national standards

NS 10010

NATIONAL STANDARD

ACCREDITATION OF COSMETIC CLINICS

Version: 2007

This National Standards' document is copyright protected by National Standards Pty Ltd. The reproduction in any form is not permitted without prior permission from National Standards Pty Ltd, neither this document nor any extract from it may be reproduced, stored or transmitted in any form for any other purpose without prior written permission from National Standards Pty Ltd.

National Standards Pty Ltd
Unit 25, 28 Barcoo Street
Roseville NSW 2069 Australia

Tel: 02 9406 8588
Fax: 02 9406 8556
ABN: 40 108 929 317

1. FOREWORD ... **3**

2. INTRODUCTION (INFORMATIVE) ... **4**

3. SCOPE ... **4**

4. RELATED DOCUMENTS ... **5**

5. DEFINITIONS ... **5**

6. ACCREDITATION CRITERIA (NORMATIVE) ... **7**

6.1 PATIENT CARE REQUIREMENTS ... 7
6.1.1 General ... 7
6.1.2 Patient journey ... 8
6.1.3 Patient records including electronic records ... 10
6.1.4 Patient feedback ... 10
6.1.5 Infection Control ... 11
6.2 ORGANISATION AND MANAGEMENT SYSTEMS REQUIREMENTS ... 11
6.2.1 Insurance ... 11
6.2.2 Governance ... 11
6.2.3 Planning and review ... 12
6.2.4 Internal audits ... 12
6.2.5 Information management ... 13
6.2.6 Incident management and reporting ... 13
6.2.7 Benchmarking outcomes ... 14
6.3 PERSONNEL RESOURCES REQUIREMENTS ... 14
6.3.1 Competence and credentialing ... 14
6.3.2 Training needs and monitoring ... 15
6.3.3 Doctors in post graduate training ... 15
6.3.4 Medical and nursing staff ... 15
6.3.5 Minimum staff and competences ... 15
6.4 EQUIPMENT REQUIREMENTS ... 16
6.4.1 Equipment maintenance and calibration ... 17
6.4.2 Equipment records ... 17

Copyright National Standards Pty Ltd 2005

1. Foreword

National Standards is a national, transparent and democratic forum for industry and community groups to develop, maintain and publish standards which benefit trade, communities and society. It is a not-for-profit company, established by stakeholders interested in standards development.

The National Standards Governing Council oversees National Standards policies generally, and specifically, the development, updating, approval and distribution of standards published by National Standards. Members are selected for their industry or policy-making involvement in standards development and/or regulatory sectors, reflecting the markets and communities within which National Standards operates. All major stakeholders are given the opportunity to participate on Council, while maintaining balanced representation so that no single interest can predominate.

This National Standard is being developed by National Standards Technical Committee [PP10].

Interested parties represented on this committee comprise:

- Health funding providers
- Surgeons
- Physicians
- Nursing representatives
- Consumers
- Accreditation provider

Sections of the text marked "informative" are for information and guidance only.

Copyright National Standards Pty Ltd 2005

2. Introduction (informative)

This standard was initiated in mid 2004 as a result of a request from industry and industry stakeholders for the definition of minimum accreditation criteria for cosmetic clinics in Australia.
The project was undertaken with contribution from industry including funding providers, nursing professionals, doctors and equipment providers.

3. Scope

This National Standard provides a model and framework for the accreditation of cosmetic clinics in Australia. It is not expected that this standard will be mandated, and may or may not be used as the basis of accreditation or certification, as a tool to demonstrate compliance.

Compliance with the standard should complement compliance with applicable regulations, legislation, circulars or other regulator or funding provider requirements.

This standard is designed to apply to clinics which are supervised by a medical practitioner. (It does not apply to, for example, beauty therapy clinics or hair removal clinics).

This standard does not cater for procedures with conscious sedation or general anaesthesia.

Copyright National Standards Pty Ltd 2005

4. Related documents

AS/NZS 4187: Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.

AS/NZS 2243.5: Safety in laboratories - Non-ionizing radiations - Electromagnetic, sound and ultrasound, together with applicable States or Territory requirements (Code of Practice or Regulations).

AS/NZS 2211.1: Safety of laser products - equipment classification, requirements and users guide.

AS/NZS 4173: Guide to the safe use of lasers in health care

State or Territory requirements (Code of Practice or Regulations).

5. Definitions

ACCS: The Australasian College of Cosmetic Surgery. Fellows of ACCS (FACCS) and Fellows of the Faculty of Medicine ACCS (FFMACCS) have undergone a formal education program and have successfully passed examinations to gain their accreditation. ACCS requires a continuing medical education process which is targeted to cosmetic procedures.

Accreditation: Independent process of review and audit to verify conformance with this standard.

Cosmetic Clinic: Centre offering cosmetic treatment(s).

Cosmetic: Treatment which is not medically necessary but is intended to alter or improve a person's appearance. A patient initiated procedure to alter/improve appearance.

Copyright National Standards Pty Ltd 2005

Cosmetic Registrar: Fully qualified and registered medical practitioners who are enrolled in an ACCS Fellowship training program (FACCS) or Fellow of the Faculty of Medicine ACCS (FFMACCS).

CPSA: The Cosmetic Physicians Society of Australasia.

Management System: A set of documented policies, procedures, forms and records to support the day to day planning, management and delivery of care within the clinic.

Medical Practitioners: Appropriately trained and registered medical practitioners.

Nursing Staff: Qualified Nurse registered with the nursing council or board in the particular state. E.g. registered nurse or enrolled nurse.

Simple Sedation: the administration of one or more drugs to a person, that depress a person's central nervous system, to allow a procedure to be performed on the person by a medical practitioner in a way that

a) allows communication with the person to be maintained while the procedure is being performed; and
b) makes loss of the patients consciousness unlikely

Source Private Health Facilities Act 1999 Queensland Health Page 12, Division 2 section 10

Supervisor: Qualified and recognised medical practitioner who provides supervision and monitoring of patient care (supervision includes medical supervision during the delivery of care).

Copyright National Standards Pty Ltd 2005

6. Accreditation Criteria (Normative)

6.1 Patient Care Requirements

6.1.1 General

The clinic should have policies in place which incorporate and recognise that patients:

- Have the right to make an informed decision regarding their care/management including the right to decline treatment.
- Have the right to know all of the costs of services prior to their appointment.
- Have the right to privacy and confidentiality regarding their medical conditions/visits to the practice.
- Have the right to obtain a second opinion on their care.
- Have the right to make formal complaints through the appropriate channels.
- Have the right to be advised of significant risks and complications.
- Are responsible, when asked, for disclosing their medical history and history of previous cosmetic procedure(s).
- Are responsible for payment of all costs for services provided to them.
- Are responsible for bringing referrals, x-rays, scans and other medical information to assist clinicians in prescribing suitable treatment.
- Are responsible for asking questions if they are unsure of any aspect of their care.

Both clinic and patient should recognise that perfection is not an expected outcome and no guarantee of a particular result can be promised.

Copyright National Standards Pty Ltd 2005

6.1.2 Patient journey

Patients should be given accurate information in response to their enquiries. When patients are not seen in person they should be informed of the limitation of clinical advice which can be given prior to being assessed face-to-face.

When an appointment is made, the patient should be told at the time, who they will be seeing, the location of the clinic and the consultation fee. The patient should also be informed that only the most minor of procedures could be performed at the time of the initial consultation, e.g. those requiring minimal down time and those requiring no preparation time on the part of the patient or clinic.

On arrival for a first appointment, staff should ensure the correct details for the patient are on file or obtained. If there is a delay, staff should inform the patient of the likely duration of waiting.

During the consultation, the patient's presenting concerns should be elucidated and possible treatments discussed. This should not be limited only to the treatments available at the clinic. The likely outcomes and significant side effects should be discussed.

If a decision is made about which course of action to take, appropriate arrangements should be made for the procedure, referral or future consultation. If no decision is made, or the patient decides not to proceed at that time, the patient should be allowed to leave with clinic contact details in case of further questions.

The patient is to be assessed in person by the medical practitioner prior to performing any procedure. Consideration should be given as to whether any procedure should be performed at the first consultation. The medical practitioner performing the procedure should conduct any discussion regarding treatment including the explanation of relevant material risks and alternatives to the proposed procedure. Information processes should include

Copyright National Standards Pty Ltd 2005

reference to a cooling off period. Appropriate records of all consultations and discussions and treatment plans should be maintained.

When a procedure is planned, the patient should be made aware of necessary preparation, the time and location of the procedure, how long it is likely to take, how he or she will look and feel afterwards and the post-procedure care and follow-up. The patient should be made aware of the possibility of needing time off work for recovery.

The patient should also be made aware of the cost and how and when payment is expected. If the patient should not drive or should have a responsible accompanying adult with him/her afterwards, this should also be ensured.

On arrival at the clinic for a procedure, contact details should be checked for accuracy and the nature of the procedure confirmed.

If required the patient should be escorted to a preparation area and preparation begun, e.g. anaesthetic cream applied.

The patient should have any questions answered and sign an appropriate consent form prior to any treatment.

Following the procedure, the patient should be provided with contact details for the clinic including an after hours contact number.

If the patient has received any centrally-acting sedatives or anaesthetic agents, he or she should be released to the care of a responsible adult once the staff are satisfied with the physical and mental state of the patient. There should be documented discharge criteria, and a record of the patient assessment against these criteria.

It is the responsibility of the medical practitioner to discharge patients. If the medical practitioner is unavailable in the post procedure period then there needs to be trained and credentialed personnel to whom this responsibility can be delegated. Records of the delegation and credentialing of that person should be documented and available.

Copyright National Standards Pty Ltd 2005

Arrangements should be made for follow-up, appropriate to the procedure.

In the event of a clinical emergency at the clinic the doctor should be contactable and resuscitation equipment available appropriate for the types of procedures performed. For after-hours emergencies, the doctor or an appropriate service should be readily available and the patient should have these contact details.

6.1.3 Patient records including electronic records

The clinic should identify, define and document the type of records, recording system, retention period and access restrictions for all records which relate to the governance and management of the clinic and its management system of all patient care. This applies to records kept on site or at a remote location.

The above requirement should also include electronic records, which should have sufficient controls to ensure these are safe, secured and cannot be altered once generated and approved.

In defining the retention period and control parameters the clinic should comply with the applicable standards and regulations.

6.1.4 Patient feedback

The clinic should have a documented strategy to seek patient feedback. This is to ensure that patients have the ability to express their views about the clinic, staff, processes, level of care and treatment outcomes.

If a sampling method is used in the selection of patients to be surveyed, the sampling should ensure that no bias can occur.

Patient feedback should provide quantifiable data comparing patient expectations with outcomes.

Copyright National Standards Pty Ltd 2005

The Clinic should have a documented process for dealing with grievances and complaints: this process should be effective in dealing with first line resolutions. This could also include an action plan for responding to needs identified through feedback mechanisms.

6.1.5 Infection Control

The clinic should have infection control practices and equipment which comply with AS4187.

This would include hand washing, personal hygiene, non-re-use of disposable items, training in aseptic technique and competencies.

6.2 Organisation and management systems requirements

6.2.1 Insurance

The clinic should maintain up to date records of the following insurance policies:

- Professional Indemnity for the doctor, the clinic and/or contracted staff as appropriate; and
- Public Liability

6.2.2 Governance

The clinic should have a medical governance framework.

If the clinic does not have a Medical Advisory Committee it should maintain and be able to provide records of external peer review of its medical practices and officers, via a reputable and duly recognised external organisation.

If the clinic has a Medical Advisory Committee, the composition of the committee should be representative of the clinic's practitioners, nursing and management staff, and should ensure that no interest dominates. Meetings should be held regularly and minuted.

Copyright National Standards Pty Ltd 2005

The management structure, roles, responsibilities, authorities and reporting channels of the various positions within the organisation should be defined and documented.

An "accreditation representative" should be appointed by, and report to, the designated medical practitioner of the clinic and be the central coordinator for all accreditation matters, including compliance with this standard. This position should also have the organisational freedom and authority to;

- report breaches of the standard,
- review patient care incidents or accidents (either actual or potential), and
- review patient feedback data.

6.2.3 Planning and review

The clinic should have a planning process to include;

- patient care methods and procedures review,
- equipment maintenance,
- internal audits,
- staff training, education and competence review,
- review of management system documentation, and
- review of patient information.

The planning process should ensure that the performance of the clinic is reviewed regularly, based on its plans and targets, and also patient/outcomes data and analysis.

6.2.4 Internal audits

The clinic should conduct regular internal audits of its activities against its internal policies and procedures, legislation and circulars, as appropriate.

Copyright National Standards Pty Ltd 2005

Audits should be undertaken by a person who is competent as an internal auditor.

Actions arising from the audit should be formally reported, and processed.

6.2.5 Information management

The management system of the clinic should demonstrate evidence that:

- It has been reviewed and approved before being released and used within the Clinic (this also applies to revisions of the system)
- It is distributed on a controlled copy basis within the Clinic, and is maintained up to date.
- Staff members are trained in the updates to the system, and have the ability to make or request changes.

The Clinic should have a system to access, review for relevance (and take actions as appropriate), and store external documents (standards, codes, legislation, circulars etc).

6.2.6 Incident management and reporting

The clinic should have in place documented procedures for medical and non-medical emergencies.
The clinic should have a procedure in place to record and manage incidents, accidents, failures, complaints and other unexpected variations, either actual or potential.

The procedure should ensure that;

- such issues are identified,
- immediate action is taken,
- the effectiveness of action is followed up,
- an investigation of the cause is undertaken,

Copyright National Standards Pty Ltd 2005

- if appropriate and given the risks involved, action to prevent re-occurrence is identified (including system/training changes), and
- action to prevent re-occurrence is followed up, to ensure it is effective.

Records should be available to demonstrate that the above have been undertaken.

6.2.7 Benchmarking outcomes

The clinic should have systems in place to validate and benchmark its patient outcomes and processes. This should involve the definition, collection, sharing and review of key performance indicators.

The outcome of the review should be documented and support the decision making process, including review of the clinic operation, equipment, staffing, training, systems and processes as appropriate. Refer to Planning and Review.

6.3 Personnel resources requirements

6.3.1 Competence and credentialing

The clinic should credential all medical and nursing staff including visiting practitioners, locums and agency staff. All attending staff should not only provide documented evidence of training but also be assessed as competent before performing procedures (records of credentials, reviews and competencies should be maintained).

All staff (including non medical/ nursing personnel) who work in a procedural facility should be regularly trained in CPR, emergency procedures.

The clinic should maintain credential records of medical and nursing staff. These should be maintained up to date and reviewed at least yearly.

Records should include:

- Registration with relevant industry board or college.
- Insurance details.

Copyright National Standards Pty Ltd 2005

- Referral and peer review records.
- Immunity to Hep B.

The review process is aimed at ensuring that medical and nursing staff are and remain fit to undertake work within the clinic.

6.3.2 Training needs and monitoring

The clinic should have procedures in place to assess staff in identifying their key competences (including administration and support staff), and to identify training or education needs. This in turn should be used to plan the delivery of training and education, and for the maintenance of records.

The above procedures should include emergency, infection control and fire safety, together with induction and training into the clinic, its equipment, patients, systems and processes.

Identified or mandated training needs must be completed within 12 months.

6.3.3 Doctors in post graduate training

The clinic should comply with the standards set published by the ACCS, or other relevant training authority. Should a conflict exist between the standards the higher requirement shall be applied.

6.3.4 Medical and nursing staff

The clinic should ensure continuing cosmetic medical and/or cosmetic surgical education of all medical and nursing staff and maintain such records. All nurses should be able to show evidence of training in the particular area, e.g., injectables, skin care, peels, microdermabrasion, laser and IPL, as appropriate).

6.3.5 Minimum staff and competences

The clinic should ensure that the following staff are on duty and resources available to support patient care.

Copyright National Standards Pty Ltd 2005

Based on the level of sedation, the minimum staff/competences in the clinic during procedures should be:

No anaesthesia	Local anaesthesia	Simple sedation
Registered nurse, doctor or appropriately trained technician	Registered nurse or doctor	Registered nurse or doctor
Fire trained	Fire trained	Fire trained
		CPR trained
		Doctor in the clinic

6.4 Equipment requirements

The following table defines the minimum equipment levels for each type of clinic (the equipment should be owned or leased by the clinic, and in place for each procedure undertaken by the clinic).

No or local anaesthesia	Procedures with simple sedation
Procedure room – no size limit. Adequate lighting.	Procedure Room with impervious vinyl flooring. Adequate lighting.
Hand washing sinks and appropriate antiseptic wash.	Stainless steel washing sinks with hands free taps and appropriate antiseptic wash.
Table/bench/chair- height appropriate	Table/ bench /chair- height appropriate
Medical standard trolleys as required	Medical standard trolleys as required
Consumables, needles, syringes, dressings etc.	Consumables, needles, syringes, dressings, etc.
NA	Sterilizer with contaminated wash area and separate clean wrap area.
Storage area for stock away from heat and moisture.	Storage area for stock away from heat and moisture.
NA	Storage area for equipment.
Laser room with safety signage, appropriate wavelength specific protective eyewear and smoke evacuator if relevant.	Laser room with safety signage, appropriate wavelength specific protective eyewear and smoke evacuator if relevant.
Oxygen (small cylinder) and mask. Emergency drugs for anaphylaxis	Oxygen (small cylinder) and mask. Emergency drugs for anaphylaxis. O2 saturation monitor and blood pressure monitoring equipment.

Copyright National Standards Pty Ltd 2005

The size of the room should be such that there is sufficient clearance around the table to allow unimpeded access to the patient in the event of an emergency.

The clinic should have receptacles for disposal of sharps and contaminated waste. Documented procedures for the disposal of such waste should be in place.

6.4.1 Equipment maintenance and calibration

Equipment which has an effect on patient care should be calibrated or certified. Calibration or certification should be done to demonstrate that:

- Equipment measurements or readings are within acceptable tolerances (to be defined by the clinic based on the use of the equipment, manufacturer's recommendation, local or national standards).
- The calibration is traceable to national or international standards of calibration.
- The calibration method used is documented and covers all the parameters and range of the equipment.

All testing should be done at least once a year. All equipment should be tagged or marked, with the date of service and the next date of service.

Equipment found to be unsafe, un-serviced, out of calibration range or date should be clearly marked "Do not use" and/or removed from the clinic.

6.4.2 Equipment records

Records of the above equipment service, maintenance and calibration should be maintained, including preventive and breakdown maintenance.

Records including laser compliance certificates should be available at the clinic.

Copyright National Standards Pty Ltd 2005

The clinic should also develop and complete a pre-procedure checklist covering all its critical equipment.

End of the document

Copyright National Standards Pty Ltd 2005