

23 October 2015

Dear practitioner

Consultation on a proposed Infection Prevention and Control Practice Standard

The Dental Council ('the Council') established the Cross Infection Working Group ('working group') to assist in the review of the Council's current Control of Cross Infection Practice Standards. The working group was tasked to investigate and report on local and international cross infection standards and guidelines, and develop a single practice standard for all registered oral health practitioners.

The working group's report and recommendations were considered by the Council, and the draft Infection Prevention and Control Practice Standard approved for consultation with stakeholders.

The Council now seeks your feedback on the proposed Infection Prevention and Control Practice Standard, provided as Attachment 1.

In accordance with the Council's Guidelines on Consultation, the consultation document has been made available to all practitioners, relevant associations and societies, the Ministry of Health, District Health Boards, educational institutions and other organisations with an interest in this area. The consultation document will also be published on the Council's website, with a similar invitation to comment.

Submissions

Stakeholders are invited to comment on the proposed Infection Prevention and Control Practice Standard by responding to the following questions:

- Q1. Do you agree/disagree with the proposed Infection Prevention and Control Practice Standard? If you disagree, please detail why.
- Q2. Does any element of the proposed Infection Prevention and Control Practice Standard require clarification or further guidance? Please explain.
- Q3. Do you have any further comments on the proposed Infection Prevention and Control Practice Standard?

All submissions received will be published on the Council's website shortly after receipt, and will remain there as a public document. For submissions made by individuals, only your name and profession, if you are a registered health practitioner, will be published on the Council's website. All contact details will be removed from your submission.

As this is a public consultation, "In confidence" information will only be accepted under special circumstances. Contact the Council before submitting this material. The Council holds the right not to publish any derogatory or inflammatory submissions.

The Council seeks any comments on the proposed practice standard by the close of business on **18 December 2015**.

Responses should be sent to:

Dental Council
PO Box 10-448
Wellington 6143

Fax: 04 499 1668
Email: consultations@dcnz.org.nz

Yours sincerely



Marie Warner
Chief Executive

Consultation Document for the proposed Infection Prevention and Control Practice Standard

Issued: 23 October 2015

Submission closing date: 18 December 2015

Proposed Infection Prevention and Control Practice Standard

1. Introduction

In November 2014 the Dental Council ('the Council') established the Cross Infection Working Group ('working group') to assist in the review of the Council's current Control of Cross Infection in Dental Practice – Practice Standards.

The working group members were:

- Andrew Gray: Dental Council member, Chair
- Sharon Boutell: Dental hygienist
- Michael Holdaway: Dentist
- Brent Norton: Dental technician/ Clinical dental technician
- Diane Pevreal: Dental therapist
- Megan Sharpe: Subject-matter expert- private practice environment
- Shelagh Thomas: Subject-matter expert – public practice environment.

The working group considered the Australian/New Zealand standards related to reprocessing of reusable medical devices¹; the New Zealand Dental Association's code of practice, the Australian Dental Association's guidelines; and other international guidelines/standards related to this area.

The documents reviewed and considered by the working group are listed in the Bibliography provided at the end of the consultation document.

The working group's report and the draft Infection Prevention and Control Practice Standard were considered by the Council at its meetings in April and May. The Council decided to defer the consultation on this practice standard until the Standards Framework for Oral Health Practitioners had been fully embedded.

2. The Infection Prevention and Control Practice Standard

The purpose of the proposed Infection Prevention and Control Practice Standard ('practice standard') is to set minimum standards that must be observed by all practitioners to:

- (i) Eliminate or reduce the number and quantity of infectious agents in the oral health practice environment; and
- (ii) Prevent the transmission of infectious agents from any person within the practice environment to another; and from one item or location to another item, location or person.

¹ AS/NZ 4815:2006: Australian/ New Zealand Standard Office-based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment and AS/NZ 4187:2014: Australian/ New Zealand Standard Reprocessing of reusable medical devices in health service organisations.

The Infection Prevention and Control Practice Standard contains:

- The minimum standards related to infection prevention and control that all registered oral health practitioners² ('practitioners') **must** meet; and
- Compliance measures describing the actions and behaviour that enable practitioners to meet the minimum standards.

The standards are presented in five parts:

- I: Standard precautions
- II: Reprocessing of reusable items
- III: Performance testing, maintenance and validation
- IV: Blood or body fluid exposure procedures
- V: Documentation and Education.

Some introductory comments appear throughout the practice standard to give added context to particular standards. Those comments do not form part of the standards.

3. Summary of principal changes within the draft practice standard compared with the current versions

3.1 Hand hygiene and personal protective equipment

The content in the draft practice standard related to hand hygiene reflects the emphasis given to the role of hand hygiene in preventing transmission of infectious agents, and the contemporary use of alcohol-based hand rub (ABHR) as the preferred method of hand hygiene when hands are not soiled.

The compliance measures of the draft practice standard state fluid resistant masks³ are to be worn as a protective barrier during any procedure that could result in the production of aerosols and/or droplets (splashes or sprays), to minimise the transmission of infectious micro-organisms.

It is also states in the compliance measures that masks be changed between patients or when damp, wet, or visibly contaminated during treatment; this is consistent with the known decline in filtration capabilities of a mask following exposure to moisture.

Further details can be found in practice standards 1, 2 and associated compliance measures.

² Dentists, dental specialists, dental hygienists, dental therapists, clinical dental technicians, dental technicians and orthodontic auxiliaries.

³ Which meet AS/NZS 4381 standards

3.2 Environmental controls – use of chemical disinfectant agents

The compliance measures of the draft practice standard state all work surfaces in the various contaminated zones in the dental practice environment, and equipment surfaces are to be cleaned with a neutral clinical detergent prior to patient treatment.⁴

Barrier protection may be used for surfaces and equipment within the contaminated zone that are difficult to clean. If used, barrier protection is disposed of after each patient, equipment surfaces cleaned, and new barrier placed.

The risk of transmission of infectious agents from environmental surfaces following appropriate and effective cleaning procedures is negligible, and for that reason the draft practice standard does not require disinfection of these surfaces prior to patient treatment, or in-between patients, in its compliance measures.

Effective disinfection of the dental environment is achieved by following the product manufacturer's specifications for use. This typically includes: applying the disinfectant to a pre-cleaned and dried surface; preparing to the correct dilution; and being left in contact with the surface being disinfected for the correct length of time. Due to the limited time available between patients, effective disinfection of environmental surfaces in the dental environment might typically only be achievable at the beginning of the day, at the end of a clinical session, and at the end of the day.

Further details can be found in practice standards 5, 6 and associated compliance measures.

3.3 Reprocessing requirements for reusable items

Practitioners must ensure they use reprocessing procedures appropriate for the intended use of contaminated reusable items.

Reusable items are categorised in the draft practice standard using the Spaulding classification system which classifies items according to the risk of transmission of infectious agents associated with their intended use. Examples of critical, semi-critical and non-critical items related to dental practice are included in the draft practice standard to assist practitioner's understanding of the classification system, and reprocessing procedures for each category are given.

Classification of items may change depending on the intended use of the item, for example dental tweezers may be classified as critical or semi-critical.

Periodontal instruments have been included in the example list of critical items. The Council considers there is a significant risk these items might enter into sterile tissue during use; hence their classification as critical items.

The compliance measures for the reprocessing of reusable items within the draft practice standard are as follows:

- Reusable critical items must be cleaned, packaged prior to sterilisation, sterilised and stored in a manner that maintains sterility of the packaged item up until its point of use. Critical items require batch control identification.
- Reusable semi-critical items must be cleaned and sterilised, and stored in a manner that prevents contamination before re-use; packaging prior to sterilisation is not a requirement.

⁴ Neutral detergents are indicated for use in cleaning environmental surfaces as they leave little residue and are less likely to damage metal surfaces than acidic or alkaline detergents.

- Reusable non-critical items must be cleaned, may be disinfected, and do not require sterilisation.

The classification of single-use items in the draft practice standard acknowledges that even if a critical or semi-critical item is classified as reusable and deemed capable of sterilisation by the manufacturer, if the item cannot be adequately cleaned then it cannot be effectively sterilised, and that item is regarded as single-use. Examples of items to be treated as single-use are given: matrix bands, endodontic reamers, barbed broaches and files (with the exception of nickel-titanium files, if the verified process provided as Appendix B of the practice standard is followed).

Further details can be found in practice standard 11 and associated compliance measures.

3.4 Cleaning of contaminated reusable items

Automated cleaning is indicated as the preferred cleaning method in the draft practice standard, as the process is verifiable. Automated cleaners include ultrasonic cleaners and instrument washer-disinfectors.

Disinfection is not a necessary step in the safe reprocessing of critical and semi-critical items. (Details in practice standard 13 and associated compliance measures).

3.5 Steam sterilisation and cycle monitoring

The draft practice standard requires all reusable critical and semi-critical items to be sterilised using a steam steriliser with an appropriate cycle type/s, equipped with a data recording device⁵ and/or printer.

The requirement for a data recording device and/or printer ensures verifiable data is accurately recorded for monitoring purposes. The purpose of sterilisation cycle monitoring is to verify that the physical parameters (time, temperature and pressure) have been met, as the indicator that the steriliser has functioned satisfactorily. Monitoring of every sterilisation cycle and permanently recording the result are requirements in the AS/NZS Standards⁶.

To implement the requirement for a steam steriliser to have a data recording device and/or printer, it is proposed that dental practices⁷ will have up to two years from the time of implementation of the updated practice standard to meet the requirement.

- A proviso is proposed in the draft practice standard that dental practices sterilising ONLY solid, unpackaged semi-critical items, with a steriliser not capable of being fitted with a data recording device and/or printer, be required to meet the above requirement at the time of purchasing a replacement steriliser.

This requirement within the draft practice standard, the two year lead-in period for compliance, and the proviso as described above, are based on the recognition that:

- The most precise method of verifying that the required physical parameters for the sterilisation cycle have been met is to check and confirm the record of these parameters.

⁵ Data recording devices may include process recorders, data loggers or electronic storage devices.

⁶ AS/NZ 4815:2006: Australian/ New Zealand Standard Office-based health care facilities – Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment & AS/NZ 4187:2014: Australian/ New Zealand Standard Reprocessing of reusable medical devices in health service organisations.

⁷ The “dental practice” is defined as all settings in which registered oral health practitioners perform activities associated with their scope of practice.

- The intended use of a critical item carries with it a greater risk of transmission of infection, and hollow items provide a greater challenge to the sterilisation process.
- With the modified requirements for annual performance re-qualification of the sterilising process as described in the draft practice standard , a precise method for verifying that physical parameters have been met for every sterilisation cycle are of heightened importance.
- Costs are likely for practitioners/ practices in meeting this requirement.
- An adequate alternative to a data recording device and/or printer which meets the requirements of the Standard: AS/NZS 4815:2006, can be used in the interim (Class 4, 5, or 6 chemical indicator), thus ensuring continued patient safety.

Further details can be found in practice standards 15-17 and associated compliance measures.

3.6 Validation

Validation consists of 3 stages: Installation qualification (IQ); Operational qualification (OQ); and Performance Qualification (PQ).

Owing to the nature of IQ and OQ, a qualified contractor performs IQ and OQ on-site, and the calibration status of the reprocessing equipment is first confirmed to verify the accuracy of the measurements to be taken.

PQ of the sterilising process is performed by a qualified contractor with the appropriate training and equipment to meet ISO 17665-1 standard, in conjunction with a practice staff member/s, on-site. The need for this approach relates to the nature of the PQ process which involves steps that can only be performed by a qualified contractor (thermocouple testing) and process steps specific to the practice which require a practice staff member to ensure the authenticity and reproducibility of the process (packaging; load configuration of the steriliser; instruments used; and checking the completed load).

The AS/NZS Standards require annual performance qualification.

The working group has highlighted that current compliance with validation requirements are poor and believes that a pragmatic, staged approach is needed to improve compliance, thus changing behaviours and ultimately lifting standards in this area.

With this in mind, the process in the draft practice standard for annual performance re-qualification of the sterilising process is a modified PQ process; it mirrors all the normal PQ process steps, without the thermocouple testing, and may be performed by practice staff.

The Council believes that the key principles of performance qualification remain supported by this abridged approach, which may be re-visited by the Council in the future. (Details in practice standard 21 and associated compliance measures).

3.7 Modification of dental appliances

The draft practice standard contains a standard and compliance measures related to the handling of dental appliances, especially those in-use, aimed at minimising the risk of transmission of infectious agents from this source.

Similar to the validation requirements, a pragmatic approach to this environment was taken to increase compliance and ultimately lift the standards to protect the safety of the public. (Details in practice standard 9 and associated compliance measures).

Consultation Questions

Stakeholders are invited to comment on the proposed Infection Prevention and Control Practice Standard by responding to the following questions:

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- Q2. Does any element of the proposed Infection Prevention and Control Practice Standard require clarification or further guidance? Please explain.
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Bibliography

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