Health guidelines for personal care and body art industries

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Foreword

The principle purpose of this set of guidelines is to assist those involved in the personal care and body art industry to comply with the Health (Infectious Diseases) Regulations 2001 by providing information on: (1) how infection can be associated with the procedures employed in the industry, and (2) precautions to protect clients and employees. The guidelines are designed around a risk management approach to the transmission of infection from client to client, client to operator, and operator to client. Risk management involves an analysis (identification) of potential hazards, the controls (policies/procedures) required to minimise the hazard, and the corrective action to be taken if the control (action) does not achieve its aim of preventing or minimising the transmission of infection.

The guidelines also provide information on general matters that may be useful to the industry in performing its practices, and on infection control in general. Some personal care and body art body industry practices are not specifically covered by the Health (Infectious Diseases) Regulations 2001, but these guidelines include information on general infection control and prevention to assist these practices.

These guidelines are not intended to replace industry-specific guidelines for personal care and body art body premises. Proprietors and operators should also consult with their professional organisations and other organisations relevant to aspects of their business. These guidelines should be used as a guide to best practice and as a reference tool for people associated with the industry, including environmental health officers. A 'Business self-summary' form is provided on page v for cross-referencing purposes.

The guidelines are divided into the following five parts.

Part A: General information on infection (transmission and prevention); regulations related to the establishment of business premises; occupational health and safety issues; and details on how to clean, disinfect and sterilise instruments and equipment used to perform personal care and body art industry procedures.

Part B: A consideration of the personal care and body art industry under five general headings:

(1) beauty therapy procedures, including waxing, facials and nail treatments

(2) physical therapies, including massage, solariums and spas

(3) hairdressing

(4) body art, including tattooing and body piercing

(5) colonic irrigation.

The Department of Human Services, in conjunction with the Chinese Medicine Registration Board, is developing separate infection control guidelines for acupuncture. Existing departmental standards of practice for acupuncture are to be followed until the review is completed.

Part C: General information on risk analysis and management, to assist proprietors and operators to develop policies and procedures to improve infection control and prevention practices. Appendix 2 contains risk analysis tables with examples.

Part D: Glossary

Part E: Appendixes

Business self-summary

Proprietor

Manager

Business name

Business address

Telephone number

Email address

Business type

Name of local government

Activities	See
Example	
Use of disposable razor blades	Part B, section [add relevant no.]
Cosmetic tattooing	Part B, section [add relevant no.]

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Part A: General requirements

1. General information

1.1 Introduction

Personal care and body art businesses should supply professional, competent, safe and hygienic practices in clean premises. Unsafe or unhygienic practices can lead to the spread of infectious diseases that can affect the health of the client as well as jeopardise the health of the operator. Illnesses such as hepatitis B, hepatitis C and HIV/AIDS can spread by blood-to-blood contact, so it is essential for staff to understand the precautions required for any procedure that may involve skin penetration and possible blood contamination.

Infection may also be spread during procedures that do not involve skin penetration. These infections include staphylococcal infections such as impetigo, the wart and herpes viruses, and fungal infections such as tinea.

1.2 How infections occur

Instruments that penetrate the skin – for example, lances, electrolysis needles, comedone extractors, body piercing and other instruments – become contaminated by blood or body fluids/substances. Infection may occur when contaminated instruments are not effectively cleaned and sterilised before use on another person, or when single-use instruments are not discarded immediately after use.

The person at risk may be the next client or the operator if accidental penetration of the skin occurs. This is called a sharps or occupational exposure injury. Contact between blood and contaminated instruments, and then with open cuts, sores or broken skin, can also lead to infection.

Blood does not have to be visible on an instrument or needle for infection to be transmitted, so all reusable skin penetration instruments must be cleaned and sterilised before use on another client. Items required to be sterile at the time of use should be packaged before sterilisation and then stored sterile. All reusable instruments not required to be sterile at the time of use should be cleaned after each client use.

Contamination is the spread of microorganisms from one item to another. This is how organisms that cause infection can spread in personal care and body art premises. Contamination can occur when:

- strict operator hygiene is not observed
- operators share the same equipment or materials
- used and clean instruments come into contact with one another
- clean instruments are placed on unclean surfaces
- sterile instruments are placed on unsterile surfaces or come into contact with unsterile instruments
- contaminated dressings, spatulas and single-use gloves are not disposed of immediately and appropriately after use

- the structural facilities, furnishings and fittings of the premises cannot be, or are not, adequately cleaned between clients
- towels and other articles used on clients are not changed or thoroughly cleaned between clients.

The guidelines refer to single-use items. Any item marked by its manufacturer as being for single-use must not be cleaned and sterilised for reuse on the same client at another time or on any other client.

1.3 Legislation

The Health (Infectious Diseases) Regulations 2001 set out the requirements that proprietors of premises registered under the *Health Act 1958* must observe.

- The premises must be kept clean.
- Any article used for penetrating the skin must be sterile at the time of use.
- Any article that has penetrated the skin or is contaminated with blood or body fluids/substances must be either disposed of immediately after use or cleaned and sterilised before being used on another person.
- Any other used article must be cleaned before being used on another person.
- Operators must keep themselves and their clothing clean, and have no exposed cuts, abrasions or wounds.
- Proprietors must provide written health information to each client about the potential health risks associated with skin penetration procedures.

1.4 Benefits of compliance with these guidelines

The proprietor or operator should balance the benefits of using these guidelines against the costs, and against the consequences of not having specific infection control and prevention procedures. The use of single-use, cartridge-type ear and nose piercing guns, for example, is insignificant compared with the reduced risk of transmitting blood-borne infections. Businesses are expected to have sufficient supplies of equipment to enable them to comply with the cleaning, disinfection and sterilisation sections of the guidelines.

Businesses have a legal responsibility to provide a safe service, and a risk management program enables them to take all reasonable precautions. The identification of potential hazards and their management reduces the likelihood of untoward incidents. Further, the provision of a consistent quality service enhances both business reputation and client loyalty.

Compliance with the guidelines is therefore in the best interest of personal care and body art industries because every client and operator is at risk if proper infection control procedures are not followed. Proprietors and operators should be familiar with the Australian and New Zealand standards as they relate to their premises and practices. The Department of Human Services recommends compliance with the standards cited throughout the guidelines as established best practice.

2. Premises

These guidelines provide suggestions for improvements in premises design to promote good hygiene practices. New premises should comply from the outset, while established premises should plan for these improvements over the next two years. Proprietors can liaise with their local government environmental health officer to develop a strategy/works program to implement improvements. When a business changes hands, these improved design features should be required before the transfer of registration to the new business.

2.1 Registration

Before operating a personal care and body art business, the proprietor/operator has to consider a number of compliance issues. The following information provides a best practice guide.

A person conducting a personal care and body art business – including hairdressing, beauty parlour work, tattooing, ear piercing or any other process involving the penetration of the skin – must register such premises with the local government under the *Health Act 1958*. Current legislation does not require the registration of solaria, colonic irrigation or massage businesses.

A new registerable business in existing premises **must**:

- ensure the premises has current registration
- apply to transfer the registration of the premises to the new proprietor before that proprietor takes over its operation.

A new registerable business in new premises **should**, before applying for registration:

- consult with the local government health department to discuss the proposal, preferably before selecting a site
- submit detailed plans of the interior layout of the proposed premises to local government, in accordance with these guidelines
- obtain local government approval for the plans before commencing work on the premises
- contact the Business Licence Centre for information
- contact Small Business Victoria for business advice and information
- contact the appropriate industry association for advice.

Any new business **must**:

- submit an application for registration to the local government
- obtain local government approval before opening.

2.2 General requirements

Equipment, furniture, fittings, floors and walls should be purpose built or purchased specifically for the task to be performed. They should be durable, safe and suitable for cleaning and maintenance, and constructed of sealed, nonporous material. There should be adequate lighting and ventilation throughout the premises. Particular attention should be paid to those areas that are frequently damp, such as above, behind and under wash basins. The premises should be planned to provide separate function-specific client and cleaning/sterilising areas. The area of client procedure rooms/cubicles should be no less than 2.5 metres square. The cleaning area should be designed to ensure movement of instruments/equipment in a one-way direction from dirty to clean to sterile areas (figure 1). It should also have sufficient bench space for good working practices.

2.3 Specific requirements

2.3.1 Hand basins

A hand basin with hot and cold running water supplied through a single outlet, liquid soap and paper towels should be installed in the procedure room/cubicle. An appropriate splashback should be provided behind plumbing fixtures. In addition to a hand basin in the procedure room/cubicle there should be a hand basin in the cleaning area.

Where skin penetration procedures are performed, the hand basin should be hands free (for example, foot operated, electronically controlled or knee operated). Elbow-operated taps are not desirable.

In establishments where hairdressing only takes place, a hair washing basin with hot and cold running water supplied through a single outlet can also be used for washing hands.

2.3.2 Equipment sinks (hairdressing)

Separate sinks with hot and cold running water supplied through a single outlet (hot water not less than 70°C) should be located in the cleaning area for instrument and equipment washing.

2.3.3 General plumbing

Plumbing must conform with the requirements of the Plumbing Industry Commission (Victoria) and Standards Australia. These include:

- Australian Standard/New Zealand Standard (AS/NZS) 3500.1:2003 Plumbing and drainage – Water services
- AS/NZS 3500.2:2003 Plumbing and drainage – Sanitary plumbing and drainage
- AS/NZS 3500.4:2003 Plumbing and drainage – Heated water services.

Hot water installations should have sufficient capacity for the business being undertaken.

Premises may include other plumbing fixtures beside the handbasin, such as that used for general cleaning.

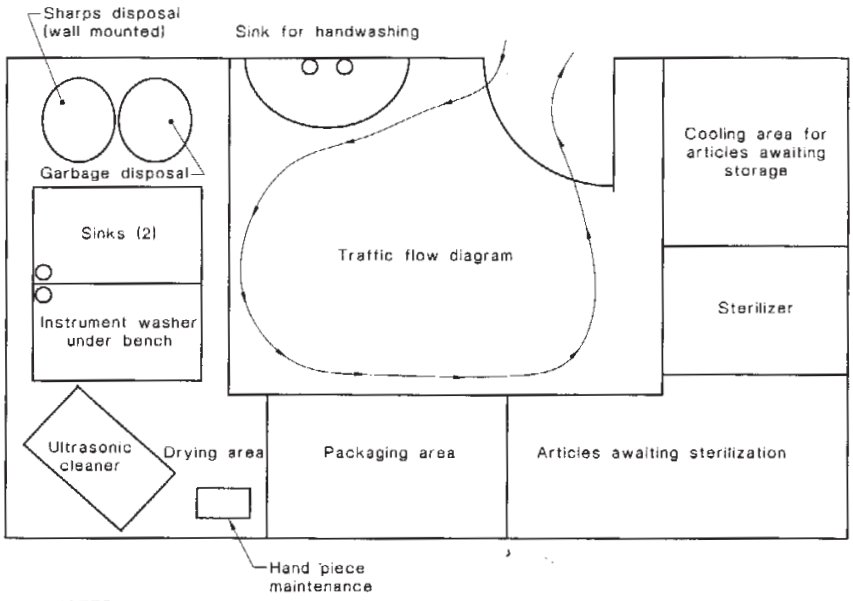
2.3.4 Electrical safety

All electrical equipment must meet prescribed electrical standards.

2.3.5 Linen

Paper towel, paper strips or clean linen are recommended and must be changed between clients. Soiled linen, towels and protective clothing should be placed in a washable, leak-proof receptacle, and laundered using hot water (70–80°C) and detergent. All clean linen, towels and clothing must be stored in a clean environment to reduce contamination.

Figure 1: Suggested layout for a cleaning area



NOTES:

1 Arrow direction indicates the flow of instruments and equipment from dirty—clean—sterile.

2 Personnel working in the processing area should wash their hands—

(a) after handling soiled items and removal of gloves;

(b) before handling clean items; and

(c) before handling sterile items.

Source: AS/NZS 4815:2001.

2.4 Disposal of waste

All bins used for waste must be lined with a plastic bag that can be sealed for disposal. It is essential that clinical and related waste (formerly known as infectious waste) is properly packaged, labelled, handled and transported to minimise the risk of occupational exposures and the transmission of infectious diseases to both waste handlers and the community. The Environmental Protection Authority has requirements for the management of clinical and related waste.

2.4.1 Handling and disposal of sharps

Sharps are considered clinical waste. Sharps used for skin penetration, such as needles, must be handled carefully during procedures to avoid needle stick injuries and the possible transmission of blood-borne diseases.

Sharps containers must comply with AS 4031:1992 Nonreusable containers for the collection of sharp medical items used in health care areas, AS 4031:1992/Amdt 1 Nonreusable containers for the collection of sharp items used in health areas and AS/NZS 4261:1994 Reusable containers for the collection of sharp items used in human and animal medical applications.

Suitable sharps containers are rigid-walled, puncture-proof containers with tight-fitting lids that prevent sharp objects, such as razor blades that may be contaminated with blood, from injuring another person. These containers can vary in size up from 1 litre containers. Disposal of sharps containers need occur only when the container is full, but before it is overflowing. Ask your local government environmental health officer if you require further advice.

Immediately after use, the operator should:

- not recap sharps
- place single-use sharps into a sharps container that meets Australian standards
- place multiple-use reusable sharp instruments into the container at the end of their useful life
- not force items into the container, so as to prevent injury.

Sharps containers should be placed a minimum of 1 metre above floor level, out of the reach of children. When the container is full, seal and dispose of it in accordance with Environmental Protection Authority requirements.

2.4.2 Disposal of other clinical and related waste

Clinical and related waste, such as blood-stained swabs, cotton wool and gloves, must be placed into a plastic bag-lined washable bin with a close-fitting lid marked ‘infectious waste’, and disposed of according to Environmental Protection Authority requirements.

2.4.3 Disposal of general waste

All general waste, such as papers and powdered pigments, should be placed into a plastic bag-lined washable bin with a close-fitting lid marked ‘general waste’. General

waste can be disposed via normal refuse collections. Bins should be regularly emptied and washed.

2.4.4 Disposal of liquid waste

All liquid waste may be disposed of via the sewer, provided the local water authority has given prior permission. Plumbing must meet regulations. All liquid waste must be diluted well during disposal, via the running of four times the amount of cold water through the system at the same time.

2.5 Dispensing

To avoid contamination, the operator must ensure any make-up, fluid, cream, ointment or similar substance is removed from its original container/tube (including self-dispensing pumps) using a clean disposable applicator. Leftover creams, ointments and similar substances must not be returned to the original container and must not be used on any other client. Applicators used for dispensing must not be re-dipped into the original container and must be discarded after each client. Single-use applicators are recommended.

2.5.1 Pumps/spray bottles/nozzles

Pump outlets, bottles and nozzles are a potential source of contamination, particularly due to the build-up of contents around the outlet. Nozzles should be cleaned frequently and dried before being replaced. Wash bottles and nozzles in warm water and detergent, rinse them under hot running water, and dry them using a lint-free cloth, before refilling the bottle or replacing the pump/spray nozzle. Pump/spray bottles should never be topped up. Drop-in cassette dispensers are more convenient and economical (see part A, section 3.4.2).

2.6 Animals

Animals, other than guide dogs for the hearing- or sight-impaired client, should not be permitted in procedure areas. Having animals in premises should be discouraged.

2.7 Records

For all premises covered by these guidelines, it is important to keep accurate records of every procedure carried out on each client. All businesses should also record every incident relevant to occupational health regulations. Accurate and detailed records are valuable if there is any infection or possibility of a blood-borne virus transmission. In the case of a blood-borne virus, for example, these records can be cross-checked for the probability for or against a reported infection resulting from a specific procedure or incident (see part E, appendix 3 for examples of records).

Operators should also ensure that they comply with the relevant legislation regarding the collection, storage, use and disclosure of personal and/or health information.

For body art/colonic irrigation industry requirements please see specific sections.

3. Occupational health and safety

3.1 Health and safety in the workplace

Employers are responsible for providing a safe work environment to minimise risks to the health of employees, clients and other persons entering the premises. This effort involves providing:

- adequate staff training, including training in hygiene and infection control
- properly maintained facilities and equipment, including personal protective equipment
- a suitably designed and clean workplace to minimise potential hazards, such as the safe storage of equipment and chemicals, sharps and other clinical and related waste.

3.1.1 Immunisation

No vaccine is available for the prevention of hepatitis C and HIV/AIDS. There is, however, a safe and effective vaccine for the prevention of hepatitis B. Immunisation is recommended for all operators involved in skin penetration procedures and for staff involved in cleaning instruments/equipment. A primary immunisation course in hepatitis B consists of three injections over six months. Hepatitis A immunisation is recommended for personnel working in colonic irrigation premises. Immunisation can be arranged through a general practitioner or the local government.

3.1.2 Smoking

Operators should not smoke during client procedures because the operator risks transferring bacteria from their mouth and nose onto their fingers and then to the client, as well as providing a passive smoking hazard.

3.2 Emergency situations

It is essential for premises to have contact numbers for local and emergency services at hand.

3.2.1 First aid

WorkCover Victoria can provide information on first aid kits. Each workplace should conduct a risk assessment (see part C) to determine likely workplace hazards and develop a first aid kit accordingly. The contents of the kit will depend on factors such as the number of employees, the nature of any hazards and the location of the workplace. In most workplaces, a basic first aid kit would include the following items.

- Basic first aid notes
- Sterile eye pads
- Eye bath
- Individually wrapped sterile adhesive dressings
- Disposable gloves
- Scissors
- Triangular bandages

- Sterile coverings for serious wounds
- Normal saline
- Adhesive tape
- Crepe bandage
- Safety pins
- Different-sized sterile, unmedicated wound dressings
- Addresses and telephone numbers of emergency services
- Names and contact details of workplace first aid officers

3.2.2 Training/education in first aid

It is strongly recommended that proprietors/operators of personal care and body art premises complete a first aid course. The course should cover basic first aid, including cardiopulmonary resuscitation (CPR) and the management of burns and eye injuries/hazards such as splashes.

Infection control/prevention and sterilisation training is also strongly recommended as a way of reinforcing the principles and practices in these guidelines. Contact an environmental health officer from local government or the Department of Human Services for further information.

3.2.3 Burns

Burns are a type of soft-tissue injury that can occur when the body is exposed to certain chemicals, electricity or extreme heat or cold. The severity of the burn depends on the temperature of the object or gas causing the burn, the length of exposure to the source, the location of the burn, the extent of the burn, the victim's age and the victim's medical condition. The people most at risk of severe burns are those aged over 60 years and those aged under 5 years, because their skin is thinner. Burns are classified by the source (such as heat, cold, chemicals, electricity or radiation) and depth. Most burns caused by flames or hot oil require medical attention.

What to do for burn care

- Cool burns by flushing with cool water.
- Remove rings and jewellery.
- Cover the burn with a dry sterile dressing.
- Take steps to minimise shock.
- Seek medical attention.

What NOT to do for burn care

- Apply ice directly to burns.
- Touch burns with anything except sterile or clean dressings. Do not pull clothes over any burned area.
- Remove pieces of cloth that stick to a burned area.
- Try to clean a full thickness burn.
- Break blisters.
- Use any kind of oil or ointment on severe burns.
- Use cotton wool or other fluffy material on burns.

Treat scalds by removing any nonadherent clothing because it traps the heat. Cool the scalded area with water for up to 20 minutes and treat as a burn. With chemical burns, the strength of the chemical and the length of the contact will determine the severity of the burn. The chemical will continue to burn as long as it is on the skin, so the chemical must be removed from the body as quickly as possible. Burns to the eyes from a chemical must be flushed with water (preferably sterile saline) until ambulance personnel arrive. Ensure water flushes underneath the eyelids.

3.2.4 Bleeding

When bleeding occurs either during a personal care and body art procedure or accidentally, the operator should:

- put on single-use gloves if not already wearing them
- prevent the bleeding by applying pressure to the wound until it stops, using a dry sterile single-use dressing
- apply an additional dressing, bandage very firmly if bleeding continues, and call for medical assistance
- handle both the dressing and the contaminated implement carefully to avoid coming into contact with blood or body fluids/substances from the client or the instrument
- place contaminated dressings or swabs in a plastic bag before disposing of them in the clinical and related waste bin
- thoroughly wash hands with soap and hot water after treating wounds or handling contaminated dressings, then pat dry
- discard single-use instruments into the appropriate clinical and related waste container
- place contaminated reusable instruments in the appropriately marked container, and clean and sterilise them according to the procedures outlined in part A, section 5
- document the incident and all actions taken in an incident record book (see part E, appendix 3).

3.2.5 Occupational exposure to blood and/or body fluids/substances

The following details expand on the procedures described in part A, section 3.2.4.

Intact skin

If blood and/or body fluids/substances come into contact with intact skin, then wash the area thoroughly with liquid soap and warm water, then pat dry.

Nonintact skin

If blood and/or body fluids/substances comes into contact with skin that is chapped, cut or abraded, or has dermatitis, or if accidental penetration (for example, a sharps injury) occurs, then the operator should:

- flush with warm, running water, then wash with liquid soap and warm water
- thoroughly pat dry
- cover with a waterproof dressing
- apply firm pressure to control bleeding if required.

Mucous membranes (eyes/mouth)

If blood and/or body fluids/substances come into contact with mucous membrane, then the operator should:

- for eyes, rinse gently with eyes open, using copious amounts of warm tap water or saline
- for the mouth, spit out the blood or body fluid, then rinse the mouth thoroughly and repeatedly with warm water.

Follow-up action

Report the incident to the proprietor/manager immediately and ensure appropriate follow-up with a general practitioner. Document the following:

- the name of the exposed individual
- the date and time of exposure
- how the incident occurred
- a description of the injury and treatment provided
- the name of the individual who is the source of the blood or body fluid (if known).

A general practitioner should evaluate all exposures as soon as possible for both the source individual and the person exposed. This examination may include serological testing for evidence of hepatitis B, hepatitis C and HIV antibodies, after appropriate pre-test counselling and informed consent.

3.3 Hand care

3.3.1 Broken skin

Small areas of broken or infected skin on exposed parts of the operator's body should be covered with a waterproof dressing that completely covers the affected area. If a cut or abrasion is on the hands, then single-use gloves should be worn during all procedures.

3.3.2 Hand-washing techniques

The spread of infection from hands has been recognised. Washing hands is the single most important factor in preventing infection (after cleaning and sterilising equipment) and cannot be overstated. Unbroken skin is the best defence because it provides the perfect barrier against infection. The purpose of washing hands is to reduce any microorganisms that may be present. Unless the fingernails are visibly dirty, a nailbrush should not be used because it may cause breaks in the skin during vigorous brushing. Obvious dirt under the nails must be removed.

Good hand-washing facilities are essential and should be located within the treatment area. Hands-free taps are required for premises carrying out high-risk procedures (for example, skin penetration). Liquid soap dispensers using single-use cassettes are recommended, because they do not permit a topping-up process and they minimise the risk of contamination.

When to wash hands

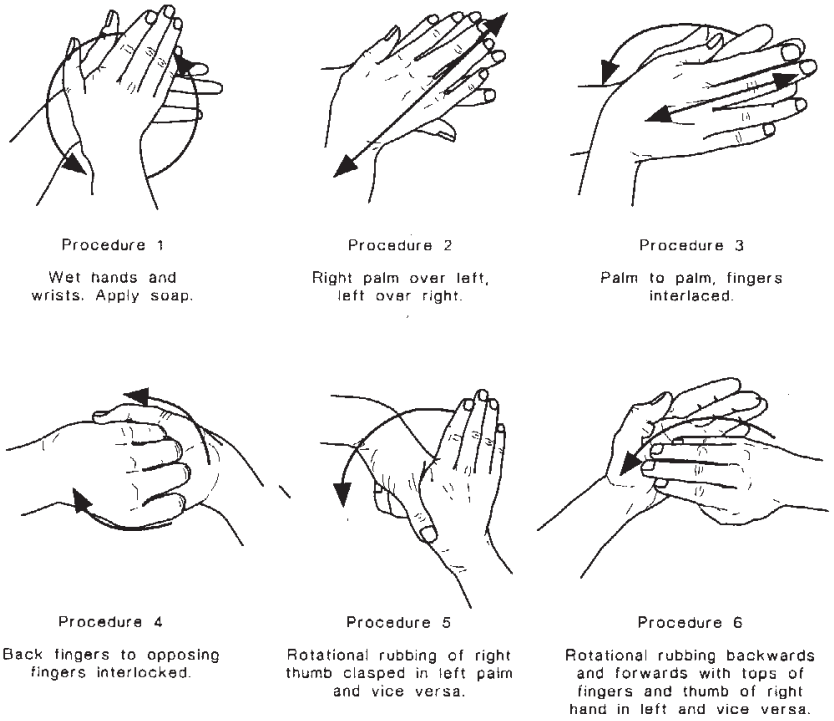
- Before and after contact with each client
- After contact with blood or body fluids
- After using a tissue or handkerchief
- After smoking
- After going to the toilet
- Before and after eating
- After answering the phone or touching any potentially contaminated objects, and before returning to a client

How to wash hands (see figure 2)

- First, wet hands with warm running water, use liquid soap (one pump measure is sufficient), then rub hands vigorously for a minimum of 15 seconds.
- Wash hands all over, including:
  - backs of hands
  - wrists
  - between fingers
  - under fingernails.

- Rinse hands well.
- Pat dry hands thoroughly using a paper towel.

Figure 2: Routine hand-washing technique



NOTE: Repeat procedures 1-6 until the hands are clean. Rinse hands and pat dry.

Source: AS/NZS 4815:2001.

What to use for hand washing

For an ordinary and hygienic hand wash, applying plain liquid soap is sufficient. For all skin penetration practices, a procedural hand wash is required. This procedural hand wash should last for 3 minutes, working through each of the steps in figure 2. The wrists and the lower part of the lower arm (just above the wrist) should be included as part of this hand wash.

Operators should use one of the following antimicrobial soap solutions:

- aqueous 2% chlorhexidine-based solution
- aqueous 4% chlorhexidine-based solution
- aqueous povidone-iodine.

People with an allergy to the chlorhexidine or povidone-iodine solutions should use a triclosan 2% solution.

3.3.3 Use of protective hand creams and lotions

Hand creams and lotions should be applied regularly during the day to provide protection and help prevent chapped and cracked skin.

3.4 Personal protective equipment

3.4.1 Gloves

The use of sterile single-use gloves is encouraged when skin penetration procedures are being performed and the operator's hands are likely to be contaminated with blood or body fluids/substances or come into contact with mucous membranes or nonintact skin. Sterile gloves should also be worn when sterile equipment is being used (see part A, section 4.1). Sterile gloves should comply with AS/NZ 4179:1997 Single-use sterile surgical rubber gloves – Specification. They should remain in the manufacturer's carton until required, and they should not be opened until immediately before the procedure. The use of nonsterile single-use gloves is the minimum requirement if sterile gloves are not provided on site.

Wearing gloves must not replace hand washing because gloves may have defects that are not immediately obvious, or they may become damaged during use. Single-use gloves (sterile and nonsterile) should be carefully removed to avoid contamination of hands or other surfaces. They must not be washed or reused.

Single-use gloves should be:

- removed when leaving the client for any reason, and/or
- removed if they become torn, and
- changed after each client, and
- disposed of in the clinical and related waste receptacle, and
- used before the expiry date.

Some operators may develop an allergy or sensitivity to latex gloves. This reaction is likely to be due to contact with latex proteins that might not have been adequately removed during the manufacturing process. In the presence of sweat or moisture, these proteins may become absorbed into the lubricant powder used in the latex gloves. Operators who develop sensitivities or allergies to latex can use powder-free latex gloves or alternatives to latex, such as neoprene.

3.4.2 Clothing

The operator should wear clean washable garments or coveralls that enable them to thoroughly wash their hands when attending to clients. Personal protective equipment protects the clothing and skin from contamination with blood or body fluids and substances. Watches, wrist and finger jewellery, including wedding rings, should not be worn when attending to clients because these items provide a potential source of infection. Hand jewellery should not be worn during skin penetration procedures because it may tear the gloves.

3.4.3 Masks

Operators should wear masks when there is a possibility of splashing or splattering of blood or other body substances. The type of mask best suited to a particular situation depends on the nature of the activity. There are two main types of mask used in skin penetration procedures and cleaning.

1. *Surgical masks* reduce the risk to operators from splashing and spraying of body fluids/substances. They are generally loose fitting without a tight air seal, and they are not efficient in preventing the wearer from inhaling air-borne particles. See AS/NZS 4381–2002 Single-use face masks for use in health care.
2. *Particulate filter personal respiratory protection devices* are close fitting and capable of filtering up to 95 per cent of air-borne particles. They should be worn when using lasers. See AS/NZS 1715:1994, Selection, use and maintenance of respiratory protective devices, and AS/NZS 1716:2003 Respiratory protective devices.

Masks should:

- be fitted and worn according to the manufacturer's instructions
- not be touched by hands while being worn
- cover both mouth and nose while being worn
- be removed as soon as practicable after they become moist or visibly soiled
- be removed by touching the strings and loops only
- not be worn loosely around the neck, but be removed and discarded immediately after use.

3.4.4 Eye protection

Eyes should be protected from splashing created during cleaning procedures, although the practices used by the operator should ensure these events are kept to a minimum. Various types of eye protection are available, including goggles, face masks, visors and full-face shields, which have either reusable or single-use guards.

3.4.5 Aprons

Waterproof aprons should be worn when attending to clients during colonic irrigation procedures and also when undertaking cleaning procedures.

3.4.6 Footwear

Footwear should cover the foot, to protect against accidental injury from dropped items of equipment.

3.5 Use and storage of chemicals

Many chemical products used in personal care and body art procedures have the potential to harm the health of the operator and client if they are not labelled, handled and stored with care. To protect the operator and the client, consider the following practices.

- Ensure premises are well ventilated.
- Only use drop-on or brush-on products.
- Try to avoid aerosol products.
- Wear gloves when decanting or mixing products such as chemicals (including ready-made inks and powdered pigments) because they should not come into contact with the skin of the client or operator.
- Label all solutions decanted from bulk containers, and date them with the day of decanting and a use-by date if applicable.
- Do not eat, drink or smoke in areas where chemicals are stored or used, because food and drink may absorb emitted vapours that can be flammable. (A specific staff room should be set aside for breaks and the consumption of food.)
- After handling chemicals, wash hands before consuming food or drink, because chemical residues on the hands will contaminate food and will be ingested.
- Label all chemical containers, secure their lids and store them in a cool area away from gas appliances.
- Secure chemicals to prevent unauthorised access.
- Remember that cotton wool and similar articles soaked with chemicals will be present in waste, so fumes will be dispersed into the room if not adequately contained. Remove waste regularly from the immediate client area to a larger, covered bin.

Proprietors and operators should request (from manufacturers/suppliers of chemicals) material safety data sheets relating to the safe handling, storage and first aid requirements for chemical products. All personal care and body art proprietors/operators should refer to these sheets for advice and keep copies on the premises at the point of use.

Glutaraldehyde (sold under various names) is an instrument-grade disinfectant that is not suitable for the personal care and body art industry. There are major occupational health and safety requirements for the use of this product, such as the required use of personal protective equipment and elaborate air removal systems. Contact the Victorian WorkCover Authority and the Department of Human Services for additional information (see part A, section 5.3).

4. Practices – general

4.1 Preparation

4.1.1 Preparation of client procedure areas

To provide a safe working environment, the operator should:

- ensure the work area is clean and tidy
- ensure all required items are within reach, and remove items not required from the immediate area
- ensure work surfaces including procedure chair, couch etc, are cleaned with warm water and detergent, then rinsed and dried
- place leak- and puncture-proof washable containers (only used for these purposes) with a firm-fitting lid labelled 'dirty instruments for cleaning and sterilisation' in the work area for the collection of used instruments.

Sterile items should be opened on to a sterile single-use towel that has been placed on the workbench. Packages containing sterile instruments or needles should be opened and handled using a non touch technique, in front of the client to demonstrate that sterile instruments are used.

Items should be sterilised on a fully perforated metal or plastic tray. The packaging can be opened by removing (peeling) either the laminate or paper side of the packaging off, leaving the tray and its contents on the other half of the packaging as a sterile surface. The tray contents can be used and replaced on the tray during the procedure (as necessary) to maintain sterility and to reduce the contamination of work surfaces. All items opened or contaminated during a procedure must be fully cleaned and sterilised after each procedure even though they have not been used for the procedure. The use of a tray may also prolong the life of items provided the tips of sharp items are protected. Fully perforated trays are readily available in various sizes and tip protectors that are steam penetrable are also readily available. See part A, section 6.1.

4.1.2 Client preparation

The client should be provided with privacy, depending on the type of procedure being undertaken. A clean gown and drapes that cover the privacy of the client should be provided. Each client should also be provided with additional equipment where necessary (such as goggles for solaria procedures), along with a full explanation before any procedure commences.

4.1.3 Preparation for skin penetration

When performing skin penetration procedures, wear sterile single-use gloves. Nonsterile single-use gloves are a minimum requirement if sterile gloves are not provided.

Preparation of needles

The operator must replace needles that become contaminated during preparation and procedure, such as if they accidentally touch a nonsterile surface. Take care not to contaminate needles when inspecting them for defects, such as damaged or blunt points. Needles must never be tested for sharpness on either the skin of the operator or client before use. Reusable needles are **not** recommended for electrolysis; only sterile single-use needles should be used.

New, nonsterile single-use needles should be cleaned, sterilised, inspected for defects and soldered on delivery and then cleaned and sterilised again, prior to use on a client for a tattooing procedure. Use a lead-free solder and effective cleaning should remove the flux residues from the soldering process.

Preparation of the client's skin

The client's skin should be clean and free from cuts, abrasions and any visible sign of infection. The skin can be washed with a liquid soap or anti-microbial solution and dried. Before any skin penetration procedure, the treated area must then be disinfected. Check with the client for iodine allergy before using iodine-based preparations. Areas around the eyes should only be cleansed with warm water or aqueous (water-based) skin disinfectants. If unsure whether a disinfectant is water-based or not use only warm water.

Skin may be disinfected with any one of the following:

- 70% w/w ethyl alcohol
- 80% v/v ethyl alcohol
- 60% v/v isopropyl alcohol
- alcohol (isopropyl or ethyl) formulations of 0.5 to 4 % w/v chlorhexidine
- aqueous formulations of 0.5% w/v chlorhexidine
- aqueous or alcohol povidone-iodine (1% w/v available iodine).

The disinfectant can be applied to the skin using a clean single-use swab from a clean single-use pack, or dispensed from a pump pack or single-use bottle. Leave the solution on for a minimum of 30 seconds or until dry, before commencing skin penetration. Do not touch the area to test for dryness. Sterile single-use swabs with 70% w/w ethyl alcohol are also available for skin disinfection. At the end of a skin penetration procedure, any remaining disinfectant must be discarded. Observe the use-by dates on disinfectants.

4.2 Cleaning

4.2.1 Cleaning up after a procedure

After completing any procedure, carry out the following steps.

1. Place all contaminated single-use sharp instruments into a sharps container immediately after a skin-penetration procedure has been performed.
2. Place all reusable skin penetration instruments, or other reusable instruments contaminated with blood, into the container labelled 'dirty instruments for cleaning and sterilisation.'
3. Place all reusable instruments from low- and medium-risk procedures into a container labelled 'dirty instruments for cleaning.'
4. Place the containers in the area set aside for cleaning.
5. Do **not** store instruments or needles in chemical disinfectant either before or after cleaning, sterilisation or thermal disinfection.
6. Dispose of all used single-use items (such as applicators, paper toweling and protective coverings from surfaces) into the clinical and related waste bin.
7. Place used linen into a washable leak-proof receptacle with a close-fitting lid labelled 'dirty linen' and launder (see part A, section 2.3.5).
8. Remove and dispose of gloves in the clinical and related waste bin, then wash hands and thoroughly pat dry (see part A, section 3.3.2).

Care should be taken when handling sharp instruments to avoid potential sharps injuries.

4.2.2 Routine cleaning of work surfaces

General-purpose utility gloves should be worn for general cleaning procedures. Utility gloves may be reused but should be washed in detergent after use and stored in a dry place, or replaced if torn, cracked, peeling or showing signs of deterioration. Proprietors should use gloves robust enough to stand general cleaning and not tear. Vinyl gloves should not be used, because they are more likely to develop large holes and are prone to tearing.

Following client treatment, all work surfaces used, for example, procedure couches/chairs, solariums, benches and tables, should be washed with warm water and detergent, rinsed and dried using a clean lint-free single-use cloth. Additionally, at the end of each working day, wash all visibly soiled surfaces with warm water and detergent. Rinse and dry using a clean lint-free single-use cloth (see part E, appendix 3).

4.2.3 Cleaning standards for change/shower rooms and toilets

Cleaning requires surfaces to be free from smudges, smears, body fats and mineral deposits. Surfaces include plumbing fixtures, tiles and other polished surfaces. Sanitary disposal units should be regularly emptied.

4.2.4 Clean-up procedures following blood or body fluid spills

Surfaces contaminated with blood or body fluid should be cleaned in accordance with the following procedures.

1. Handle all soiled dressings and contaminated instruments carefully, wearing single-use gloves, apron, protective eyewear.
2. Dispose of contaminated single-use instruments into a sharps container, then clean and sterilise reusable instruments according to part A, sections 5 and 6.
3. Soak up blood using paper towels.
4. Wash affected areas with warm water and detergent.
5. Rinse and dry affected areas using paper towels.
6. Dispose of all used paper towels by placing them in the clinical and related waste bin.
7. After treating wounds, handling contaminated dressings or cleaning up blood, remove gloves and dispose of them in the clinical and related waste bin.
8. Wash hands and thoroughly pat them dry.

For major spills:

- follow procedures 1–4 from the above list
- mix a fresh solution of 1:4 diluted bleach–for 1:4 dilution, add 1 cup (250 millilitres) of bleach to 3 cups (750 millilitres) of warm water
- wipe over the area using paper towels
- rinse the area thoroughly and dry well, because bleach is corrosive
- follow procedures 5–8 from the above list.

5. Cleaning and disinfection of reusable instruments and equipment

For an excellent reference on the cleaning, disinfection and sterilisation of used items, see AS/NZS 4815:2001 Office-based, health-care facilities not involved in complex patient procedures and processes – Cleaning, disinfecting and sterilising reusable medical and surgical instruments and equipment, and maintenance of the associated environment. It provides clear instructions for all steps in the processing of reusable items.

5.1 Categories of instruments

Instruments and equipment, together with their cleaning, disinfection and sterilisation requirements, can be classified into categories based on their intended use (see part A, section 6). Table 1 provides examples of the instrument types, procedures and cleaning processes required. Use the risk analysis chart (see part E, appendix 2) to assess the risks for each instrument or item of equipment.

Table 1: Suggested level of risk associated with a particular procedure/site (examples only)

Risk	Procedure	Cleaning/disinfection/ sterilisation
High risk	• Penetration of sterile or mucosal tissue with a sharp instrument	Clean, sterilise
	• All body piercing and tattooing procedures	Clean, sterilise
	• Accidental breaks of intact skin, such as shaving or occupational exposure	Clean, sterilise
Intermediate risk	Manicure/pedicure	Clean, dry, disinfect (as necessary), rinse off disinfectant with distilled water, dry (Alcohol evaporates, so does not require rinsing.)
Low risk	Hairdressing (for example, combs)	Clean, dry

Disposal or cleaning (and sterilisation) is required for intermediate- and low-risk categories if items are contaminated with blood, body fluids or substances.

5.2 Cleaning procedures

5.2.1 General cleaning procedures

- Wear personal protective equipment while cleaning (including heavy utility gloves – see part A, section 3.4) and clean all equipment items before their first use.
- Remove used items from the labelled containers and sort them according to the appropriate cleaning method.
- Clean instruments and trays immediately after a procedure. (If cleaning cannot be performed immediately, then instruments should be covered in warm water to prevent soils from becoming fixed, which would make cleaning difficult.)

- Do not leave instruments soaking for longer than one hour. (Instruments that cannot be immersed should be cleaned immediately).
- Protect the tips of sharp reusable items from damage during cleaning and clean carefully to avoid a sharps injury to the operator.

5.2.2 Cleaning process

- Rinse under warm running water to remove organic material. Do not use either very hot or very cold water because this will fix the soil to the item, making it more difficult to clean.
- Fill the sink with warm water and liquid detergent (preferably low-foaming, nonabrasive, noncorrosive, biodegradable, free-rinsing, nontoxic detergent of a mild alkaline formulation). Common household detergents should not be used because they have high-foaming properties and their residue is difficult to rinse off.
- Follow the manufacturer's instructions for detergent use. (Material safety data sheets contain information on the formulation, use and suitability of particular items.)
- Ensure all staff are familiar with each chemical used in cleaning items.
- Use cleaning products containing enzymes, which break down proteins in organic matter, only if suitable for the item. (They are not recommended for routine use.)
- Use products containing enzymatic matter according to standard precautions, and wear nitrile-type gloves.
- Note that cannulated (hollow or lumened) items such as stainless steel receiving tubes used in body piercing are a particular challenge to clean. (Immersion in an ultrasonic cleaner may assist in the manual cleaning by removing or loosening soils.)
- Note that reusable tubing is also a challenge to cleaning and has the potential to generate infectious aerosols. Use single-use tubing instead.

For most personal care and body art industries, manual cleaning will be the best method. Manual cleaning is used when items require care in their handling and are not suited to mechanical cleaning methods (for example, an ultrasonic cleaner). Ultrasonic cleaners may be used for some parts of the manual process (depending on the fragility of the item).

Ultrasonic cleaner method

Ultrasonic cleaners work by producing high-frequency, high-energy sound waves that cause organic material to dislodge and drop to the bottom of the tank. Use only a manufacturer-recommended detergent because others may limit the effectiveness of the ultrasonic cleaner. Cannulated items may require additional manual cleaning, because these items are not always successfully cleaned in an ultrasonic cleaner. Cannulated items should be brushed thoroughly and rinsed before being carefully placed into the ultrasonic tank, to ensure air is not trapped within the lumen. They should be brushed again on removal (using a clean brush) to remove loosened

debris. Ultrasonic cleaners do not sterilise or disinfect instruments, but they provide a safe and effective means of cleaning most reusable instruments before sterilisation.

It is important that the cleaner is tested (via an aluminium foil test) each day to ensure the correct operation of the ultrasonic transducer. Do not submerge fingers or body parts into the fluid of an operating ultrasonic tank because the energy will damage joint tissues and result in long-term arthritic conditions. A notice should be attached to each ultrasonic cleaner, stating 'while operating the ultrasonic cleaner, do not submerge fingers or other body parts into the fluid'. Keep the ultrasonic cleaner lid on during the operation to reduce the emission of high-frequency sounds to a safe level, because they may damage hearing (and also to contain aerosols emitted from the surface of the cleaning fluid, which can pollute the surrounding atmosphere and be a source of air-borne organisms). Table 2 summarises the steps.

Table 2: Summary of steps in manual and ultrasonic cleaning

Manual cleaning
1. Put on personal protective equipment, including heavy-duty household gloves.
2. Separate items according to the method of cleaning.
3. Rinse items in warm running water to remove soil.
4. Dismantle or fully open items to ensure all parts are present.
5. Immerse items (a few at a time) in the sink with warm water and detergent.
6. Scrub items using a soft nylon-bristle brush.
7. Keep each item low in the sink (below the surface) to prevent splashing and the formation of aerosols.
8. Rinse items in warm to hot running water.
9. Dry items with a lint-free cloth
10. Inspect the item for cleanliness and completeness
11. Do not reassemble the items before thermal disinfection or sterilisation.
Ultrasonic cleaning
Follow steps 1–4 for manual cleaning
5. Operate the machine to degas the solution.
6. Immerse items in the ultrasonic cleaner (which is filled with warm water and detergent).
7. Keep the lid on during the operation to prevent aerosols and splashing.
8. Rinse items in warm-to-hot running water.
9. Dry items with a lint-free cloth
10. Inspect the item for cleanliness and completeness.

Items that cannot be fully immersed should be wiped over using a lint-free cloth dampened in warm water and detergent, then rinsed and dried. A 70% ethanol alcohol solution should then be used to chemically disinfect the item.

Monitoring of ultrasonic cleaners

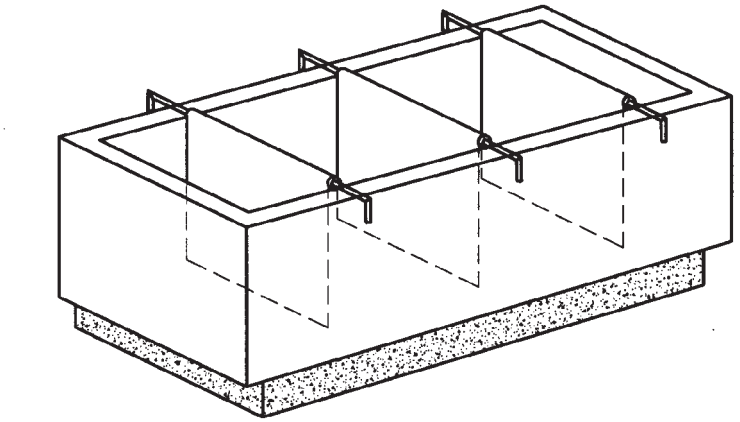
Ultrasonic cleaners should be cleaned daily. The base plate, gaskets, water strainers and filters must be checked and cleaned, and a daily performance test is essential to check the transducer function.

Ultrasonic transducer performance test (aluminium foil test)

This test is designed to test the transducer function of the ultrasonic cleaner.

- Cut a strip of aluminium foil that is approximately the width of the tank and twice its depth.
- Fill the ultrasonic cleaner tank, add detergent and degas the tank (see the manufacturer's instructions).
- Lower the foil vertically into the tank until it almost touches the bottom of the tank. (Do not immerse hands.)
- Operate the ultrasonic cleaner for 10 seconds (without the lid).
- Remove the foil and inspect it for an even distribution of perforations and pitting. If pitting or perforations are uneven, then the ultrasonic cleaner should be checked for faults or serviced.
- An uneven distribution of perforations and pitting of the aluminium foil indicate that the ultrasonic cleaner is not functioning at maximum efficiency and should not be used until it has been serviced.

Figure 3: Aluminium foil test–wire frames for supporting sheets of aluminium foil



Maintenance of ultrasonic cleaners

Ultrasonic cleaners should be operated and maintained according to the manufacturer's instructions. Ultrasonic cleaners must comply with AS 2773.1:1998 Ultrasonic cleaners for health care facilities, Part 1: Nonportable and with AS 2773.2–1999 Ultrasonic cleaners for health care facilities, Part 2: Benchtop. All cleaning equipment should be nonabrasive, and washed and dried after use.

5.2.3 Drying instruments/equipment

Do not dry items in ambient air (for example, on a bench) because this will allow air-borne contamination. Equipment wiped over with a 70% alcohol solution should be

wiped dry before storage. Use a lint-free cloth to dry items. Paper towelling is not appropriate because it is not lint free.

Do not handle cleaned items or packaging materials if a hand cream/lotion has been recently used; wash hands first. Hand creams/lotions, especially oil based ones, will leave marks that may attract contaminants and provide an impenetrable barrier to steam. Once items are dry, they may be handled with clean, ungloved hands.

5.2.4 Offsite sterilisation

Instruments being sterilised offsite must be cleaned and packaged before being transported in a clean, closed puncture-proof container. Loose instruments should be transported in a clean, closed puncture-proof container ensuring they are not damaged in transit. Some offsite sterilising services may wish to do the packaging; in this case, cleaning is still necessary before transport.

5.3 Disinfection

5.3.1 General

Instruments used on intact skin may be washed and stored in a dry place, but instruments that penetrate the skin must undergo cleaning and sterilisation. The use of disinfectants does not replace the need for good cleaning practices, and all items/equipment/surfaces must be thoroughly cleaned before disinfection. Disinfectants should be used only when equipment or the environment is contaminated with blood or other body substances however, items that can be, must be sterilised after cleaning. Detergent solution is sufficient for cleaning off perspiration, for example. Disinfectants can become easily contaminated and are a potential source of infection. Solutions should be labelled appropriately (with the name, date and dilution strength). Do not mix detergent or disinfectant solutions because they may react with each other and, in doing so, reduce their effectiveness or cause harm. Some disinfectants, such as those producing chlorine, must be freshly prepared.

Only disinfectants specified in the Australian Register of Therapeutic Goods (ARTG) should be used by operators for disinfection. This disinfectant should only be used for the approved purpose.

5.3.2 Storage of chemicals

See part A, section 3.5.

5.3.3 Use of bleach (sodium hypochlorite)

- All references to ‘bleach’ (sodium hypochlorite) throughout the guidelines relate to household-grade bleach products with a concentration of 40,000 parts per million (ppm) of available chlorine (ppm avCl) or 4% avCl.
- To dilute bleach for a 1:4 dilution, add 1 cup of bleach (250 millilitres) to 3 cups of warm water (750 millilitres).

- Prepare bleach solution as required, or prepare daily (label bottle) as its effectiveness deteriorates rapidly.
- To prevent deterioration, store bulk bleach containers in dark cool areas (and strictly adhere to use-by dates on bleach products).
- Wear gloves when handling bleach, because it can cause skin irritation.
- If splashing occurs, rinse the affected area immediately, following the instructions contained in part A, section 3.2.5.
- Rinse bleach solution from all surfaces, because bleach is corrosive.
- Dry surfaces.

It is not necessary to routinely use bleach or other disinfectants.

5.3.4 Disinfection processes

Chemical disinfection should be used only for items for which sterilisation and thermal disinfection are not suitable–for example, items unable to be immersed in water (thermal) or unable to withstand high-pressure gradients (sterilisation). Items that can be fully immersed but are unable to withstand high-pressure gradients may be disinfected in a suitable chemical disinfectant solution if necessary. Thermal disinfection is recommended for items that can be immersed but are not required to be sterile at the time of use.

Due to the misuse and overuse of chemical disinfectants, many microorganisms have become, or are becoming, resistant to them. For this reason, the routine use of disinfectants is **not** recommended.

Items of equipment should be immersed in a chemical disinfectant solution only for the time specified by the manufacturer. They should be removed and rinsed with distilled water before being dried and stored. Chemical disinfectant solutions should be discarded immediately after use (see part A, section 2.4.4). The container should have a close-fitting lid. Spray bottles are **not** a suitable method of disinfecting equipment because the aerosols produced do not come into contact with all parts of the equipment.

Proprietors/operators who choose to use chemical disinfectants as part of their practices should consider each chemical and its use carefully, and follow the manufacturer's instructions. (Table 1 in part A, section 5.1 provides a guide for when a disinfection process [thermal or chemical] can be used.)

Thermal disinfection

Thermal disinfection uses heat and water (moist heat) at temperatures that destroy most organisms. It is the most cost-effective and efficient method of disinfection. It is only suitable for items that can be fully immersed in water at high temperatures. All items must be fully immersed for the entire time once the water boils. Additional items must not be added during this boiling stage.

Table 3: Time/temperature ratios for thermal disinfection

Surface temperature (°C)	Minimum disinfection time (minutes)
90	1
80	10
75	30
70	100

Thoroughly clean and dry items before the thermal disinfection process (see part A, section 5.2.2).

Chemical disinfection

- All items that can be fully immersed in water may be disinfected in a chemical disinfectant solution.
- All items should be cleaned and dried before chemical disinfection (see part A, section 5.2.2).
- Fully immerse items for the time specified by the item/equipment and chemical manufacturer, then rinse them with distilled water and dry with a lint-free cloth.
- Wipe over nonimmersible items with a 70% alcohol solution, then dry them using a lint-free cloth.

It is essential to dry items fully after cleaning (before either wiping or immersing the item in a chemical disinfectant) because any moisture will dilute the solution, making it ineffective. Wiping instruments with disinfectants before use does not sterilise them. Instruments must not be stored in disinfectants before or after cleaning or sterilising.

Suitable equipment disinfectants

Suitable disinfectants are those with the following strengths:

- 70% w/w ethyl alcohol
- 80% v/v ethyl alcohol
- 60% v/v isopropyl alcohol.

Observe the use-by dates on all disinfectants, including those on decanted containers.

6. Sterilisation of reusable instruments and equipment

In addition to AS/NZS 4815:2001, an excellent reference is AS 2182:1998 Sterilisers – Steam – Benchtop.

This section of the guidelines outlines the process for steam-under-pressure sterilisation as the recommended process for businesses in the personal care and body art industries. Read and implement part A, section 5 before commencing any part of the sterilisation process.

Sterilisation is a validated process used to render an item free of all forms of viable microorganisms. Unless items are processed under controlled conditions, they will have microorganisms on them and, by definition, are nonsterile. The purpose of sterilisation is to destroy all of these micro-biological contaminants.

Sterilisation requires special training and skills to select the correct steam sterilisation process for the processed item, validate the sterilisation process and monitor each cycle. Skill, knowledge and understanding are required to interpret when the sterilisation cycle parameters (time, temperature and pressure) have been met, to interpret changes in both the chemical and biological indicators used to monitor the sterilisation process, and to decide the actions required to correct cycle failures. It is recommended that a business, unless its operators have received adequate training, should purchase sterilisation services from an appropriate local provider.

Steam is the most widely used and appropriate method of sterilisation in the personal care and body art industry. Steam sterilisation occurs when a combination of heat and moisture is maintained at a pre-set, temperature-pressure-time relationship. It coagulates cell proteins and efficiently kills all microorganisms, including spores. The available latent heat generated is responsible for the rapid destruction of microorganisms. It is nontoxic and more economical than other sterilisation methods.

6.1 Packaging of equipment to be sterilised

Do **not** handle cleaned items or packaging materials after recent use of a hand cream/lotion; wash hands first. Hand creams/lotions, especially oil-based ones, will leave marks that will attract contaminants and provide an impenetrable barrier to steam.

Items to be used sterile should be cleaned, dried and placed on fully perforated metal or plastic trays to allow steam to penetrate all parts of the package and its contents. Trays should be inserted into the package with the contents clearly visible through the laminate side of the packaging. Tray inserts to hold items in position are also available.

The tray can be used as a sterile surface during a procedure when either the paper or laminate side is fully removed. The use of an instrument tray may prolong the life of instruments as they are less likely to move around. Suitable fully perforated trays are readily available in various sizes and tip protectors that are steam penetrable are also readily available.

6.1.1 Packaging materials

The correct type and method of packaging must be used for the type of steriliser available; for example, sterilisers without a drying cycle must **not** be used for packaged items. Many different types of packaging are available, such as laminate/paper (pouches) or all-paper bags. All laminate/paper or all-paper packaging is single-use only. Nylon packaging is **not** suitable for use in a steam steriliser. Hollowware (bowls) should be packaged separately from instruments, with the opening facing the paper side of the laminate/paper packaging (pouches) to allow air to escape.

If drapes are used, then they should be single-use and packaged separately from all other items. Sterile single-use drapes are available commercially. Items should not be too heavy for the type of packaging used, because they may break the package, particularly if they are also sharp. Packages should not be overfilled. The tips of sharp items should be protected to maintain sharpness and to prevent damage to packaging. Bundling of items in the bottom of a package may inhibit air removal and steam penetration.

Do not use rubber bands around packages (or items within packages), because air/moisture will be trapped during sterilisation. The use of rubber bands to hold sterile packages together can cause crinkling and creasing that can weaken the paper packaging and compromise sterility. Items with ratchets/clips should not be sterilised in the locked position. Leaving items open allows steam to penetrate all surfaces during the sterilising process. If the integrity of a sterilised package is compromised, then the items should be completely reprocessed, commencing with the cleaning process. Packages must not be re-labelled and re-sterilised.

6.1.2 Labelling

Packaging must be dated and labelled immediately before being sterilised. Do not use a sharp pen or 'Biro' pen because it will damage the packaging material. Water-based ink pens should not be used, because they will 'run' during sterilisation. Each item being sterilised should have an identifying code for tracing steriliser faults if required. This code should be recorded on the sterilisation monitoring record (see part A, section 6.4).

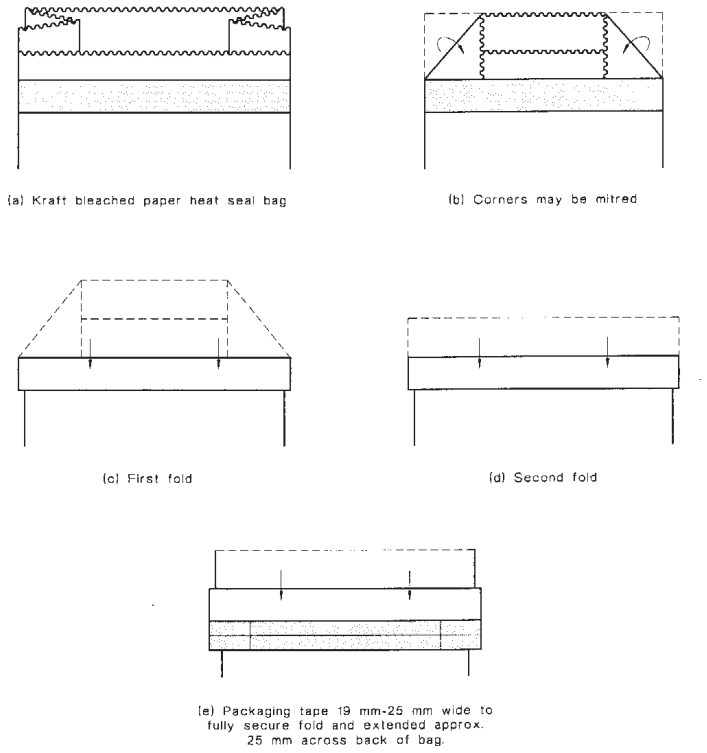
If items are not for immediate sterilisation, then the package must be dated only when the package is to be sterilised. Care should be taken to keep these packages separate from sterile items: they should be stored in a separate, clearly labelled cupboard or covered container. Best practice is always to sterilise items as soon as possible after packaging.

6.1.3 Sealing packaging

The most suitable packages are usually a laminate/paper material, and they are self-sealing using steriliser indicator tape or a heat-sealing unit. Steriliser indicator tape can be used to seal a package (usually a paper bag type). Steriliser indicator tape

should be pressure sensitive and clearly demonstrate a colour change after the sterilising process. The opening of a nonself-seal bag/pouch is to be folded over two or three times with the indicator tape so it is long enough to completely seal the front with a small fold to the back (see figure 4).

Figure 4: Sequential procedure for sealing bags with adhesive tape



Source: AS/NZS 4815:2001.

A heat-sealing unit may be used for sealing both laminate/paper and paper bags. Inspection of the package after heat sealing is essential to ensure the seal is complete, especially if pouch-type packaging is used, because air can be trapped inside and cause a 'popping' of the seal during sterilisation. A heat-sealing unit requires cleaning and servicing to ensure an efficient sealing action. The unit should be checked before sealing to ensure the temperature setting is correct. Scorching occurs if the temperature is too high, resulting in the packaging not withstanding the sterilisation process; if the temperature is too low, then sealing is defective and the sterility of the article is compromised.

Staples, string, nonadhesive tape, masking tape and elastic bands are not suitable as sealing agents.

- They do not provide a complete seal.

- They cause compression within the package, particularly during the sterilisation process.
- They cause damage to the outer packaging.
- They do not act as external indicators.

All packages should be checked after sterilisation to ensure integrity of the seal.

6.2 Sterilisation

6.2.1 General

The following equipment will not sterilise items, so do not use any of these items for this purpose.

- Microwave ovens
- Pressure cookers
- Incubators
- Ultraviolet cabinets
- Boiling water units
- Ultrasonic cleaners
- Household ovens
- Other similar units, such as pie warmers
- Dishwashers
- Glass (heat) bead 'sterilisers'

6.2.2 Steam sterilisation

Follow the manufacturer's instructions for steriliser use, for example only using distilled water, because each steriliser is designed to achieve specific sterilisation cycle parameters (time/temperature/pressure) that should not be altered without the manufacturer's agreement. Time, temperature and pressure settings reflect the type of load content and packaging materials to be used.

Sterilisers without a drying cycle must not be used for packaged items, but sterilisers with a drying cycle can be used. Sterilisers should have a sterilisation cycle process recorder/printer that monitors cycle parameters because this saves the proprietor/operator time during the sterilisation process. If a process recorder printer is not fitted, then every sterilising cycle must be monitored every 10 seconds and the time, pressure and temperature of every cycle must be recorded. Existing sterilisers without process recorder/printers should be upgraded or replaced to ensure automatic parameter (time/temperature/pressure) monitoring.

Table 4: Time/temperature/pressure relationships (parameters)

Temperature (°C)	KiloPascal	Millibar	psi *	Holding time (minutes)
121	103	1030	15	15
126	138	1380	20	10
132	186	1860	27	4
134	203	2060	30	3

** psi = pounds per square inch.*

Total processing time includes penetration time and holding time, plus a safety factor. Penetration time is the time taken for all parts of the load (inside the packaging) to reach the required sterilising temperature after the temperature has been reached in the sterilising chamber. These times and temperatures are based on the assumption that all items within the chamber are completely clean.

Steam sterilisers use gravity to remove air from the chamber by displacing it with steam. This is a relatively slow process, but some sterilisers have built-in mechanisms that assist this process by either pulsing additional steam into the chamber or using a vacuum and a pulsing action to withdraw the air.

Sterilisers should have their internal water reservoir emptied on a minimum weekly basis. The reservoir and pipes should be regularly cleaned. Sterilisers with a drying cycle use the internal chamber heat to dry items, but this only works when the door of the steriliser chamber is closed. This means the door must not be opened during the drying cycle. (Some sterilisers require a switch to be moved to initiate this drying stage.)

Packaged items that are still damp at the end of this drying stage must not be considered sterile and must be reprocessed. Check both cycle parameters and the method of chamber loading to ascertain the cause of cycle failure. The number of items per load should be limited to allow the sterilising cycle to work effectively.

Cannulated items and reusable tubing

These items and tubing pose a particular challenge to the sterilisation process with possible air (cannulated items) or air/water (tubing) entrapment during the sterilisation cycle. Air remaining in the steriliser chamber and/or cannulated items/tubing will prevent effective sterilisation, leading to sterilisation failure. Water remaining in reusable tubing will wet the packaging, rendering the tubing nonsterile. The use of single-use tubing is recommended.

6.2.3 Chemical and biological indicators

These indicators are designed to detect failure of the sterilisation process by monitoring one or more process parameters. The proprietor/operator should check with the steriliser manufacturer to ascertain the most appropriate type of indicator (chemical/biological) to be used, following AS/NZS 4815:2001. The type of indicator chosen will depend on the type of steriliser, packaging or cycle parameters,

including the presence or absence of a process recorder/printer, and on whether loads have been validated.

Chemical indicators

The manufacturer's instructions should be followed when using chemical indicators. The operator should discuss the most appropriate indicator for use (with both steriliser and indicator manufacturers), taking into account the types of item being sterilised, the type of packaging and the type of steriliser being used.

Chemical indicators are divided into six classes, and various indicators are available (see table 5). They should not be used, however, as a substitute for a permanent record of the sterilisation process. The exposed indicator may alter with time (for example, it may fade) and it is not reliable for record-keeping, so the result should be documented.

Chemical indicators should be used according to their classification, and a chemical indicator failure should be investigated to establish the cause of the failure of the sterilisation cycle before continuing to use the steriliser. Items from a sterilisation cycle with a failed chemical indicator must be re-cleaned and re-packaged before being re-sterilised.

Table 5: Classes of chemical indicators and their use

Class	Test for	Example of indicator	How used
Class 1	Evidence of a process	Indicator tape	With a single item–external indicator.
Class 2	Specific tests of the process	Air removal or Bowie Dick type test	Specific tests as per AS/NZS 4187:2003
Class 3	A specific parameter	Temperature	For one critical parameter essential to the sterilisation process
Class 4	More than one parameter	Temperature and time	For two or more critical parameters essential to the sterilisation process
Class 5	Integrating indicators	Time, temperature and moisture	React to all critical parameters over a specified range of sterilisation cycles, based on stated microorganism inactivation
Class 6	Emulating indicators	Cycle verification (134°C for 3.5 minutes in steam)	React to all critical parameters over a specified range of sterilisation cycles, based on the steriliser settings

Biological/enzymatic indicators

This type of indicator monitors the microbial killing power of the sterilisation process. Biological/enzymatic indicators may include bacterial spores, bacterial spores coated with an enzyme preparation, or enzymes extracted from bacterial spores. For steam sterilisation, the preferred test organism is *Geobacillus stearothermophilus* (formerly *Bacillus stearothermophilus*).

As a minimum biological/enzymatic indicators must be used after the installation of the steriliser, after major repairs and as part of validation procedures. Failures, when growth is detected, must be investigated before continued use of the steriliser. Items from a sterilisation cycle process with a failed biological/enzymatic indicator must be re-cleaned and re-packaged before being re-sterilised.

Incubation of biological/enzymatic indicators should be used according to the manufacturer's instructions (incubation kits are available from manufacturers). An indicator not exposed to the sterilisation process is incubated as a control for the exposed biological/enzymatic indicator. A permanent record of these results should be kept on file.

6.2.4 Loading the steriliser

Correct loading of the steriliser is essential for effective sterilisation: correct loading techniques permit efficient air removal from the chamber, total steam penetration and saturation of all items, allow drainage of condensate, assist in the drying stage and reduce damage to packaging. In effect, correct loading maximises efficient steriliser use. Items should not exceed the boundaries of the loading tray within the chamber and should not touch the walls of the chamber (because this will bring them into contact with condensate on the chamber walls).

Hollowware (bowls) should be tilted on their side to permit drainage of both air and condensation during the sterilisation process, and linen should be loaded so the layers are vertical for efficient air removal and steam penetration. Hollowware or instrument packages should not be loaded above linen because any condensation will wet the linen/packaging, making it difficult for steam to penetrate the linen/packs and sterilise the items.

Packaging of laminate/paper design should be positioned on its edge, with each package surface being paper to laminate. Do not place too many packages together because air removal and steam penetration may be compromised; however, they may be laid flat on the loading tray in a single layer with the paper side downwards on the tray surface. Items to be processed unpackaged may be laid directly on the loading tray in a single layer, but do not over fill the tray with items.

6.2.5 Unloading the steriliser

Sterilisers with a drying cycle

Once the sterilising (including drying stage) cycle is complete, the load should be removed immediately from the chamber and visually inspected to ascertain that the load is dry, that the indicators used have changed to the required colour and that the seals are intact. Unpackaged items should not be directly handled, because this would render the item unsterile. All other parameters (time, temperature, pressure) must be checked, then recorded and signed as correct by the operator removing the load.

Items should be placed in an area where disturbance is minimal, to cool down. Forced cooling is not permitted because it will compromise the integrity of the item

and its packaging. Items should not be placed on solid surfaces during this cooling phase, because condensation will result from vapour still inside the package. Wet packaging, dropped items or nonintact seals mean the item cannot be considered sterile and must be re-cleaned, re-packaged and re-sterilised.

Sterilisers without a drying cycle

Removal of these items depends on whether the item is intended for immediate use or for storage. Items for immediate use as sterile items must be removed using sterile gloves (the nontouch [aseptic] technique – see part D, Glossary.) Items for storage should be dried with a single-use lint-free cloth before being stored. It should be noted that unpackaged, stored items must not be used as sterile items and must be reprocessed prior to use.

6.3 Storage of sterile items

All sterilised packaged items should be stored in a way that will prevent contamination and damage to packaging. Storage may be in cupboards with close-fitting doors and smooth washable surfaces, or in washable plastic containers with close-fitting lids. Cupboards and containers should be dust free, used only for sterile items. (Cupboards should be cleaned and dried weekly, and the cleaning process should not compromise sterility of the item.)

Ultraviolet cabinets are **not** suitable storage places. The ultraviolet rays act only on surfaces that they contact, and they damage packaging compromising sterility. Cardboard boxes are not suitable containers for storage of sterile items because they are porous, cannot be cleaned and may harbour harmful microorganisms. Items purchased sterile from commercial sources require similar storage conditions to those items sterilised in-house.

Sterile stock is event related (see part D, Glossary), and influential factors include the shelf life of the type of packaging material used, the type of storage and handling conditions (the likelihood of product material deterioration and package design).

All premises should develop a system of stock rotation based on either the date of sterilisation or the steriliser load number. Packaging is considered nonsterile and unsuitable for use when: it is incorrectly wrapped; it has been opened or damaged; it is still wet after the sterilising cycle; it has been placed on a wet surface; it is placed or dropped onto a contaminated surface such as the floor; or there is no indication that it has been through a sterilising process.

Factors that compromise sterile stock include incorrect cleaning procedures in storage areas, the presence of moisture and condensation, climatic extremes, excessive exposure to sunlight or other sources of ultraviolet light, vermin or insects, inappropriate packaging materials, incomplete sealing of packaging, the presence of sharp objects or rough handling causing damage, and incorrect handling during transportation.

6.4 Monitoring/maintenance of the steriliser and associated equipment

6.4.1 Sterilisers

Monitoring of sterilisers

Sterilisers require commissioning on installation before being used. Commissioning involves testing the steriliser cycle parameters for performance on-site. Performance testing (or validation – see part D, Glossary) of the sterilising cycle parameters must be undertaken on installation, after routine servicing, after major repairs and when validating steriliser loads and packaging materials. Routine calibration testing must be performed at least every six months.

Monitoring of the sterilising process includes the cycle parameters (time, temperature, pressure), chemical indicators (results) and/or biological/enzymatic indicators (results), load contents and load number, date and time. Steriliser service records must be maintained, including those completed during calibration testing.

Maintenance of sterilisers

Sterilisers should be cleaned weekly and when soiled, and maintained in strict accordance with the manufacturer's recommendations. The chamber drain should be kept clear and the recording device should function correctly. All gauges should be accurate and the door gasket should be intact.

The loading trays should be cleaned daily and the steriliser should be cleaned when cool enough to permit the chosen cleaning agent to work efficiently and to prevent occupational health and safety hazards.

6.4.2 Heat-sealing units

Heat-sealing units should be cleaned weekly and tested daily to ensure the operating temperature is correct. The package seal must be checked before and after sterilisation.

6.4.3 Records

See part E, appendix 3.

6.5 Validation of steriliser loads

Validation is a process that must be documented. It includes identification of the steriliser, the process parameters (time, temperature, pressure), steriliser chamber characteristics (such as hot and/or cold spots), the types of item being routinely sterilised, and details of the cleaning and packaging processes used with the items being sterilised.

Three successful, consecutive and identical loads are required for a demonstrated validated cycle, although routine monitoring of the steriliser cycle is still required. Validation must be repeated if changes occur in the type of packaging used, major servicing of the steriliser is performed, the package contents are changed, or the routine load or cycle parameters are changed (see part E, appendix 3 for information on validation procedures).