation, for which there are adhesive stick-on covers that completely cover the panel. These covers are pulled off and discarded. The touch panels need to be cleaned after barrier removal, unless the manufacturer's IFU state not to do this.

In summary, if the manufacturer states that a barrier is required, use a barrier (typically the manufacturer would also supply or specify the type of barrier). If the manufacturer states that the item is to be sterilised, then sterilise the item – do not simply cover it with a barrier. An important example is piezoelectric ultrasonic scalers, many of which are designed to be sterilised. If this is the case, it will be specified in the manufacturer's IFU. Likewise, many modern dental chairs have membrane switches designed to be cleaned by wiping using specified products – in this case, use the specified products for cleaning the area and do not use a barrier.

The second aspect relates to the responsibility of registered dental practitioners to follow the manufacturer's instructions (as per the TGA approval process described above).

Most modern equipment has been designed to be cleaned, with minimal use of barriers. For example, on most modern dental chairs, the suction tubing is very smooth (rather than ribbed) and has been designed for wiping. Follow the instructions for use regarding how such surfaces are to be managed.

Older dental equipment may need barriers when the surfaces to be protected are very hard to clean (e.g. because of their complex shape) or where appropriate instructions from the manufacturer are lacking. Apply the principles articulated in these *ADA IPC Guidelines* for any situation not covered by instructions from the manufacturer. This will be an uncommon situation. Professional judgement will be needed. Consider the situation at hand with the device and decide whether the suggested barrier will be adequate and will not introduce additional risks. If a staff member devises an improvised barrier using cling (polyethylene) film, aluminium foil, or a sandwich bag, the result is dependent on this device; in some cases, this may work, but in other cases, its integrity may be compromised because of poor fit or limited adaptation.

When replacing barriers, remove the contaminated barrier while gloves are still on, then check the surface for any visible contamination. Wipe the item before replacing the barrier (unless wiping is contraindicated by the manufacturer's instructions for the item). At the end of the day, surfaces that were covered with barriers during patient treatment should be cleaned by wiping.

Curing light

Curing light tips are considered semi-critical items. Steam sterilisation of the tips causes the optical performance to degrade. Barrier protection is an appropriate level of IPC for all curing light tips. This barrier will also prevent adhesive materials from contaminating the end of the curing light tip. The handle of the curing light and the tips must always be cleaned prior to placing new barriers. A new barrier must be used for each patient.

Air abrasion, electrosurgery units, and lasers

High-volume suction devices are essential when using electrosurgery units, dental lasers, and air abrasion/particle beam or powder jet devices as these create bio-aerosol hazards. Air abrasion devices used in restorative dentistry create alumina dust, which can be a respiratory irritant for dental practitioners, clinical support staff and patients. Powder jet devices used to remove stains from teeth and to clean the surfaces of dental implants use powders such as sodium bicarbonate, calcium carbonate, glycine or trehalose in a water spray. While such powders are not considered to pose significant occupational risk, all powder jet devices generate large amounts of splattered fluid and aerosols. Having high-velocity evacuation located close to the tip of the unit is essential.

Some pathogenic viruses such as human papillomavirus (HPV) are not inactivated by laser or electrosurgery procedures and remain viable within the plume (smoke) created from vaporisation of soft tissue lesions such as intra-oral warts or dysplastic oral mucosa. When undertaking a procedure on HPV lesions that generates surgical plume, a PFR N95/P2 respirator must be worn to prevent exposure to the contaminants present in surgical plume. Surgical masks are not considered adequate PPE in relation to fine aerosols present in surgical plume that contains HPV.

Aside from HPV, other viruses and bacteria are rendered non-viable by laser or electrosurgery, even though fragments may be present in the plume. Blood-borne viral diseases such as HIV or HBV are not transmitted through the inhalation of aerosols or plume. Correct placement of high-volume suction and the use of high-filtration surgical masks can prevent inhalation of particles. These will remove gases (e.g. hydrogen cyanide, benzene, and formaldehyde) that are irritant and noxious. Evacuation systems which remove plume must always be employed when using electrosurgery units or surgical dental lasers.

3. Implants

For surgical procedures involving placement of implants, both RMDs and the implants must be sterile at the time of use. Surgical aseptic technique must be employed. Explanted devices and components must not be reprocessed and reused in the same or other patients. All items in an implant kit marked as single use are to be discarded at the end of the appointment.

4. Impressions

To remove contamination from impressions, thoroughly rinse them with cold running water to remove saliva and traces of blood. Then apply a diluted detergent. This can be done by immersion in a solution of detergent or by spraying the diluted detergent onto the impression (e.g. in a plastic bag). The detergent will have a surfactant action which assists in removing the remaining microorganisms from the impression. Thorough rinsing is then undertaken to remove the detergent. This second rinsing step must continue until all visible contamination is removed. Once this is completed, the impression is deemed to be decontaminated.

A range of commercial products have been developed for the treatment of impressions. If using these rather than a plain detergent, follow the instructions for use exactly, and pay particular attention to shelf life and dilution ratios.

Where a risk assessment indicates that additional treatment may be needed (e.g. a patient known or suspected to be colonised with multi-resistant organisms such as MRSA), additional chemical treatments may be undertaken. A common protocol for additional treatment is immersion in a weak (0.5%) sodium hypochlorite solution for 3 to 15 minutes, as this does not cause deterioration of the impression material. Note that higher concentrations or longer exposure times will degrade the quality of the impression and the resulting cast. Other commercial solutions designed for impression disinfection can also be used, as per the instructions for use.

Once decontaminated, impressions can be scanned or can be used to pour up study models. If sent to an external (off-site) laboratory, impressions need to be packaged correctly and labelled as having been decontaminated.

5. Dental laboratory and dental prosthetics

Single-use dental laboratory and dental prosthetic items should be used where appropriate. Do not attempt to reuse single-use impression trays. Metal reusable trays must be cleaned to be free of all residues of impression material as part of their reprocessing.

Use standard precautions when taking impressions or when inserting dentures or appliances, and when performing any intra-oral adjustments.

All materials transported to and from dental laboratories must first be cleaned and then placed in a sealed bag or container. Check with local authorities about whether items need additional processing other than decontamination (as described in the previous section) prior to transport or posting as some regions specify disinfection plus cleaning.

Never touch saliva-contaminated items with ungloved hands.

Keep bulk supplies of impression materials and prosthetic supplies (such as wax) away from potential contamination from dust, splashes of water, or patient fluids.

Employ safe working practices in the dental laboratory to prevent environmental contamination of items used in laboratory work. Perform hand hygiene before working with clean items such as articulators and surveyors. Never place contaminated casts onto these.

Before inserting dental prostheses, or intra-oral or extra-oral appliances, clean them thoroughly to remove any environmental contamination.

Reprocess semi-critical RMDs used in dental prosthetics that come into contact with saliva, using one of the following three methods. These are ranked from most preferred to least preferred:

1. Clean them with an ultrasonic cleaner to remove soil and organic material, and then sterilise them. This would normally be done in a steam steriliser, but could be undertaken using HPGPS sterilisation for heat-sensitive items that cannot withstand steam sterilisation or thermal disinfection.
2. Use a WD that has a thermal disinfection cycle, for both cleaning and thermal disinfection.
3. Clean the item (e.g. with an ultrasonic cleaner) and then use a high-level (instrument-level) disinfectant. After being thoroughly cleaned, the item is then immersed into a TGA-approved high-level (instrument-level) disinfectant, such as OPA, exactly as stated in the instructions for use. These agents can be used to disinfect surgical guides for implant surgery. After disinfection, RMDs must be rinsed thoroughly to remove all traces of disinfectant. BCI (tracking) is required for terminally disinfected (i.e. not sterilised) RMDs, as per AS/NZS 5369:2023 section 2.5.3.2 and Table 9.1.

Non-critical RMDs (i.e. those that come into contact with intact skin, but not saliva) can be cleaned using detergent.

Areas for laboratory work (such as areas for pouring up models or grinding models) must be well separated from patient treatment areas and from the reprocessing area. Ideally, there should be physically separate areas for patient treatment, laboratory work, and reprocessing of RMDs. When these areas are in the same room, patients cannot be treated at the same time as undertaking laboratory work or reprocessing RMDs.

When polishing appliances or prostheses that have been worn in the mouth, or when repairing or relining appliances, prevent contamination of the polishing lathe by dispensing single-use pumice, and then clean the pumice tray after each use.

6. Handpiece management

All dental handpieces must be cleaned and lubricated in accordance with the instructions for use and must be sterilised after each patient. Similarly, ultrasonic scaler tips must be sterilised between patients. The handpiece of piezoelectric scalers must be sterilised between patients if specified by the manufacturer (not just covered with a barrier or wiped down after use).

Burs must be removed from restorative handpieces and the exterior surfaces of the handpiece must then be cleaned thoroughly using a detergent-based product before reprocessing it. Never clean or immerse the handpiece in disinfectant solutions or in the ultrasonic cleaner. Never fully immerse dental handpieces or ultrasonic scaler handpieces in water at any stage when they are being reprocessed. Note that few brands of restorative dental handpieces are compatible with WDs, so do not use these unless so instructed by the manufacturer.

For restorative handpieces and surgical handpieces, follow the manufacturer's instructions for approved methods of lubrication of the internal aspects. This is normally done prior to steam sterilising. Two common approaches are as follows:

1. There are dedicated systems that perform automatic lubrication of dental handpieces. These use low viscosity lubricants and achieve better lubrication than manual methods using pressure packs (spray cans). They also reduce concerns from excess oils being released during the sterilisation cycle or during use in the operatory. They achieve greater consistency in outcomes than pressure pack units. Thus, it is strongly recommended that these dedicated systems are used.
2. If performing manual lubrication using a pressure pack (spray can) unit, care must be taken to ensure that excess lubricant is completely drained from handpieces prior to sterilisation, otherwise the excess lubricant on packages compromises the sterilisation process. To enable the complete removal of lubricant from handpieces, either run the handpiece briefly or allow the handpiece to completely drain while sitting vertically prior to packaging and undertaking the sterilisation process. If draining the handpiece, allow it to sit vertically until no further lubricant is visible. If using a steam steriliser that condenses the steam and reuses water for later cycles, it is essential to prevent the accumulation of residues of lubricants, as these cause deterioration of the quality of steam and lead to superheating. When this happens, the steam is unable to condense onto the surfaces of RMDs. For such sterilisers, completely replace the deionised water every week, after draining out the water reservoir and flushing it with deionised water.

For steam sterilisation of restorative dental handpieces, there are two options:

1. Use an S cycle steriliser that has proven performance (validated claims) for steam sterilising dental handpieces and is approved for that purpose by the TGA. Note that there are very few such units on the market. When using such a unit, ensure the load configuration of the dental handpieces is exactly as specified by the steriliser manufacturer.
2. Use a B cycle steriliser with vacuum cycles for air removal.

It is not acceptable to use an N cycle steriliser, since air removal from hollow areas of the handpiece is insufficient.

Surgical handpieces must be packaged and then steam sterilised using a B cycle steriliser with vacuum phases.

Following sterilisation, handpieces used for restorative dentistry must be stored in such a way that they are not contaminated by splashes or aerosols. They should not be fitted to the dental unit until required for use on a patient. Once fitted to the dental unit, they are deemed to have been exposed to contamination during treatment, and thus they must be reprocessed at the end of the appointment, even if not used on the patient.

For further information on handpiece management see the chapter on this topic in the ADA's *Infection Control Practical Guide.*

7. Specimens

Place biopsy specimens into an appropriate leak-proof specimen container labelled with the patient's name, and then place this in a zip lock bag labelled with the biohazard symbol. The outer bag reduces the chance of leakage during transport, should the specimen container leak. Gloves must be worn when handling pathology specimens and specimen containers. If the biopsy specimen container is visibly contaminated, transfer it to another container, or clean and disinfect the outside of the container before placing it into the transport bag.

8. Endodontic irrigants

Practitioners should ensure that any sodium hypochlorite products used in the root canal as endodontic irrigants are approved by the TGA for the particular clinical use. Approved products for endodontics differ from domestic products in many ways (chemical composition, pH, tissue dissolving capabilities, and antimicrobial effectiveness).

Domestic sodium hypochlorite products, approved by the TGA for low-level disinfection (sanitising), may be used to decontaminate gutta percha points, plastic-enveloped radiographic films or dental impressions undertaken on the bench. Domestic sodium hypochlorite products cannot be used for irrigation of root canals during endodontic treatment.

The status of a product can be checked with the supplier. Labels also disclose registration on the ARTG.

9. Gutta percha points

Immediately prior to use, gutta percha points can be disinfected on the bench by one-minute immersion in a sodium hypochlorite solution with a concentration between 1.0 and 5.25%. This could be either a domestic sodium hypochlorite product approved for sanitising purposes or an approved sodium hypochlorite endodontic irrigation solution.

10. Hand-operated endodontic files

All hand endodontic (root canal) files used in root canal treatment (regardless of their metallurgical composition) are single-use items. They are to be disposed of into a sharps container at the end of the appointment. Reprocessing hand files is not practicable as manual or mechanical cleaning is ineffective and unsafe, and likely to result in a sharps injury. Rotary (engine-driven) stainless-steel files cannot be reprocessed and must be discarded after use. There are no verified protocols for cleaning these items, using any method.

For hand pluggers and other hand-operated endodontic instruments, check the manufacturer's instructions. Typically, these are labelled as single-use items and must be disposed of after use.

11. Rotary nickel-titanium (NiTi) endodontic files

Rotary NiTi files may be used once and then discarded. If they are to be reused, they must be reprocessed using the specific protocol below. This could allow for reuse of rotary NiTi files up to three times. However, it is important to check the labelling and the manufacturer's instructions for NiTi files. Those marked as single use cannot be processed.

If a dental practice intends to reuse rotary NiTi files, they must be cleaned using a verified protocol that combines a specific enzymatic agent with ultrasonic cleaning.

The following protocol has been shown to be effective for all types of rotary NiTi endodontic files. It relies on both mechanical removal of gross debris by plunging the file into a sponge, followed by enzymatic breakdown of dentine residues during a soaking step, and then ultrasonic cleaning in the same enzymatic agent. The protocol comprises the following steps:

- immediately after use, remove stoppers and insert the files into a scouring sponge soaked with chlorhexidine gluconate aqueous solution (e.g. 0.2%);
- clean the files by applying 10 vigorous in-and-out strokes in the sponge;
- place the files in a wire mesh basket and immerse it in a suitable enzymatic cleaning solution (i.e. Empower™) for 30 minutes;
- follow this with 15 minutes of ultrasonic cleaning in the enzymatic cleaning solution;
- drain and rinse in running water for 20 seconds;
- perform packaging and steam sterilisation.

12. Relative analgesia equipment

Reusable relative analgesia masks must be cleaned and sterilised. Manual cleaning of masks and the hoses in the circuit can be performed, or preferably, cleaning can be done using a WD. All sterilisable components can then be processed in a steam steriliser at 134 °C.

Disposable single-use relative analgesia masks and a circuit are available, and may be more cost effective than reprocessing these items through a WD.

13. Visits to residential aged care

There are many dental patients whose dental treatment must be provided in residential aged care, and occasionally bedridden patients need dental care in a private home, nursing home or hospital. The facilities are often inadequate and can make it difficult to provide treatment. In these settings, standard precautions as a minimum should be followed when providing dental care, including wearing gloves and other protective clothing, and rigorous hand hygiene practices.

Hand hygiene is essential when caring for the older person as the persons are more susceptible to colonisation or infection. Hand hygiene with ABHR is preferable in private homes as hand washing facilities may not be readily accessible. Clinicians must also consider that hand washing facilities in a private home may not be well equipped and the use of ABHR might be the best option available.

Standard precautions should be always used for patient/resident contact and dental staff/ HCWs should perform hand hygiene before and after patient contact and as per the 5 moments.

Certain viral pathogens such as noroviruses can spread rapidly in aged care facilities via the hands of staff when hand hygiene practices are suboptimal. Hence, dental staff need to be vigilant about hand hygiene when working in aged care facilities.

Transmission-based precautions may also be required during patient care if the patient/resident is known or suspected to be colonised or infected with an MRO or other infectious condition such as norovirus, influenza or *Clostridioides difficile. (Clostridium difficile* is also known as *Clostridioides difficile*.)

Dental practitioners and clinical support staff may need to carry all necessary PPE to the site. During transport, all RMDs and materials must be carried in clean lidded metal or rigid plastic containers to prevent damage or spillage. Such containers must be labelled clearly (e.g. clean or contaminated) as appropriate. After use, RMDs must be placed in a labelled rigid sealed container for transport back to the dental practice for reprocessing. Where possible, RMDs should be cleaned immediately after use with detergent and water. If this is not possible, they should be sprayed with a suitable instrument cleaner to prevent hardening of debris before transportation back to the dental practice.

Use of disposable instruments may be cost effective when working outside the practice in settings such as domiciliary care. These are to be disposed of into an approved sharps container.

After on-site decontamination, items such as impressions, try-ins and articulators must be transported in sealed plastic containers.

Waste should be separated at the point of generation. General waste should be disposed of in the general waste stream of the nursing/private home or hospital. Sharps and medical waste must be dealt with according to jurisdictional regulations. A designated sharps container, as described in AS/NZS 3816:2018 Management of clinical and related wastes, must be used for sharps waste. This can be transported with other instruments and equipment.

Special areas and their dental IPC requirements

- Consider which areas of the clinic may pose unique challenges and how you will manage these items/areas.
- Review instruction manuals published by the manufacturer for items that pose infection control challenges and include any key information in the practice infection control manual.

Section G. Infectious diseases, and transmission-based precautions for IPC

In some circumstances, patients have a specific, highly infectious condition that necessitates the use of transmission-based precautions in addition to standard precautions to address the increased risk of transmission. The agents of most concern to dental practice are respiratory viruses. It is important that clinicians do not treat suspected or confirmed acute cases of contagious respiratory disease when dental care can be appropriately deferred.

Where risks are identified, systems should be in place to manage patients appropriately. This may include appointing a suitable person (e.g. a senior clinician) to assess whether treatment should be deferred or if it is appropriate to provide treatment, and if so, what additional patient management and infection control processes may be required. Consideration should be given as to how to manage patients who may be poor historians and/or may not have the capacity to answer screening or risk assessment questions accurately.

Assessment and management of risk remains a key responsibility of dental practitioners. One of the key principles underpinning risk management is recognition that some strategies will be more effective than others in controlling risk. This is known as the hierarchy of risk controls. Wherever possible, a risk should be identified and eliminated. If it is not possible to eliminate the risk, the likelihood and consequences should be analysed, evaluated and managed by applying appropriate controls.

Details of the diseases and specific precautions are given in the NHMRC 2019 AICG (*Australian Guidelines for the Prevention and Control of Infection in Healthcare*), which cover conditions such as viral influenza, tuberculosis, and chickenpox (varicella), in Appendix 2 Table A2.5. Precautions for specific infections and conditions are in Table 6.4, which shows the type and duration of precautions for specific infections and conditions.

These diseases are readily transmitted in a dental practice environment. In each case, the transmission-based precautions depend on the route(s) of transmission of the infectious agent, and may include measures to prevent airborne, droplet or contact transmission.

Contact precautions are intended to prevent the transmission of infectious agents through direct and indirect contact with people, equipment and environmental surfaces. They are important in containing multi-drug resistant organisms (MROs) in hospital environments, in the management of outbreaks of norovirus gastroenteritis in institutions such as hospitals and nursing homes, and for limiting spread of *Clostridium difficile* or other pathogens that are not effectively contained by standard precautions.

Droplet precautions are intended to prevent transmission of infectious agents, such as influenza and coronaviruses, through respiratory or mucous membrane contact with respiratory secretions. These microorganisms do not travel over long distances in droplet form due to their size (larger than 5 microns).

Airborne precautions, which include the use of surgical PFRs, are designed to reduce the likelihood of transmission of microorganisms that remain infectious over time and distance which remain suspended in the air for longer periods of time due to their small size (less than 5 microns). These agents may be inhaled by susceptible individuals who have not had face-to-face contact with (or been in the same room as) the infectious individual. Infectious agents for which airborne precautions are indicated include measles, chickenpox (varicella), and *Mycobacterium tuberculosis*, as well as novel respiratory pathogens such as H5N1 influenza, avian influenza, SARS-CoV-2 (the virus responsible for COVID-19) and certain other coronavirus infections.

Most procedures undertaken in dentistry generate aerosols (AGPs). Some items of equipment are more likely to generate intense aerosols, such as ultrasonic scalers and high-speed air turbine handpieces. Therefore, it is important to recognise that patients with viral influenza, active tuberculosis, measles, or chickenpox pose a considerable risk to dental staff and to other patients if they undergo dental treatment. For patients for whom airborne precautions are indicated, a formal risk assessment should be undertaken to determine the need for dental treatment. Non-urgent treatment should be delayed or postponed.

Although surgical masks do not protect the wearer from transmission of infections via the airborne route, surgical masks that conform to AS 4381:2015 and are fluid-impervious protect the wearer from droplet contamination of the nasal or oral mucosa. A surgical mask that is sealed tightly to the face has been shown to block entry of 95% of total influenza virus particles.

When there is an increased risk of airborne transmission due to the infectious agent or procedure, scientific principles and evidence supports the use of PFR to prevent transmission (NHMRC, 2019, p. 114). Fit testing and fit checking are essential for wearing PFRs .

Patients on droplet or airborne precautions, whose treatment is unable to be postponed, must be asked to wear a surgical mask when moving from one area to another (NHMRC, p. 99).

1. Measles, mumps and tuberculosis

Infection by airborne infected respiratory secretions or aerosolisation of infected droplets produced during dental procedures can occur with pathogens that cause diseases such as tuberculosis.

Tuberculosis is spread by droplets, or by direct contact.

Tuberculosis has been transmitted as a result of dental procedures. Patients with these diseases should have their dental treatment deferred until they are no longer infectious and have reached the end of any mandatory quarantine period.

2. Human viral influenza

As with the above-mentioned illnesses, patients who are currently unwell with influenza should have their dental treatment deferred until they are no longer infectious, 72 hours after commencing antiviral medications or five days after onset of symptoms, though this may be longer for young children or the immunocompromised (NHMRC 2019, p. 239), or until symptoms have resolved.

A dental practice considering treating these patients should do so only after having conducted a written risk assessment. Most patients for whom contact and droplet transmission-based precautions for influenza are required would normally be quarantined to their home or too ill to consider any treatment other than relief of a severe dental infection. Pain can be reduced through the appropriate use of analgesics until the patient is no longer infectious and has reached the end of any mandatory quarantine period.

Where treatment cannot be deferred (e.g. facial swelling), transmission-based precautions must be used for provision of dental treatment. These are described below.

- Schedule the patient to be seen as the last patient of the day.
- Patients on droplet or airborne precautions must be asked to wear a surgical mask when moving from one area to another (NHMRC 2019, p. 99).
- Ensure staff working in the treatment room have been immunised against the current strains of influenza in circulation.
- Have the patient use a suitable antimicrobial pre-procedure mouth rinse (e.g. chlorhexidine gluconate, essential oil mouth rinse, hydrogen peroxide, povidone iodine or ozonated water).
- Wear high-filtration surgical masks that are adapted well to the face, for the duration of the appointment. PFR of the P2 (N95) type should be worn if aerosol-generating procedures will be undertaken. Staff wearing these should have been trained properly in how to wear these respirators, with proper fit checking before use.
- Consider the use of barriers for high-risk items (optional).
- For restorative dentistry, use a dental dam and high-velocity evacuation to reduce the formation of aerosols. For other procedures, use techniques that minimise the production of splashes of fluids and generation of aerosols.
- At the end of the appointment, the operatory should undergo cleaning, with all surfaces cleaned with a detergent solution, combined with or followed by a hospital-grade disinfectant. This process can be undertaken by a 2-step clean (physically cleaning with a detergent, followed by physically cleaning with a disinfectant), or a 2-in-1 clean (physically cleaning with a combined detergent/disinfection wipe or solution)

3. Human coronavirus infections caused by SARS-CoV-2 (COVID-19)

Examples of approaches that dental practitioners can follow to mitigate COVID-19 transmission risks are as follows:

- **Screening** (elimination): Use signage at the facility entrance asking patients not to enter if they are unwell or have COVID-19 symptoms. Screen all patients, workers, and visitors for clinical and epidemiological risk factors for COVID-19. Note that case definitions may change from time to time, and are available from the CDNA Series of National Guidelines (SoNGs). Do not treat suspected or confirmed COVID-19 patients when care can be appropriately deferred. Consider the management of patients with urgent needs, or where deferring care is likely to lead to adverse health outcomes (such as uncontrolled bleeding, infection, or trauma).
- **Preparation of facilities** (engineering controls): Implement patient 'check in' and deliver key messages such as respiratory hygiene; Remove high-touch items such as toys and magazines from communal areas; Provide facilities for hand hygiene (such as alcohol-based hand rub) and respiratory hygiene (such as tissues).

Use appropriate measures to remind patients of the need for hand hygiene, cough etiquette and physical distancing. Household members who are normally in close contact can be permitted to sit together, and patients may also be given the option to wait in their vehicle if practical. If a patient requires a support person, this person should also be screened. Minimise the number of people in the facility by encouraging only one support person to attend to assist with social distancing and reduce the overall risk that a person with COVID-19 will enter the facility. Identify and clean frequently high-touch surfaces, using detergent and disinfectant for all patient surrounds and high-touch surfaces.

Review and optimise air flow, ventilation and air quality (including consideration of availability of negative pressure facilities in the catchment area; otherwise avoid positive air flow). There is some evidence to support and recommend the use of negatively pressurised rooms for patients who are at risk of transmitting infectious organisms via the airborne route. This means that patient care under airborne precautions is often not possible in a private small office practice setting (unless special modifications have been made to the air-conditioning plant and approved by an appropriately trained engineer).

Use mouth rinses before dental treatment to reduce the viral load in saliva (hydrogen peroxide, essential oils, cetylpyridinium chloride, povidone iodine, chlorhexidine or freshly ozonated water).

All patient surrounds and frequently touched objects are to be cleaned with a TGA-registered Hospital Grade Disinfectant using either a 2-step clean, which involves a physical clean using detergent solution followed by use of a chemical disinfectant; OR a 2-in-1 clean in which a combined detergent/disinfectant wipe or solution is used and mechanical/manual cleaning action is involved. Follow the manufacturer's instructions for correct use of the product(s).

- **Planning, protocols and procedures** (administrative controls):
  - maintain a current risk management plan in response to COVID-19 that takes into consideration any state-based/local guidance;
  - implement vaccination policies for healthcare workers consistent with legal requirements in each jurisdiction;
  - implement physical distancing requirements;
  - ensure staff training on IPC and implementation of relevant guidelines;
  - adopt protocols that reduce viral load and saliva being aerosolised by use of protocols such as pre-procedural mouth rinse, dental dams and high-volume evacuation (suction);
  - consider appropriate 'fallow times' if COVID-19 suspect or confirmed patients are being treated in the facility.
- **PPE:** Adopt PPE protocols consistent with current guidance for healthcare workers, including airborne precautions (including appropriate PPE:
  - disposable single-use long-sleeved fluid-resistant gown;
  - PFR P2/N95 respirator;
  - face shield or a visor mask for procedures with high risk of splash) when patients with suspected or confirmed COVID-19 are being treated in the facility;
  - have enough PPE supplies available based on the risk-based infection control precautions required for patients receiving care in the facility;
  - ensure that PPE is appropriately used (e.g. team training on selection, donning, doffing, fit testing, fit checking)

  For effective airborne precautions, a PFR P2 (N95) surgical respirator is required, which forms an airtight seal with the face. To be effective, these respirators must be fit tested at regular intervals, and then fit checked at the time of each use. HCWs with facial hair must be aware that this prevents the formation of an airtight seal between the respirator and the facial skin. PFR P2 (N95) surgical respirators are designed to reduce the likelihood of transmission of aerosol particles containing SARS-CoV-2 virus that remain suspended in the air for longer periods of time due to their small size (less than 5 microns).

Defer or transfer care if appropriate PPE is not available. If unable to source PFR P2/N95 respirators for moderate risk patients (with no AGP) consider possible alternative use of level 2 or 3 surgical mask plus full-face shield or visor, e.g. when assessing only.

Dental team members using a PFR P2/N95 respirator should be trained in their correct use. Fit testing is recommended as the gold-standard to ensure that the PFR is appropriate for the person wearing it. As a minimum, a well-fitting PFR that has been fit checked to ensure that there is an airtight protective seal at the time of each use should be adopted. If a suitable PFR cannot be found, or if facial hair impedes an adequate seal, an alternative respirator (e.g. powered air-purifying respirator) should be considered.

When it is determined that a patient is known or suspected to have COVID-19, the risk of transmission should ideally be eliminated by deferring treatment. If care cannot be safely deferred, the practice will need to determine if they have the appropriate facilities, protocols, PPE and IPC measures to provide care. Patients with COVID-19 typically cannot have elective dental care until five days after their symptoms of cough and fever have resolved. Certain jurisdictions may prescribe specific periods. There will be few situations encountered where the dental emergency is such that analgesics and other conservative measures will not allow a temporary delay in dental treatment, until the patient is no longer infectious.

4. Avian influenza viruses

H5N1 and H7N9 are forms of avian influenza that are highly pathogenic and contagious. Normally, they only infect birds and occasionally pigs. Both have much higher mortality than human influenza strains that do not have avian components. To date, there is limited evidence for person-to-person transmission. Nevertheless, practitioners should be aware of the importance of respiratory illnesses that develop in patients who have recently returned from regions where such conditions occur, particularly within the timeframe of 10 days of onset of illness. Patients with suspected avian influenza should not undergo any elective dental treatment. Urgent dental treatment requires both contact and droplet precautions, as described above.

Some novel respiratory pathogens require airborne precautions. These precautions cannot usually be implemented fully in private practice small office settings. Unless airborne precautions can be comprehensively implemented, it is unsuitable for infected patients needing urgent dental care to be seen in such settings. When such pathogens cause pandemics, public health authorities may dictate limits on what healthcare facilities may see such patients.

5. *Staphylococcus aureus* and methicillin-resistant *Staphylococcus aureus* (MRSA)

Antimicrobial resistance (AMR) poses a serious risk to health care. Multi-resistant organisms (MRO) can include bacteria, fungi and viruses. These have developed resistance to multiple antimicrobial agents (such as antibiotics, antifungals and antiviral agents). One of the most important ones for dental practice is methicillin-resistant *Staphylococcus aureus* (MRSA). This bacterium is resistant to common antibiotics and, as a result, infections caused by this organism are difficult to treat. MRSA colonises the nose, axillae and perineum, as well as abnormal skin (such as wounds, ulcers and eczematous skin). Normally it is not found in the oral cavity, but occasionally it may be isolated from oral infections, including those associated with dentures.

Anyone can become infected with a MRSA infection, but people have an increased risk of getting a MRSA infection when they:

- have other chronic health conditions, including diabetes, dermatitis, chronic wounds or weakened immune systems;
- have been treated with antibiotics, and have been in a healthcare facility or a nursing home;
- regularly have medical equipment entering their body, such as catheters and feeding tubes;
- spend time in crowded living conditions or in environments where frequent direct physical (skin to skin) contact may occur.

In office-based dental practice, transmission of MRSA is relatively unlikely as vulnerable patients will recently have had major procedures in a hospital or other large institution and are unlikely to be ambulant or seeking dental care during the immediate post-operative phase.

Patients in long-term care facilities are another group of patients vulnerable to MRSA; however, for most office-based dental practices this group does not form a large proportion of patients.

When treating patients colonised with MRSA, it would be prudent to use a disinfectant on impressions and on dentures or appliances being sent for repair, and minimise contamination of surfaces during treatment of the patient. At the end of the appointment the operatory should undergo cleaning, with all surfaces cleaned with a detergent solution, combined with or followed by a hospital-grade disinfectant. This process can be undertaken by a 2-step clean (physically cleaning with a detergent, followed by physically cleaning with a disinfectant), or a 2-in-1 clean (physically cleaning with a combined detergent/disinfection wipe or solution).

HCW known to be colonised with MRSA must check hospital policy prior to participating in procedures in that hospital. They should seek medical advice and undergo treatment to ensure they do not cause contamination of the operatory. MRSA carriers are likely to have MRSA on the facial skin, and in particular, the peri-oral skin. Organisms may be distributed by air coming from the nose, and particularly by nose blowing. Effective hand hygiene is the most important measure to prevent and control the spread of MRSA.

6. Prion diseases, including Creutzfeldt-Jakob disease (CJD)

For all patients with potential Creutzfeldt-Jakob disease (CJD) infection, RMDs used during routine dental procedures (including endodontics) that come into contact with oral mucosa, gingiva, dental pulp and other oral tissues can be routinely reprocessed, with no special measures needed, because oral tissues have low or zero infectivity due to the absence of prions. Prions are not found in saliva. Any patients with suspected or confirmed prion diseases can undergo normal dental treatment, including dentoalveolar surgery, without additional measures. This applies to those with classical or iatrogenic CJD as well as other prion diseases such as fatal familial insomnia (FFI).

While no special precautions are needed for routine dentistry, maxillofacial surgery involving the central nervous system and the cranial vault needs additional measures, as prions are found in the central nervous system. Details of this are given in the CJD Infection Control Guidelines.

The most recent version of these is from 2022; however, further updates are likely in the future. For further information regarding CJD, refer to the Creutzfeldt-Jakob disease – Infection control guidelines.

Variant CJD (vCJD) is excluded from the scope of this document, as vCJD has not been reported in Australia to date.

Key compliance items for transmission-based precautions

- Review how conditions that warrant transmission-based precautions are screened, how treatment for these patients can be delayed, and what protocols are used when treatment cannot be delayed.
- Determine the circumstances in which referral is warranted due to facility/equipment limitations or risk assessments.

Section H: Allergies and sensitivities

1. Allergies to chlorhexidine

Practitioners using chlorhexidine mouth rinses, hand washes or irrigants should be aware of the potential risks of allergic responses. The chlorhexidine molecular structure has two identical epitopes and can cross-link IgE antibodies on the surface of mast cells and basophils, causing them to degranulate. This leads to histamine release and the possibility of anaphylaxis in sensitised individuals.

Increased usage of chlorhexidine by consumers and HCWs has resulted in a number of adverse reactions including contact dermatitis, anaphylaxis and septic shock, although anaphylactic reactions to chlorhexidine are rare (NHMRC 2019, p. 189). There have been over 60 reports of anaphylaxis to chlorhexidine in the literature since 1983, with the majority involving systemic exposure, such as through contact with broken skin and open wounds (including in the oral cavity).

The greatest risk situation is when chlorhexidine gains access to the systemic circulation. This concern underpins advice that chlorhexidine rinses, irrigants or gels should not be applied onto bleeding sites (e.g. subgingival irrigation during periodontal debridement or by irrigation into extraction sites).

The NHMRC *Australian Guidelines for the Prevention and Control of Infection in Healthcare* (2019) discuss emerging issues with allergy and resistance to chlorhexidine and recommend that its use be limited to clearly defined applications that are evidence based, so that it is not used injudiciously.

2. Latex sensitivity

Suspected natural latex allergy (NLA) in dental practitioners, clinical support staff or patients must be treated as a serious medical issue. Symptoms may manifest as delayed hypersensitivity such as rash, conjunctivitis or rhinitis (Type 4), which could then progress with time to an acute allergic anaphylactic reaction (Type 1), which may result in death.

All patient medical histories and new dental staff employment forms must include questions about NLA and/or sensitivity or allergy to latex/rubber products.

Patients, dental practitioners or clinical support staff with proven anaphylactic reactions to latex may need to wear a medical alert bracelet and carry self-injectable adrenaline.

If latex sensitivity is identified, then a 'latex-free' environment should be created for the persons affected. This involves the use of latex-free gloves and removal of identifiable latex products likely to cause a reaction from the operatory. Such items include latex gloves, latex prophylaxis cups, latex dental dams, rubber bite blocks and latex rubber alginate mixing bowls. Non-latex versions of these items are available.

Further information on latex allergies can be found on the ADA's website.

Section I. Sustainability

Sustainability of IPC measures

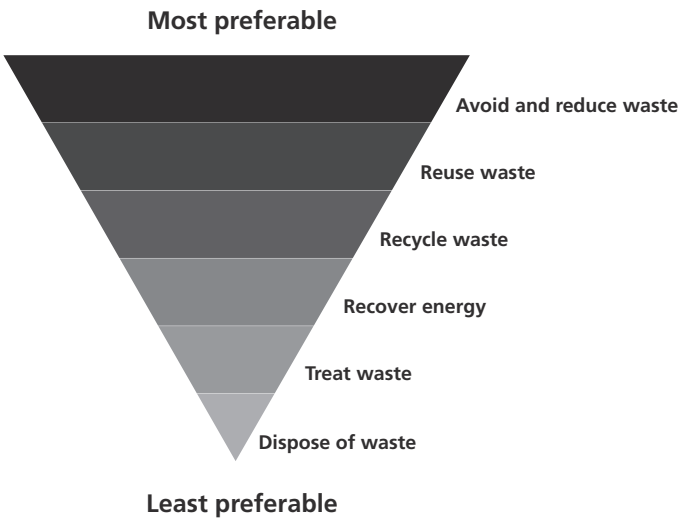
Patient and staff safety is always first and foremost in decision making around IPC in practice. However, sustainability of the approaches being used should also inform the protocols, materials and supplies adopted. These considerations are covered in greater detail in other ADA resources, but are summarised below.

The primary sustainability considerations in IPC are as follows.

Reduce

Manufacturing and distributing IPC resources requires input of raw materials and energy and often results in the release of pollutants to air, land and water. More than 90% of the environmental impact of most products occurs in their manufacture and distribution stages, i.e. before a package is ever opened. Avoiding the purchase and use of items in the first place will achieve the greatest environmental (and financial) savings. A firm understanding of IPC practices and effective work systems allows practices to reduce their overall waste. For example, inappropriate use of full-length disposable polypropylene gowns, and use of unnecessary plastic barriers, would ideally be avoided altogether by understanding the specific circumstances in which these should be used.

Minimisation of clinical waste is particularly important as this is typically incinerated in most jurisdictions. The Waste Avoidance and Resource Recovery Act 2001 (Commonwealth) underpins the National Waste Policy, which provides a framework for waste and resource recovery in Australia. The waste hierarchy is based on the National Waste policy. Checking with your local and state government requirements to ensure only necessary items reach the clinical waste, and all possible items are diverted from general waste, will reduce the overall environmental impact.



Plastic barriers

Shared equipment that is easily cleaned can be wiped between uses. Time between patients must permit appropriate management. As discussed earlier, barriers should only be considered for complex equipment that is difficult to clean and is touched and handled with gloved hands and soiled with body fluids, where it is specified by the manufacturer.

Chemical waste

Many commercially available products contain chemicals that are not necessary for achieving the cleaning or disinfecting outcomes required. It is unlikely that practices will require a complex array of commercially available products for cleaning various parts of the practice. Minimising cleaning product inventory to only a few well-researched, effective products is likely to reduce the chemical waste produced by your practice. Before purchasing any chemical for cleaning, consider what are the necessary features of the product (for example, a neutral detergent) and what products contain these necessary elements while minimising unnecessary chemicals. Consider the areas of the practice in which the product can be safely and effectively used and what other products can be eliminated by using just this product. Always check the safety data sheets of chemicals purchased for your practice. If the chemicals are hazardous to the environment, ensure you follow the instructions for proper disposal.

Improved documentation (paper-free)

Consider your ability to create and complete task monitoring sheets (cleaning, testing, stocking drawers etc.) electronically. This will eliminate the use of paper, the need to scan to store, or space to physically store critical documentation. Some steriliser and washer-disinfector manufacturers now have software programs that allow staff to document all elements required for loading, processing and releasing loads. Generated at the time of processing, secure electronic documentation has many benefits, such as ease of retention, retrieval and auditing.

Reuse

Many dental products are available in both disposable (single use) and reusable forms, such as sharps containers, hand hygiene dispensers, impression trays, suction tips and triplex tips. This means a decision must be made about whether to adopt a single-use or reusable alternative. First and foremost, consider whether these can be reused safely in accordance with the manufacturer's instructions. Some items simply cannot be

reprocessed effectively, so are recommended for single use only (such as hand files used for endodontics). If an item can be reused or reprocessed safely, the potential environmental effects of reuse should then be considered. For instance, consider how much water, power and packaging will be required to reprocess the item, and store it safely until it will be reused. It is likely that as technology improves, so too will the range of single-use items with biodegradability, to simplify this choice. In the interim, the full life cycle of single use versus reusable alternatives must be considered when determining the best way to minimise adverse environmental effects.

Recycle

Dental practices generate a large amount of paper waste and some of this comes from IPC practices. However, just as for office-based waste, some elements may be recyclable. Consider, for example, the paper backing from sterilisation packs used commonly in sterilisation processes. These can usually be readily separated from plastic components and disposed of in recycled waste. Many local government areas will have waste consultation services that will enable the dental team to learn what items may be recycled in your local area. Consider the IPC items that you frequently discard (such as sterilisation pouches, bottles for hand hygiene products, paper towels etc.) to facilitate guidance to team members on what items should be recycled in your local area to minimise landfill. In addition to local waste management, you may also want to consider commercially available recycling options.

Stock control

Procurement (obtaining goods and services) has been estimated to account for approximately 20% of the total greenhouse gas emissions of dental services. IPC supplies are usually predictable as they are used regularly and average usage can be established for items required per patient, per procedure or per chair. This allows calculation of amounts of supplies likely to be used within a set period to optimise ordering. Many IPC supplies such as gloves and sterilisation packs have long expiry periods, so can be ordered in bulk once needs are calculated (for example, monthly or quarterly) to reduce the need for multiple orders with associated packaging and transportation impacts. The ADA provides stocktake templates that can assist in setting and checking required levels of IPC items to ensure that supplies are readily available when needed, and stock control is efficient.

Storage

It is important if storing RMDs that the manufacturer's storage requirements for the item are followed. Some items require special conditions such as temperature or humidity control, so only ordering items that you can safely store will avoid unnecessary waste if the RMD cannot be used due to deterioration in storage.

Life cycle assessment (LCA) and research

There are continual improvements in the environmentally friendly credentials of items used for IPC. To determine the benefits of new and emerging options, it is often desirable to consider a life cycle analysis. This process considers what resources were used in the processing and manufacturing and distribution of an item, how it is used, and how it is managed at the end of its life. The requirements for a formal LCA are detailed in ISO 13030:2006 *Environmental management – Life cycle assessment – Principles and framework.* A formal LCA is a substantial undertaking and is usually performed by the manufacturer. If this is not available, a smaller scale LCA can be performed; there are several software tools available to assist with this (such as OpenLCA, openLCA Nexus). Periodically re-assessing the products and strategies used in practice is likely to yield ongoing benefits for sustainability. The ADA will continue to keep members informed as options emerge.

Appendix: Blood and body fluid exposure (BBFE) protocol

A blood and body fluid exposure (BBFE) involves exposure to blood or other human material. This can occur through needle stick injuries, cuts with sharp objects, or contact of mucous membranes or non-intact skin with blood, tissues or other bodily fluids that are potentially infectious.

First aid

- Stop work immediately, regardless of the situation (e.g. even if administering local anaesthetic or undertaking a surgical procedure).
- Allow the wound to bleed and clean it thoroughly with a soap and lukewarm water wash. There is no benefit in squeezing the wound. Do not apply disinfectants as some are irritants and retard healing.
- Flush mucous membranes/conjunctiva with normal saline or water. If contact lenses are worn, remove after flushing eye and clean as usual.
- Further management of the wound is dependent on the nature of the injury.

Risk assessment

For an exposure to HIV, an assessment of the risk of transmission is of urgent priority to determine whether post-exposure prophylaxis (PEP) for HIV is necessary. Expert medical advice from an S-100 prescriber or an infectious disease specialist is required to determine the need and type of HIV PEP for the exposed person and the necessity, or otherwise, of testing the patient's blood after appropriate pre-testing counselling. Both the risk assessment and baseline tests need to be undertaken as a matter of priority, so that valid baseline results are obtained and PEP can be given within 72 hours of the injury occurring if needed.

Each dental practice should have a clear set of written instructions on the appropriate action to be taken in the event of a sharps injury to either staff or patients. These instructions should include emergency contact numbers for expert advice (including the name of a medical practitioner experienced in dealing with such cases). These instructions must be easily accessible and understood, and all staff must follow them.

A full record of the incident must be made, including details of:

- who was injured;
- how the incident occurred;
- type of exposure;
- presence of visible blood on the device causing the injury;
- whether a solid sharp object, hollow bore object or needle was involved;
- gauge of the needle;
- time the injury occurred;
- what action was taken;
- who was informed and when; and
- details of the patient being treated.

Factors influencing whether a BBFE has the potential to transmit a BBV infection include:

- type of exposure (mucosal splash vs. a deeply penetrating skin injury);
- type of body substance (e.g. how much blood is present in the saliva);
- volume of blood or body fluids;
- whether the source patient is viremic (e.g. known to be living with or receiving treatment for a BBV, and current viral loads);
- the length of time that has elapsed since the exposure (as post-exposure prophylaxis for HIV needs to be instituted within 72 hours of the sharps injury);
- in the case of HBV, immunity against HBV.

In addition, to complete an accurate assessment after a sharps injury, the following factors should be considered:

- type of device involved;
- procedure for which the device was used (e.g. into a vein or artery);
- whether the injury was through a glove or clothing;
- whether a deep injury occurred in the exposed person; and
- whether the source patient is viraemic (e.g. with advanced/terminal HIV disease or a high viral load).

Finally, the record of all these details should be signed by those involved in the incident.

Testing

Testing should be offered following all occupational exposure to blood or body substances, particularly all 'contaminated' sharps injuries (e.g. those involving exposure to blood or blood-contaminated saliva via an instrument, bur or contaminated wire).

A key element is that dental practitioners should never be the ones requesting BBV serology for themselves; this should always be done by an independent medical practitioner. There are several reasons for this. (1) The DBA Code of Conduct states that practitioners are expected to attend a general medical practitioner to meet health needs, and to seek expert, independent, objective advice when a practitioner needs healthcare, taking on board the many risks that come from self-diagnosis. (2) The person ordering the serology must be able to provide counselling in terms of the outcomes from that serology (both positive and negative results) for all the tests ordered, i.e. HIV, hepatitis B and hepatitis C). Few general dentists have the training and expertise to do this, however, some specialists in oral medicine or in special needs dentistry will because of advanced training in managing patients with BBV.

The risks of a 'DIY' approach are that (a) incorrect serology is requested, (b) risk assessment is incorrect, resulting in incorrect follow-up and review of BBV status, and (c) the untrained practitioner is not competent at having to relay a positive BBV status result, and has a potential/perceived conflict of interest in doing do. The importance of being able to accurately, effectively and empathetically inform an individual of a positive BBV result cannot be overstated. This requires training, and the support of a network of clinicians to be able to refer the person to after their result is known. (3) For proper workflow, when a dental staff member or patient sustains a sharps injury where the source is a known HIV+ person, urgent assessment by a suitable medical practitioner (such as an on-call infectious disease registrar at an acute hospital) is needed so that antiviral prophylaxis can be delivered within a 72-hour period, if this is required.

Baseline tests

Baseline serum is requested from the injured staff member AND the patient (where the source is known). The injured staff member should be tested soon after the injury to establish their serological status at the time of the exposure for:

- HIV antibody;
- HCV antibody; and
- antibody to hepatitis B surface antigen (anti-HBs).

This testing should be completed as soon as possible after the injury (ideally the same day, and definitely within 24 hours), bearing in mind the window period of the tests.

If the source patient is found to be positive for a BBV, it is recommended that additional testing and assessment of the injured person be conducted by an infectious disease physician.

If the injured staff member has ever had a blood test that demonstrates HBV immunity (anti-HBs antibodies) – whether from vaccination or past infection – they are protected, and there is no need for hepatitis B immunoglobulin after a potential or confirmed exposure to HBV.

Testing the source patient

When a situation arises where there is a need to know the infectious status of a patient (such as a sharps injury), the patient has a right to choose if they wish to provide information or consent for testing. Explaining to the patient how this knowledge can assist in the management of the injured staff member may assist in gaining the patient's co-operation.

Informed and voluntary consent must be obtained before taking a blood sample to test for any purpose. When the responsible medical practitioner is obtaining consent, the patient should be offered pre-test counselling to provide details of the test procedure and the long- and short-term consequences of the test results for the patient.

Post-test counselling may also be required, particularly if the result is positive.

The source individual should be tested for:

- HIV antibody;
- HBsAg; and
- HCV antibody.

If the source individual tests positive for either of the hepatitis B or C markers, additional tests would usually be ordered to assess infectivity (e.g. hepatitis B 'e' antigen, HBV DNA, and HCV RNA – the latter two by polymerase chain reaction assay).

Refusal of testing

If the source patient refuses testing, this refusal should be documented. In this case, treat the situation the same as the 'positive patient' scenario, and consider whether post-exposure prophylaxis and appropriate long-term follow-up should be offered.

Source negative

Generally, no further follow-up of the exposed staff member is necessary if blood tests show the source patient is negative for HIV, HBV and HCV, unless there is reason to suspect the source patient:

- is seroconverting to one of these viruses; or
- was at high risk of blood-borne viral infection at the time of the exposure (because they have recently engaged in behaviours associated with a risk of transmission of these viruses).

The window period causes a FALSE NEGATIVE test result. The patient may be infectious, but this is undetectable by testing. Usually, the window period for HIV is up to three months but it can, very rarely, be longer. The use of polymerase chain reaction (PCR) testing for HIV/viral RNA can identify 90% of infections within four weeks, significantly reducing this window period. The window period is six months for HBV and HCV.

Source positive for hepatitis B

The level of antibodies is important if the source is KNOWN or SHOWN to be positive for HBsAg. If the staff member is immune to HBV (based on their anti-HBs antibodies), then they are protected. If antibody levels are low, a booster injection may be prudent.

If the staff member is NOT IMMUNE to hepatitis B, e.g. has never been immunised, did not seroconvert to the vaccine (a non-responder) or has antibody levels to HBsAg less than 10 mIU/mL (10 IU/L), the correct treatment is to:

1. Give a single dose of hepatitis B immunoglobulin (HBIG) within 48–72 hours

   AND

2. Start a course of HBV immunisation. HBV vaccine should be given within seven days of exposure, and then repeated at one to two months, and then again at six months after the first dose. Following the final vaccine dose, the level of immunity (antibodies to surface antigen) should be checked two to four weeks later.

If this HBV prophylaxis is not undertaken, the risk of transmission of HBV is more than 30% if the source is hepatitis B 'e' antigen positive.

Source positive for hepatitis C

There is no effective post-exposure prophylaxis (PEP) for HCV. The risk of transmission after a sharps injury from a positive source varies according to whether active viral replication is occurring. Viral load for HCV is assessed using the polymerase chain reaction (PCR) assay. If the source is HCV RNA positive by PCR assay, the chance of transmission of the hepatitis C virus (HCV) ranges from 0–7%, with an average of approximately 3%. When the source is PCR negative, their viral load is undetectable and they will not transmit the infection.

If the source is positive, the injured staff member should be re-tested for HCV antibodies at three and six months, in addition to their baseline test. In addition, regular liver function tests such as alanine aminotransferase (ALT) and aspartate aminotransferase (AST) (e.g. at two, three, and six months) can be undertaken, and possible clinical signs and symptoms monitored by an infectious disease physician or gastroenterologist; specific antiviral therapy should be implemented under specialist guidance.

Source positive for HIV

If the source is KNOWN or SHOWN to be positive for antibodies to HIV (or is at high risk of seroconverting), the assessment of the injured person needs to account for the risk of seroconversion as follows:

- After a sharps injury with HIV-infected blood: 0.3%.
- After a mucous membrane exposure to HIV-infected blood: 0.09%.

Only a very small proportion of occupational exposures to HIV result in transmission of the virus. The side-effects and toxicity of HIV PEP must be carefully considered against its efficacy. PEP is only indicated if there has been a significant exposure and a proper risk assessment has been undertaken by a medical practitioner experienced in HIV management.

HIV PEP is typically several orally administered antiretroviral drugs and should be administered to the recipient within 24–36 hours after exposure.

Testing for the injured person

Follow-up blood tests for the injured person should be undertaken at one, three and six months, and follow-up should be undertaken to detect any febrile illness occurring within three months of exposure (possibly representing an HIV seroconversion illness).

Frequently Asked Questions

Q: What is the difference between alcohol-based hand rub (ABHR) for regular hand hygiene versus ABHR for surgical hand hygiene?

A: ABHR for surgical hand preparation uses both a different product and different technique, which is typically much longer in duration than regular hand hygiene using ABHR. To determine whether ABHR is intended for surgical hand hygiene or regular hand hygiene, you can search for the product using the Australian Register of Therapeutic Goods search function:

Q: How do I know if a device needs to have a barrier placed on it?

A: Review the manufacturer's IFU for the item being used. If the manufacturer recommends that a barrier is used, this should be followed.

Q: Is it mandatory to use a washer-disinfector to reprocess regular dental instruments (rather than an ultrasonic cleaner or manual cleaning)?

A: Mechanical cleaning of instruments (RMDs) can be carried out in washer-disinfectors or by using ultrasonic cleaners. Mechanical cleaning is preferred to manual cleaning as it is more efficient and reduces the risk of exposure to blood, and the risk of penetrating skin injuries from sharp or pointed instruments. The use of washer-disinfectors is not mandatory unless using RMDs that are expressly required to undergo an instrument washing and thermal disinfection process. However, washer-disinfectors are more efficient at pre-sterilisation cleaning than both ultrasonic cleaners and manual cleaning.

Mechanical cleaners used in dental practices may be washer-disinfectors (which also provide thermal disinfection), ultrasonic cleaners or combination units which perform both. Not all instruments are suited to thermal disinfection or ultrasonic cleaners, so careful attention should be paid to the manufacturer's instructions to determine the appropriate management of RMDs

Q: Is checking the steriliser printout enough evidence for determining the success of the process of sterilisation?

A: Checking the steriliser printout is just one step in the process of checking that a load of RMDs has been effectively sterilised. The steriliser printout (or digital record) is a physical indicator that cycle parameters have been reached. This is used in combination with chemical indicators to show that certain temperatures, times and steam exposure conditions have been reached during the sterilising process.

Provided that the cycle selected is appropriate for the load contents and the parameters have been met (as shown by the results of the physical and chemical indicators), after inspection to ensure pack integrity, packaged sterilised RMDs can be released for use in the operatory. This release must be recorded and signed off by the person performing the task.

Q: What records do I have to keep for a steam steriliser?

A: The manufacturer will determine the appropriate tests that need to be carried out for a steam steriliser and the results of these tests should always be maintained.

The most common type of steam steriliser used in dentistry is a pre-vacuum steriliser which runs B cycles. A range of tests must be carried out and the result recorded.

A summary of the records required for this type of steam steriliser is provided below. See the section on Records for a full list of all the various records that are relevant to reprocessing.

What to record / maintain	When to record
Certificate of calibration and operational qualification	When a new steam steriliser is installed (provided by the technician).
Record of servicing and repairs to the sterilisers and any upgrades to hardware or software	When servicing, repairs or upgrades occur.
Results of annual calibration	Annually (provided by the technician).
Results of performance qualification using biological indicators (spore tests); Results of physical performance (PPQ) and microbiological performance qualification (MPQ)	Annually (provided by the technician) or when new packaging materials are being used, and when new RMDs are introduced and assessed to exceed the complexity of the load previously validated.
Results of vacuum leak rate tests	Daily for machines without automatic air leak detection, weekly if using a steriliser with automatic air leak detection (see manufacturer's instructions).
Results of air removal and steam penetration tests (hollow device or porous device test for small pre-vacuum sterilisers, and Bowie-Dick type test for large pre-vacuum sterilisers).	Daily test for all pre-vacuum sterilisers.
Results of batch monitoring PCD test	This is an OPTIONAL daily test done for each cycle, is based on a local risk assessment, and beyond the minimum requirements.

Results of individual steriliser cycles: • the steam steriliser number or code (if there is more than one steriliser in the practice, in order to identify the machine the RMD was sterilised in) • the date (and time) • the cycle or load number on that date • a list of the contents of the load • which cycle parameters were used (time and temperature) – ensuring these are appropriate for the load type being processed – whether packaged or not • batch numbers of packs included in the load (if any) • identification of the loading operator	Before each load is processed
• correct physical data has been checked (include printouts or data log) • chemical indicator results for external and internal indicators • integrity of packages (if present) – intact seals and no perforations • check that packages are not damp or wet • identification of unloading operator	After each load

It is important to maintain physical steam steriliser printouts in a way that ensures their long-term legibility by scanning, photographing, or photocopying these items, as steriliser printouts can fade or become damaged over time

Q: Do I have to store chemical indicator strips as part of record keeping?

A: No. Chemical indicators are susceptible to changes during storage and therefore there is no need to keep these as part of record keeping

Q: When do I use a spore test (biological indicator)?

A: A biological indicator (spore test) is part of an annual microbiological report to confirm functioning of the steriliser, typically provided by a trained technician. These tests may also be used when there is a change to the packaging material being used. Additionally, these may be used in each load as an indicator when physical data for the steriliser cannot be accessed (such as a temporary malfunction of a steriliser printer).

Q: What infection control documents should be available in the practice?

A: Each dental practice should make the following resources available to staff:

- NHMRC Australian Guidelines for the Prevention and Control of Infection in Healthcare (AICG) – available online
- ADA's IPC Guidelines
- IPC Manual for your practice
- CDNA 2019 Guidelines for BBV – available online
- National Hand Hygiene Initiative – available online.

It is also recommended to have available AS/NZS 5369:2023 *Reprocessing of reusable medical devices and other devices in health and non-health related facilities.*

Q: What are the essential records that I am required to keep to satisfy the Infection Prevention and Control requirements?

A: In addition to records relating to reprocessing equipment use and maintenance outlined above, the following records should be maintained:

- **Personnel-related:**
  - Induction and training processes (including staff meetings) being used to update infection control knowledge and skills, and employee training records including competency assessments.
  - Vaccination and allergy status for each staff member, and staff immune status declarations (reviewed annually).
  - Incident reports, e.g. non-conforming products or workplace health and safety incidents; workplace injuries and incidents (such as breaches in infection control protocols and how these are managed).
- **Equipment-related:**
  - Performance tests and maintenance records for washer-disinfectors, ultrasonic cleaners, and sterilisers; and records for the validation of sterilisers (IQ, OQ and PQ), including certification of validation issued by a service engineer.
  - Records of performance tests done to verify proper operation of heat sealers, and any self-seal pouches that are used (e.g. proper sealing of test samples by heat sealers).

- Records of servicing any other items of reprocessing equipment.

- **Documentation of procedures:**
  - Instructions for use and operating manuals.
  - Loading diagrams for sterilisers and washer-disinfectors.
  - Quality and procedure manuals, which cover the cleaning, inspection and assembly steps prior to packaging and sterilisation of RMDs.
  - Procedure manuals for cleaning of the operatory (patient treatment area) and the reprocessing area.
  - Procedures to follow at the beginning and end of the day; and special procedures for closing the practice down for longer breaks when equipment such as the dental chair will need to be placed into hibernation status.
  - Procedures to recall failed or missed loads of RMDs, such as lookbacks and investigations around non-conforming sterilised RMDs.
- **BCI records:**
  - Batch control identification (in patient records) when critical RMDs are used.
  - BCI and RMD details for semi-critical RMDs released from high-level disinfection.
- **Extra-mural interactions of the practice:**
  - Records for purchasing RMDs and single-use sterile consumables.
  - Records of any outsourcing of reprocessing activities off-site.
  - Records of any loaned sterilisers or loaned sets of RMDs (for loaned sterilisers: the dates for transfer in and out; whether full validation was undertaken for the loaned unit and the details for that validation; whether internal chemical indicators in packages were introduced for RMDs sterilised in the loaned steam steriliser; for loaned instrument sets, whether these were cleaned, packaged and processed on site or not).
- **Risk management:**
  - Any IPC risk assessments or audits undertaken and the results of these.
  - Records from internal audits, and the following corrective actions that were implemented to rectify deficiencies. These actions need to be reviewed to check that they have been effective in addressing the deficiencies that were identified.
  - Business continuity plans in the event of major events affecting IPC (such as steriliser failure).

See the section on records in the Guidelines for a full list of the types of records that must be kept.

Q: What daily steam steriliser (autoclave) tests am I required to do?

A: Always consult the manufacturer's instructions. In general, if using the most common type of steriliser (a small pre-vacuum steriliser which runs B cycles), you will need to run, as a minimum:

1) Vacuum leak rate test.
   This is normally performed daily (weekly in the case of sterilisers that have air detectors).
2) Air removal and steam penetration test.
   This is run each day immediately after the vacuum leak rate test and before processing any RMDs.

For small steam sterilisers (chamber capacity below 60 litres), use either a hollow device or porous device test that conforms to ISO 11140.6:2022, type based on the steriliser manufacturer's instructions for use or, if not specified in the IFU, by the type of RMDs that are sterilised.

For large steam sterilisers (chamber capacity above 60 litres), use a Bowie-Dick type test. For large steam sterilisers, also consider using a hollow PCD when indicated by a local risk assessment, e.g. when restorative handpieces or other hollow items are being sterilised regularly.

Q: Do I need to wear a gown over my uniform/scrubs for routine dental procedures?

A: It is important to distinguish a uniform worn throughout a dental practice compared with PPE. They are not the same. The key concept is that clothing (whether it be a gown, clinic coat or scrubs) worn in contaminated areas of the practice and during procedures that create aerosols, sprays and splatter, should not be worn outside of this area into a clean environment. Solutions to avoid contamination of clean areas may include:

- Wearing a gown or clinic coat over scrub uniforms or street clothes.

  Changing out of scrubs worn in contaminated areas prior to leaving contaminated areas.

It is up to each practice to ensure that PPE is worn and removed in a way that avoids contamination of clean areas.

Q: Is it acceptable to wear over-gloves to retrieve items from a clean area instead of removing gloves and performing hand hygiene?

A: It is not acceptable to wear over-gloves to retrieve items from a clean area as this poses a high risk of inadvertent contamination of clean areas and items. Removing gloves (doffing) and performing hand hygiene prior to retrieving items from clean areas is expected.

Q: Is it acceptable for dental practitioners and dental assistants who perform clinical procedures to have any type of artificial fingernails or fingernail polish (e.g. Shellac or Gel nails)?

A: It is not acceptable for dental practitioners, assistants or team members performing clinical procedures to have any type of artificial nails or polish. If any dental team member performing clinical procedures is wearing artificial nails or polish, they should be instructed to remove these, as these items harbour microorganisms and significantly inhibit the ability to perform effective hand hygiene. *"Hand hygiene is the **most important** measure to avoid the transmission of harmful germs and prevent health care-associated infections"* (World Health Organization).

Q: How should a dropped RMD be managed?

A: When RMDs are dropped, consider the reasons behind this – poor organisation, haste etc. Any dropped RMDs are contaminated by the environment, and so cannot be used in the care of the patient. Dental practices should already have developed a procedure for handling dropped RMDs and what will occur if there is not a replacement item readily available so that the situation can be handled with calm and in the proper order.

It is up to the dental practitioner to handle the dropped RMD scenario in a way that meets the expectations of safety of the patient, safety for the staff, and the smooth running of the appointment, in that decreasing order of priority. The dropped item should not be left in a location where it causes ongoing risk for the patient or staff. Once work has ceased, decisions are needed around who will retrieve the dropped RMD and deal with it, based on the situation at hand. If the decision is made to retrieve the RMD during the procedure, the item should be placed in a safe area for subsequent management, gloves should be discarded, hand hygiene performed and new gloves donned before work recommences. Always keep the interests of the patient sitting in the chair at the forefront.

Q: If my vacuum leak rate test fails because of a high leak rate, can the steriliser still be used?

A: In short, no. An unacceptably high leak rate means there is a leak in the system which allows air to enter the chamber. This air stops steam from making contact with RMDs and thus prevents sterilisation from occurring.

If a vacuum test leak rate fails, wipe the door seal with a lint-free towel and warm soapy water, to remove any deposits, and then run a second vacuum test. If the second vacuum test fails, the steam steriliser must be shut off (tagged to stop use until it is repaired by a service engineer).

Q: Where can I go if I have further questions about IPC in the dental setting?

Many questions can be answered by first consulting the IFU (instructions for use) and other manufacturer directions provided. A key word search of this document and other key IPC references listed in this document should be the next strategy. The ADA Infection Control Committee provides timely advice to ADA members via the PEER communication network. If after performing these initial enquiries, you are still uncertain of appropriate action, it is recommended that members post a question to ADA infection control advice on the PEER forum, or send an email to ADA via membership@ada.org.au.

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