

# *Regulations and Guidelines FOR PERFUSIONISTS*



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## **Foreword**

Since its formation in 1982, the aim of the Australian and New Zealand College of Perfusionists (ANZCP) formerly the Australasian Society of Cardio-Vascular Perfusionists (ASCVP), has been to improve the standards of training and clinical practice of perfusionists working in cardiac units in Australia and New Zealand. As part of this overall commitment, ANZCP has developed a system of self-regulation, to ensure that all cardiac patients can have the utmost confidence in the perfusion services being provided.

A key element in this system of self-regulation, as covered by these Regulations, is the Register of qualified Perfusionists maintained by a subsidiary body of ANZCP, the Australasian Board of Cardiovascular Perfusion (ABCP, established in 1989), thereby providing an avenue for Health Departments, Hospitals and the general public to check the status and credentials of perfusionists. The ABCP's oversees the education and training of perfusionists, Candidates who successfully complete their training and certification exams are awarded the Australasian Diploma of Perfusion. Through it's recertification program the ABCP ensures that practising perfusionists maintain their skills and are kept abreast of the latest techniques and technology.

The ABCP course had been the only structured, complete training and certification perfusion course offered in either Australia or New Zealand. However 2006 ushered in a new era, whereby Swinburne University, Melbourne, in conjunction with the ABCP, now offers an online Master's degree in Perfusion Science. Candidates who successfully complete the Swinburne course will be required to sit the accreditation examinations run by the ABCP for certification and registration. It all adds up to a major step forward in the management of the training of perfusionists.

These Regulations are the result of twenty years of clinical and professional experience by Fellows of the College and represent a significant step towards achieving what we regard as the required level of regulation. They outline how perfusion should be practiced in Australia and New Zealand. Further the Regulations contain detailed procedures of how ANZCP and the ABCP will investigate any complaints made against a perfusionist and in proven cases of professional negligence or misconduct, provision for the withdrawal of a perfusionists certification to practice.

To ensure the safety of the public, ANZCP and the ABCP believe that all perfusionists employed and practising in hospitals in Australia and New Zealand should be appropriately trained and ABCP certified. As with most documents of this nature the rules and regulations will evolve to reflect the changes in perfusion practice.

We hope that you will adopt these rules and regulations in your hospital.

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Dept. of Perfusion  
Royal Melbourne Hospital, Parkville,  
Melbourne, Victoria

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**Chairman, ABCP**  
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Melbourne, Victoria

## **1 Description of Perfusion and Perfusionists**

**(1)** Perfusion is the technology of organ preservation by the circulation of oxygenated blood outside the body, using a heart-lung bypass machine.

**(2)** In most cases, perfusion is performed to allow a patient undergoing heart surgery to be maintained in a safe and stable condition while his/her heart is stopped for the purpose of operative repair. Virtually all heart operations, therefore, require the services of a perfusionist to operate the heart-lung bypass machine.

**(3)** Approximately 25,000 adult and paediatric cases are performed in Australia annually, as reported in the most recent National Heart Foundation database.

**(4)** Other procedures requiring perfusionists include:

- a. Cardiopulmonary bypass (perfusion)
- b. Intra-aortic balloon counter-pulsation
- c. Mechanical Circulatory Support (VAD)
- d. Autotransfusion
- e. ECLS (Extracorporeal Life Support)
- f. Isolated limb perfusion
- g. Bypass for liver surgery
- h. Organ procurement
- i. Research & development.

**(5)** Perfusionists are health professionals. They are Science graduates who have successfully completed a further two-year training course in perfusion and who have been awarded the ABCP Diploma of Perfusion. They are specifically trained to operate extracorporeal circulation equipment during cardiopulmonary bypass and all its associated therapies. They may operate such equipment during any medical situation where it is necessary to support or temporarily replace the patient's cardiopulmonary or circulatory function. They work in both paediatric and adult surgical units and they are committed to maintaining the highest standards of professionalism and care to their patients.

**(6)** Standards currently defined by the ANZCP - and also by the Royal Australasian College of Surgeons - recommend that cardiopulmonary bypass should only be conducted by specialist individuals who have undergone recognised training and certification in perfusion science.

**(7)** Accordingly, only perfusionists who are currently registered as Diploma-qualified and accredited by the ABCP should take responsibility for the conduct of cardio-pulmonary bypass.

**(8)** Trainee perfusionists may only operate the heart-lung bypass machine under the direct supervision of a certified perfusionist.

## **2. Historical background of ANZCP (the College) and ABCP (the Board).**

- (1) Perfusionists have been involved in the field of cardiopulmonary perfusion since the very beginning of cardiac surgery in Australia.
- (2) In 1982 the perfusionists of Australia and New Zealand formed an international, incorporated association named the Australasian Society of Cardio-Vascular Perfusionists (ASCVP), covering all of Australia and New Zealand,
- (3) In 1989 ASCVP established a sub-committee, named the Australasian Board of Cardiovascular Perfusion (ABCP), to provide a diploma training course and examining board for perfusionists and to maintain a register of qualified perfusionists.
- (4) In 2002 the diploma was named the Australasian Diploma of Perfusion and a system of re-certification was set up, under which all ABCP-certified perfusionists are required to provide proof of ongoing clinical and educational activity before being re-certified.
- (5) In 2005, the Swinburne University of Technology, in close collaboration with the ASCVP and ABCP, established the first University-based post-graduate course in Perfusion, for the degree of Master of Science (Perfusion).
- (6) The Swinburne Masters course is now under way, so the ABCP has ceased taking new enrolments for training as perfusionists. Current ABCP Diploma trainees are required to complete their courses by the end of 2008.
- (7) In June 2006 the ASCVP implemented self-regulation for perfusionists and assigned the ABCP and its Complaints Committee responsibility for the investigation of complaints against practising perfusionists. The ABCP holds the register of currently certified perfusionists.
- (8) In October 2006 the members voted to change the name of the Society to The Australian and New Zealand College of Perfusionists (ANZCP).

## **3. ANZCP - Mission Statement**

**The Mission of ANZCP is to achieve the highest possible clinical standards of care for patients requiring cardio-pulmonary bypass.**

## 4. Management and Functions of ANZCP

### 4.1 The Executive Committee

The College is managed by an Executive Committee of Fellows of the College, chaired by the President of the Society. The Executive Committee has four other members, namely the Vice-President, the Secretary, the Treasurer and one Member. The Chairman of the Australasian Board of Cardiovascular Perfusion keeps the Executive Committee informed of all matters and decisions made by the Board.

### 4.2 Functions

The functions of the College are:

- (1) To be a **regulatory body** to uphold the clinical standards of Perfusionists
- (2) To provide a means of communication between Perfusionists - by means of:
  - a. The **Annual Scientific Conference**
  - b. The **ANZCP Gazette**, the official publication of the ANZCP.
- (3) To encourage further education, by **funding the award of scholarships** to Fellows and Members of the College.
- (4) To manage the **ANZCP Website** (<http://www.ANZCP.org>) - in order:
  - a. to provide current information to the public on the ANZCP;
  - b. to provide the public with access to the Regulations for Perfusionists.
  - c. to provide on-line access for members to contact the ANZCP;
  - d. to maintain the Perfusion Incident Reporting System (PIRS) –  
*(PIRS is an independent system for reporting perfusion-related incidents, under which perfusionists may, anonymously, submit incident details to the Society for independent assessment of action to be taken.)*
  - e. PIRS must forward reports of incidents involving medical equipment and devices to the Therapeutic Goods Administration (TGA) or relevant authorities. They must also alert the perfusion community to potential hazards.

## **5. Code of Ethics of ANZCP**

To comply with the Code of Ethics of the College, Fellows in any matter touching upon or arising out of the practice of perfusion, shall:

- (1)** Respect the rights and dignity of all individuals;
- (2)** Help all those who seek their professional services, without discrimination, fear or favour;
- (3)** Provide honest, competent and accountable professional service;
- (4)** Recognise the extent and limitations of their professional expertise and undertake only those activities that are within their professional competence;
- (5)** Hold in confidence all personal information entrusted to them, unless discreet disclosure is considered to be in the best interests of the patient/client/colleague.
- (6)** Maintain at all times the highest standard of professional competence and continually update and extend their professional knowledge and skill;
- (7)** Contribute to the planning and development of services which enable individuals within the community to achieve optimum health.
- (8)** Recognise that a Perfusionist, in all professional activities, represents the profession, whose foundation is based on the ideal of service to the individual and the community, as expressed in the ANZCP Code of Ethics.
- (9)** Recognise that a Perfusionist is expected to behave, in all circumstances, in a manner that will enhance the honour of the profession.

## **6. Australasian Board of Cardiovascular Perfusion–Perfusionists’ Registration Board**

(1) The Board is a subsidiary of ANZCP and is the registration body for perfusionists in Australia and New Zealand. The Board has a Chairman, Secretary, Co-ordinator and Member. The Chairman of the Board is responsible to the President of the Society for the management of the Register of Diploma-qualified Perfusionists.

(2) The Chairman of the Board is also responsible to the President of the College for the investigation of complaints regarding the professional conduct and fitness to practice of registered perfusionists through its Standards and Complaints Committee.

### **What is the ABCP Registration Board?**

The Registration Board is the registration body for perfusionists in Australia. The function of the Registration Board is to regulate the profession of perfusion in order to protect the public. The Board holds a Register of ABCP certified perfusionists and investigates the professional conduct and fitness to practice of registered perfusionists.

### **Who can be registered?**

Currently graduates who hold a Diploma in Perfusion from the Australasian Board of Cardiovascular Perfusion (ABCP) are eligible to be registered with the Perfusionists Registration Board.

Perfusionists who have qualified in a country other than Australia are required to submit their qualifications and evidence of perfusion practice to the Australian Perfusion Board for approval. Such registration is not automatic and may require further examination.

### **When can I register?**

Suitably qualified perfusionists may apply for registration at any time. Registration is for a period of three years and the full fee is payable at the time of application.

Contact: Secretary ABCP  
Australasian Board of Cardiovascular Perfusion  
PO Box 6103  
Hawthorn West  
Victoria 3122  
Australia

## **How does the Board ensure standards of practice?**

Registration must be applied for every three years. The perfusionist must manage a minimum of 40 cases each year and submit a record of continuing education activity. The Board provides a register of accredited professional continuing education activities.

## **Can a perfusionist be de-registered?**

**Yes.**

Incidences of unprofessional conduct, or health issues which impair a perfusionist ability to perform their work safely, can be reported to the Secretary of ANZCP. In such cases the President of the ANZCP will refer the matter to the chairman of the ABCP. The Board's Standards and Complaints Committee must investigate the report and will hold an informal or formal hearing of the complaint (refer to section 7). The perfusionist concerned may have their registration suspended until the hearing is complete. If the complaint is substantiated the perfusionist may be asked to complete specific education requirements, modify their practice, or be struck from the Register.

## **If you have a complaint please contact**

Secretary of ANZCP  
PO Box 921  
Parkville  
Victoria, 3025  
Australia

# ***Continuing Professional Education Program***

## **Introduction**

Continuing Professional Education is necessary within the health and allied health professionals to assist practitioners maintain professional knowledge, update practicing skills and ensure the highest quality care is provided for patients.

## **Why is continuing professional education necessary?**

- To ensure practitioners maintain professional knowledge;
- To ensure that practitioners update their skills;
- To ensure the highest quality is provided for patients.

At the end of a three-year cycle a perfusionist should submit a record of continuing education activities undertaken in the last three years. If sufficient continuing professional education points have been accrued and verified a Certificate of Registration will also be issued.

A Perfusion Registration Certificate indicates to employers, health insurance companies and patients that you are an appropriately qualified registered perfusionist.

## **What is the CPE program?**

The CPE program is a system for accrediting and acknowledging your continuing post graduate professional expertise. A Registration Certificate lets the public and professional bodies know that you have undertaken the activities to further your education relevant to perfusion.

A Registration Certificate is issued to registrants of based on submission of continuing education credits gained and evidence of clinical activity in a three year cycle of the registration period.

## **Regulations Concerning Registration**

1. Perfusionists who have been awarded the Australasian Diploma in Perfusion are eligible to be registered by ABCP. The Register is, on application to ABCP, available for inspection by members of the public
2. This registration provides evidence to health departments, hospitals and patients and enables hospitals to check, in advance, that an applicant perfusionist is appropriately qualified for engagement as a member of a cardiac surgery team.

3. Australian and New Zealand perfusionists who have been qualified by the ABCP may apply for registration at any time. Registration is for a period of three years and the full fee is payable at the time of application.
4. Perfusionists who have qualified in a country other than Australia or New Zealand may apply to ABCP for registration and will be required to submit their qualifications and evidence of perfusion practice to ABCP for consideration.
5. The ABCP requires all registered perfusionists to participate in continuing professional education (CPE). CPE is a process that requires practitioners to maintain their professional knowledge and to maintain and update their clinical skills, so that the highest quality service is provided for patients under their care.

**6.2.1** The following are the requirements for the award of a certificate of registration.

1. The period of each registration cycle will be 3 years. (The Registrar of ABCP will notify all registered perfusionists when their registration reports are due).
2. Applicants are required to provide evidence of having acquiring the required level of Continuing Professional Education in accordance with item 6.2.2 below.
3. Applicants are required to pay the registration fee determined by ABCP.

**6.2.2** The following tables are used by the Board in assessing the Continuing Professional Education (CPE) eligibility of a candidate for registration:

|  |                                   |
|--|-----------------------------------|
| <b>Clinical Activity Points:</b>                               | <b>150 points over 3 years</b>    |
| <b>Core Perfusion Activities</b>                               | <b>Minimum 40 points per year</b> |
| CPB Cases: Primary Perfusionist                                | 1 point each                      |
| CPB Cases: Supervising trainee<br>(Sitting with trainee in OR) | 1 point each                      |
| <b>Non Core Perfusion Activities</b>                           | <b>Maximum 10 points per year</b> |
| OpCAB standby  | 1 point each                      |
| Cell Washer  | 1 point each                      |
| IABP, VAD, ECMO, ECLS<br>(Establishment Of Support)            | 1 point each                      |

**Non-clinical activity points: 30 points over 3 years**

**Attendance of Meetings:**

|                                      |           |
|--------------------------------------|-----------|
| a) In house seminar, workshop        | 2 points  |
| b) Local workshop                    | 5 points  |
| c) National/International conference | 10 points |

**Presentations at Meetings:**

|   |           |
|---|-----------|
| Presentation at either (a) or (b) above           | 5 points  |
| Presentation at National or International Meeting | 15 points |
| Poster at National or International meeting       | 10 points |

**Publications:**

|                                     |           |
|-------------------------------------|-----------|
| Published abstracts                 | 5 points  |
| Letters                             | 2 points  |
| Journal without an editorial policy | 5 points  |
| Journal with editorial policy       | 15 points |
| Chapter in Perfusion related book   | 15 points |

**Education:**

**Trainee Related:**

|                                  |              |
|----------------------------------|--------------|
| Lectures,                        | 1 pt/session |
| Tutorials,                       | 1 pt/session |
| Marking ABCP Module Examinations | 1 pt/session |

**Self-Education:**

|  |                       |
|--|-----------------------|
| Subscription to Journal                                  | 5 points/subscription |
| Journal Club Attendance                                  | 2 points per meeting  |
| Journal Club Presentation                                | 5 points per meeting  |
| Enrolment in a professionally relevant University Course | 10 points             |

**Insufficient points for re-registration**

If a candidate believes they have insufficient points for re-registration, they should contact the Chairman of ABCP before the registration deadline.

## **Long Service Leave & Maternity Leave**

Candidates who take long service or maternity/paternity leave will have their re-registration requirements reduced on a pro rata basis. They should contact the Chairman of ABCP before the registration deadline.

## **Auditing of Registration Reports**

All participants in the registration process agree to their submissions being audited.

A number of candidates will be selected at random to have their submissions audited. Candidates who are to be audited will be contacted by ABCP to arrange a time for the audit process. At the audit the onus is on the candidate to provide evidence supporting their submission.

## **Cross Accreditation**

Currently there are no cross accreditation agreements with any other international perfusion board.

# ***Investigation of Complaints***

## **6.3 The Investigation of Complaints – General**

1. Any incidents of unprofessional conduct, or health issues, which might impair a perfusionist's ability to perform his or her work safely and effectively, should be reported to the Secretary of the College in the first instance at the following address:

Secretary of the ANZCP  
PO Box 921  
Parkville  
Victoria 3025  
Australia

2. In such cases the President of the College will consider the report or complaint and will normally pass it to the Chairman of the Board, for investigation by the Standards and Complaints Committee in accordance with Section 7, below
3. The Chairman of Board shall keep the President of the College fully informed during all investigations of complaints.

## **7. Regulations Concerning Complaints**

### **7.1 General**

These Regulations are designed to establish:

1. Standards of Practice and Ethics to be observed by Fellows of the College;
2. A system for the handling of complaints against Fellows;
3. A Standards and Complaints Committee to investigate such complaints.

### **7.2 The Standards and Complaints Committee**

1. The Standards and Complaints Committee, under the chairmanship of the Chairman of ABCP, is responsible for monitoring the Standards of Professional Practice of Perfusionists (see Section 8) and is empowered to investigate any complaints against Fellows referred to it under these Regulations.
2. Members of this Committee, appointed by the Chairman in consultation with the President of the College, shall consist of two (2) Fellows of the Society and one other suitably experienced and qualified person of good repute. One of the members shall be designated as the Secretary, who shall be responsible for maintaining records of the proceedings of the Committee.

### **7.3 Referrals to the Standards and Complaints Committee**

1. Any complaint by a person or body against the professional conduct of a Perfusionist who is a Fellow of the College shall be submitted in writing to the Secretary of the College. Receipt of the complaint shall be acknowledged in writing to the complainant.
2. Such complaints will normally be referred by the President of the College to the Standards and Complaints Committee for investigation. However the President may also refer a complaint to an appropriate Authority outside the College, if he considers the matter to be of a sufficiently serious or unusual nature.
3. If the President of the College becomes aware that a Fellow has been investigated by a statutory complaints authority, a professional standards committee, a medical board, or another relevant authority (an "Authority"), and if an adverse finding has been made in relation to the professional conduct of the Fellow, the President of the College may refer the matter to the Standards and Complaints Committee for further investigation, in accordance with these Regulations.
4. If any particular matter or conduct relating to a Fellow has been referred to the College by any such Authority, the President will normally refer it to the Standards and Complaints Committee for investigation.
5. A complaint shall be considered pursuant to these Regulations if it relates to the professional or ethical standards of conduct of a Fellow, or relates to the conduct of a Fellow, which affects the honour, good reputation, interests, or work of the College.
6. No complaint shall be considered unless it has been submitted in writing in accordance with these Regulations and includes the full name and address of the person or persons making the complaint.
7. All complaints shall be dealt with, as far as possible, on a confidential basis and consistent with the protection afforded by the legal principle of qualified privilege. The person or persons making a complaint should be informed that the College is not bound to guarantee the anonymity of those making a complaint.

### **7.4 Proceedings of the Standards and Complaints Committee**

1. Upon referral of a matter or complaint pursuant to these Regulations, the Committee shall decide whether, prima facie, there is a case to answer in respect of such matter or complaint.
2. If it is decided that there is a prima facie case to answer, the Committee shall forward appropriate details of the matter or complaint to the Fellow concerned. The Fellow concerned shall be entitled to receive sufficient details of the nature and circumstances of the allegations in the matter or complaint as will allow the Fellow to fully respond to the allegations and as the rules of natural justice may require.

3. Any Fellow, who is the subject of a matter or complaint referred to the Committee, shall be given, at least fourteen (14) days prior to the meeting of the Committee at which any determination is to be made, written notice of:
  - a) the intention of the Committee to consider the matter;
  - b) the time, date and place of the meeting;
  - c) particulars of the nature of the matter under consideration;
  - d) advice that the Fellow may attend and give oral or written submissions at that meeting in respect of the matter.
4. At the meeting of the Committee held to consider the matter, the Fellow shall be given an opportunity to be heard, and the Committee shall give due consideration to any written or oral submissions made by the Fellow. The Fellow may be accompanied by another person, but shall not be entitled to have an advocate or be legally represented before the Committee, unless the Committee has given its prior consent.
5. Any member of the Committee who was involved in the matter or complaint, or who had previously made a decision in relation to the matter or complaint or the matter, or who is a partner or has any other family or professional relationship with the Fellow concerned, shall not participate in any consideration of the matter or complaint by the Committee.
6. The proceedings of the Committee shall be confidential, except for the reporting of progress, appropriate reporting to the parties involved, and reporting of the decision and reasons to the Board.
7. Members of the Committee may meet in person, by telephone or by other telecommunications or electronic means, or by correspondence for the purposes of carrying out their functions.
8. The Committee is not bound by the rules of evidence and, subject to the rules of natural justice, may inform itself on any matter and in such manner as it thinks fit. Any information which is material to the allegations made in relation to the Fellow shall be disclosed to the Fellow, and the Fellow shall be given sufficient opportunity to make submissions in relation to that information.
9. The Committee shall be entitled to consider all relevant information which it thinks fit and may invite any person to appear before it or to provide information.
10. The Committee shall conduct its affairs with as little formality as possible, but otherwise, subject to these Rules, shall have full power to regulate its conduct and operation, including convening and adjourning any meeting as it may require.
11. In considering any matter or complaint, the Committee shall act as expeditiously as the circumstances permit.
12. The Committee may make its own enquiries and seek legal or other professional advice in relation to any matter or complaint under consideration.

13. The Committee may hold, convene or adjourn meetings as it thinks fit.
14. The Committee shall keep appropriate minutes of meetings, including decisions of any determination made in relation to any matter or complaint before it. Minutes of hearings of the Committee may be confined to a report of the decision made by the Committee.

### **7.5 Decisions of the Standards and Complaints Committee**

After investigation and consideration of a complaint or matter, the Committee may recommend to the President of the College that he may:

- a) take no action;
- b) counsel the Fellow and/or require him/her to participate in any relevant professional program or activity;
- c) censure the Fellow;
- d) refer the matter or complaint to the Executive Committee of the College for consideration (including suspension or termination of the Fellow);
- e) refer the matter or complaint to another appropriate Authority.

***Note:** The Chairman of the Standards and Complaints Committee may recommend to the President of the College that the matter or complaint be referred to any other appropriate Authority at any time after receipt of the complaint.*

### **7.6 Actions available to the Executive Committee of the College**

1. In relation to any decision of the Standards and Complaints Committee, the Executive Committee of the College may, in its absolute discretion, give notice of, publish or communicate the decision to:
  - a) all or any of the Fellows of the College;
  - b) any authority or professional body or organisation in or connected with the profession of medicine;
  - c) the public generally.
2. In the event of the suspension or termination of the membership of a Fellow, the Fellow, within seven (7) days of receipt of notice requiring the Fellow to do so, return to the President of the College the Fellow's Certificate of Fellowship, and the Fellow shall not represent or hold himself or herself out to be a Fellow of the College, or by any other means.

### **7.7 Notice of Determinations and the Right of Appeal**

1. Following receipt of notification of any determination by the Standards and Complaints Committee or ABCP in respect of any complaint or matter, the

President of the College shall, as soon as possible, notify in writing the Fellow concerned and the person initiating the complaint or matter of the determination, keeping the Chairman of the Board informed.

2. Any Fellow in respect of whom an adverse decision is made under these Rules may appeal the decision in accordance with this Regulation

### **7.8 Re-instatement**

A Fellow who has had his or her Fellowship suspended or terminated may be re-instated as a Fellow of the College at the discretion of the Executive Committee, and upon such terms and conditions as the Executive Committee may, in its absolute discretion, determine.

### **7.9 Administrative Support**

1. The Standards and Complaints Committee may request administrative assistance in connection with its functions, through the Secretary of the College.
2. The Standards and Complaints Committee may invite such appropriate persons as they think fit to participate in and observe their meetings, including Fellows of the College, and legal advisers and other advisers engaged by the College.

### **7.10 Previous Complaints**

In considering what, if any action the Committee or the Board may recommend or take in relation to a matter or complaint against a Fellow, both the Committee and the Board shall be entitled to consider any prior matter or complaint determined in relation to the Fellow, PROVIDED THAT the Fellow is given sufficient opportunity to make submissions in relation to such information.

## **8. ANZCP Standards of Professional Practice**

To comply with the College's Standards of Professional Practice, a perfusionist shall:

1. Regard the health of the patient as the first consideration.
2. Observe the laws relevant to practice of the profession at all times.
3. Supply professional advice and counselling at every appropriate opportunity
4. Keep abreast of the progress of perfusion knowledge to maintain the highest standards of professional competence.
5. Respect the trust and confidentiality of professional relationships with patients.
6. Consult professional colleagues and other health professionals when deemed to be in the best interest of the patient.
7. Assist colleagues and other health professionals when called upon for help or support
8. Ensure that all equipment utilised in the performance of perfusion duties is properly maintained.
9. Ensure that all appropriate safety precautions are taken to safeguard the patient.
10. Strive to provide information to the patients regarding professional services truthfully, accurately and fully avoid misleading patients regarding the nature, cost or value of the perfusionist's professional services.
11. Maintain effective professional relationships with colleagues and other health professionals, paying due regard to their opinions and achievements (and refrain from publicly criticising them).
12. Not knowingly engage in or associate with fraudulent and unethical practice and practitioners.
13. Practice under conditions that ensure professional independence.
14. Have available at all times a complete manual of Standard Operating Procedures.
15. Provide the fullest possible support within the bounds of the Perfusionist's experience to the patient, to the cardiac surgeon in charge of the patient and to the healthcare institution involved in the patient treatment.
16. Observe the Code of Ethics of the College.

## **9. Regulations and Standards concerning Clinical Practice**

***The Regulations set out in this section are to be regarded as minimum standards for practising Perfusionists.***

### **9.1 Range of Perfusionists' duties**

1. A wide spectrum of procedures and services can be carried out by Perfusionists. The actual procedures and services undertaken vary, depending on hospital or institution policy, and all are undertaken upon the prescription or direction of a Medical Practitioner.
2. The procedures and services which can be provided by Perfusionists include, but are not limited to, the following:
  - a) Cardiopulmonary Bypass
  - b) Extra Corporeal Life Support
  - c) Extracorporeal Membrane Oxygenation
  - d) Mechanical Circulatory Support / Ventricular-Assist Device
  - e) Induction of hypothermia / hyperthermia with reversal
  - f) Haemodilution
  - g) Haemofiltration / plasmapheresis
  - h) Administration of cardioplegia
  - i) Anticoagulation monitoring
  - j) Blood conservation techniques / autotransfusion
  - k) Blood gas / biochemistry monitoring
  - l) Physiological monitoring
  - m) Intra Aortic Balloon Counter-pulsation
  - n) Isolated limb / organ perfusion
  - o) Organ preservation
  - p) Total body washout
  - q) Dialysis
  - r) Administration, via the extra-corporeal circuit, of:
    - (i) prescribed medications
    - (ii) blood components
    - (iii) anaesthetic agents
  - s) Platelet sequestration
  - t) Full clinical documentation of duties carried out
  - u) Administration
  - v) Continuing education
  - w) Quality control

## 9.2 Regulations for the Conduct of Perfusion

1. Cardio-pulmonary bypass should only be conducted by specialist individuals who have undergone recognised training and certification in Perfusion. Only Perfusionists certified and registered by the Australasian Board of Cardio-Vascular Perfusion and approved by the Cardiac Surgeon in charge of the patient should take responsibility for the conduct of cardio-pulmonary bypass.
2. Trainees in a recognised training programme may only conduct cardio-pulmonary bypass under the supervision of a certified perfusionist, as prescribed in Section 5. This supervision should be **DIRECT** supervision for the initial months of training, and should be direct supervision where ever possible thereafter, for the duration of training.
3. The perfusionist should monitor and maintain an appropriate anticoagulation status for the patient during cardio-pulmonary bypass.
4. All measures should be taken to maintain appropriate gas exchange, adequate blood flow and blood pressure during cardio-pulmonary bypass.
5. During cardio-pulmonary bypass the perfusionist should, at all times, be able to comfortably see a monitor or monitors displaying mean arterial pressure and arterial wave-form; ECG; patient core temperature; and venous pressure.
6. Safety glasses and protective gloves should be worn by all personnel involved in cardio-pulmonary bypass who might be at risk of contact with blood or blood products.

## 9.3 Standards of Perfusion Practice

1. The perfusionist should seek to continually improve the quality of perfusion care.
2. The perfusionist should utilise properly maintained equipment in the conduct of cardio-pulmonary bypass. The equipment should be replaced when it can no longer be serviced (i.e. when spare parts are no longer available within 12 months of the last service).
3. All non-disposable equipment should undergo preventative maintenance examinations as prescribed by its manufacturer. These preventative maintenance examinations should be performed by appropriately qualified people. Dates and details should be documented, and records kept, within the Perfusion Unit.
4. Devices used to monitor or assay parameters measured during cardio-pulmonary bypass should be calibrated and verified for performance and accuracy, at the intervals prescribed by the manufacturer.
5. Regular cleaning and housekeeping routines should be established for the care of all equipment used by the perfusionist in cardio-pulmonary bypass.

6. Major incidents, involving any aspect of the cardiopulmonary bypass (either with or without patient involvement), and including device and product failures, should be fully documented, with written, detailed descriptions of the nature of the incident, causes or possible causes, results, action taken and recommendations arising.
7. Incident reports should be filed within the Perfusion Unit, and reviewed as part of continuing education, staff training, and unit review. In addition, these reports should be filed in accordance with the protocols within each individual Institution or Hospital. It is recommended that incidences be forwarded onto PIRS (Perfusion Incident Reporting System) via the College website. Failure of hardware or disposable should be reported to the TGA (Therapeutic Goods Authority) in Australia and the ? in New Zealand.
8. The perfusionist should make responsible efforts at cost containment and should uphold the highest professional standards when involved in the purchase of goods and services on behalf of the Institution or Hospital.
9. It is recommended that the Hospital or service provider employ an adequate number of perfusionists to cover all likely situations, so that, when possible, a second perfusionist can be made available to assist in the event of an emergency.

## **9.4 Hardware Equipment for Perfusion**

### **9.4.1 Heart-Lung Bypass Machine – General**

1. The heart-lung bypass machine consists of either a pump console with integrated pumps, or modular pumps mounted on a console base. These pumps may be either positive displacement - roller pumps; or constrained vortex/centrifugal pumps. Additional equipment includes (but is not limited to) pressure controllers; air emboli detectors; low level alarms; gas flow meters and blenders; and light sources, may be integrated or modular.
2. The heart-lung bypass machine should meet the current Australian and/or New Zealand Electro-medical Specifications for Electrical Safety for a Cardiac Protected procedure. The heart-lung machine must meet other Standards, as specified herein.
3. All roller pump modules should have electronic "runaway" control protection, as part of its standard circuitry.
4. Controls for reversal of pump flow should be locked or disarmed. Initiation of pump reversal should require two actions to prevent inadvertent operation. In the case of constrained vortex pumps a safety device should be used where possible.
5. Each pump module should clearly display either pump flow, or 'revolutions per minute'.
6. The occlusion mechanism of each roller pump on the heart-lung machine should be secure and protected from inadvertent movement.

7. Arterial roller pumps, or roller pumps being used for the delivery of cardioplegia should be capable of being controlled by:
  - a) Low level alarm systems;
  - b) Arterial or cardioplegia delivery line pressure alarm systems;
  - c) Air emboli detecting devices.
8. All roller pump systems should include a manual override, which inhibits control of the pump by external control systems.
9. The perfusionist should have a dedicated light source available, for general illumination of the oxygenator and blood-path; and for use in situations involving loss of lighting to the operating room. This light source may either be an integral part of the heart-lung machine, or be a portable, battery-powered source.
10. A minimum of two pump heads should have separate crank handles, for manual pump operation, in cases of power or pump failure. These crank handles should be stored adjacent to the pump.
11. Either auxiliary or battery power should be available to provide emergency power for at least one hour for the main arterial pump and for the light source.

#### **9.4.2 Heart-Lung Bypass Machine – Gas Supply system**

1. Gas flow meters, air-oxygen blenders and anaesthetic vaporisers should meet Australian and New Zealand Standards.
2. The heart-lung machine should only be connected to a gas specific connection system supplying medical gases to the operating-room, or connected using gas specific connectors to a portable cylinder.
3. The gas supply line, from a blender or flow meter, should incorporate a device to both warn of low oxygen concentration and to validate the actual oxygen concentration immediately proximal to the oxygenator. This oxygen analyser should be sited proximal to the oxygenator and there should not be any other gas line inlets between this device and the oxygenator. This device should be in continuous use whilst the heart-lung machine is in use, and should be fitted with an audible alarm to warn of a low oxygen concentration.
4. The gas supply to the oxygenating device should be filtered or guaranteed free of particulate matter.
5. If an air-oxygen blender is to be used, it should incorporate an audible alarm device which will activate if the gas source pressures differ significantly.
6. A reserve supply of oxygen, for the sole use of the heart-lung machine should be available at all times. If an air-oxygen blender is being used, a supply of medical air, for the sole use of the heart lung machine, should also

be available at all times. These reserve supplies should be checked weekly, and should be checked after each use.

7. A spare gas flow meter and/or air-oxygen blender should be readily available, in close proximity to the site of the procedure.
8. Provision should exist for scavenging waste anaesthetic gases from the oxygenating device.

### **9.4.3 Heart-Lung Bypass Machine – Heater-Cooler system**

1. The heart-lung heater-cooler system can either be a self-contained system or utilise the hospital's hot and cold water system through a mixing valve. A spare unit or system should be available, for the event of the primary system failing.
2. Self-contained heater/coolers should have dual temperature safety devices and a heater-cooler system utilising hot and cold water from the hospital supply should have temperature safety devices to prevent the water temperature from exceeding 42 degrees Celsius or dropping below 3 degrees Celsius.
3. The water flow and pressure from the heater-cooler unit should not exceed the manufacturer recommended limits for the heat exchanger.
4. The heater-cooler system should incorporate safety alarms and override facilities for overpressure and temperature, and should indicate water pump failure and low water levels.
5. The system should meet the Australian or New Zealand Standards for electrical safety.

### **9.4.4 Heart-Lung Bypass machine – Associated equipment**

#### **9.4.4.1 Low-level detection devices**

1. Low-level detection devices are safety devices mounted on, or secured to the reservoir of the cardio-pulmonary bypass circuit that will alert the perfusionist to a low level in the reservoir.
2. A low-level detection system should be used during the conduct of every cardio-pulmonary bypass procedure utilising a reservoir.
3. The sensor of the low-level detection system should be able to control the arterial roller pump.
4. The low-level detection system should incorporate both audible and visual alarms, to alert the perfusionist of a low blood level in the reservoir of the cardio-pulmonary bypass circuit.

5. The sensor should be sited no lower than the minimum operating level recommended for the oxygenator or reservoir. The perfusionist should allow a reaction time commensurate with the flows expected throughout the procedure.

#### **9.4.4.2 Line Pressure monitoring devices**

1. Line pressure monitoring devices are safety devices that give an indication as to the pressure being developed in all delivery lines to the patient, i.e., including, but not limited to, the arterial delivery line, cardioplegia delivery lines (ante grade and retrograde), retrograde cerebral or antegrade cerebral delivery lines and hemofiltration.
  - a) Electronic transducer-based pressure-monitoring systems should be used at all times to monitor all delivery lines to the patient. They should incorporate both an audible and visual alarm, set within the manufacturer's specifications, to alert the perfusionist to excessive pressures. They should be servo-linked to the delivery system. A variable delay should be an integral part of these systems to avoid "spike transient" false alarms.

#### **9.4.4.3 Air-Emboli detection devices**

1. An air-emboli detector is a safety device, which will indicate the presence of gaseous emboli passing the site of the detector.
2. An air-emboli detector should be used during the conduct of every cardio-pulmonary bypass procedure.
3. The sensor of the air-emboli detector system should be able to control the arterial pump.
4. The air-emboli detector system should incorporate both audible and visual alarms, which would alert the perfusionist to the presence of air in the circuit, at the site of the air-emboli sensor.
5. The air-emboli sensor should be positioned at a site that will allow the perfusionist to quickly, and safely remove any air, with a minimum effect on the patient.
6. With respect to Standard number 9.4.4.1 (Low level detection devices) and standard number 9.4.4.3. (Air-emboli detection devices) - BOTH of these systems should be in use during a cardio-pulmonary bypass procedure utilising a reservoir.

#### **9.4.4.4 O<sub>2</sub> Saturation and CO<sub>2</sub> Removal**

7. The oxygen saturation of the venous blood should be monitored routinely as a minimum standard.

8. An end-tidal carbon dioxide monitor should be used on the gas outlet port of the oxygenator, especially when carbon dioxide flooding of the surgical field is practised, - OR:-
9. When carbon dioxide is used to flood the surgical field, its levels should be monitored, using either end-tidal CO<sub>2</sub> monitoring or more frequent blood gas analysis.

#### **9.4.4.5 Monitoring of Temperatures**

10. The following temperatures should be monitored, as a minimum standard for every procedure:
  - a) Heater-cooler
  - b) Oxygenator arterial blood outlet
  - c) Patient (e.g. nasopharyngeal, bladder, and rectal)

### **9.5 Disposable Equipment for Perfusion**

1. The perfusionist should be satisfied that each item has been inspected. Records relating to the device history and sterility must be kept. All lot/batch numbers of oxygenators, tubing packs, haemo filters and cell saving equipment disposables must be stored.
2. All sterile perfusion items should be examined for intact packaging prior to use, and indicators realising sterility should be noted prior to use.
3. All items should be used as per the manufacturer's specifications and instructions for use, including instructions relating to re-use and re-sterilisation, and to use-by and expiry dates.
4. All disposable items used in cardio-pulmonary bypass should be stored in areas meeting manufacturer's standards with respect to ultra-violet light, temperature, humidity, moisture and environmental extremes.

### **9.6 Pre-Operative Patient Assessment**

1. In order to assess the patient for cardio-pulmonary bypass, a pre-operative evaluation of the patient and his/her related parameters, including the following details, should be noted:
  - a. Name
  - b. Unit record number
  - c. Age and date of birth
2. The following patient parameters should be evaluated:
  - a. Weight
  - b. Height
  - c. Recent full blood examination
  - d. Recent clotting profile

- e. Pathology and aetiology of the cardiac disease
- f. Other patient pathology and serology
- g. Current medications
- h. Operative procedure planned

## **9.7 Setting Up / Protocols / Check Lists**

### **9.7.1 Setting Up**

1. The oxygenator, tubing and all other devices to be used in setting up for the cardio-pulmonary bypass procedure should be visually inspected by the perfusionist with responsibility for the procedure. The perfusionist should be satisfied that all components and devices are sterile, and not compromised in any way.
2. Assembly of the circuit should be performed in an aseptic manner, as prescribed both by the manufacturer of any device utilised, and by the Hospital or Institution.
3. Instructions accompanying any device should be available for reference during the procedure.
4. Replacement or spare components should be available in close proximity to the site of the procedure.

### **9.7.2 Protocols**

1. Written protocols for the set-up and conduct of cardio-pulmonary bypass should be available.
2. Written protocols covering the management of, and the training for, "catastrophic events" that may occur during cardio-pulmonary bypass should also be available. Such events include, but are not limited to:
  - a) Massive air embolism
  - b) Oxygenator failure
  - c) Tubing rupture
  - d) Power failure
  - e) Pump failure
  - f) Heater-cooler failure

### **9.7.3 Check Lists**

1. A written, or computer-generated, check list should be completed for every procedure and should cover the following:
  - a) Verifying the integrity of the heat exchanger.

- b) Verifying the gas supply and connection to the oxygenator.
- c) Verifying the patient identification.
- d) Checking blood group and availability.
- e) Preparing and verifying all prime constituents and additives.
- f) Verifying all tubing connections secure.
- g) Verifying desired occlusion and direction of ALL pumps.
- h) Verifying calibration of arterial and cardioplegia delivery pumps.
- i) Verifying arterial-line pressure and cut-off limits.
- j) Verifying cardioplegia delivery-line pressure alarm and cut-off (if applicable).
- k) Attaching and verifying operation of the level sensor.
- l) Attaching and verifying operation of the air-emboli detector.
- m) Attaching and verifying operation of the oxygen saturation monitor.
- n) Checking "EMERGENCY EVENT" supplies, which should include: hand cranks, an auxiliary light/torch, sterile tubing, scissors, sterile blades, tubing clamps, etc.
- o) Confirming administration of the loading dose of heparin to the patient.
- p) All check lists should be signed and dated and should accompany the Patient Perfusion Parameter Sheet into the Patient Unit Record/Medical History.

## **9.8 Cardio-pulmonary Bypass Records**

1. Details relating to the patient and to the procedure should be documented electronically on a Computer Generated Record Sheet, or annotated on a Perfusion Record Sheet.
2. A record of the patient's haemo-dynamic and perfusion parameters during cardio-pulmonary bypass should be documented on a Computer Generated Record Sheet, or annotated on a Perfusion Record Sheet.
3. Adequate space for comments should be available on all Perfusion Record Sheets.
4. The Perfusion Record Sheet or Computer-Generated Record should be signed and dated by the Perfusionist performing the procedure and placed in the patient history.

## **9.9 Off-Pump Surgery**

1. Off-pump surgery is carried out when the Surgeon decides that it is in the best interests of the patient to perform a corrective procedure without the use of cardiopulmonary bypass.

2. A Perfusionist should be available during the procedure to assist the Surgeon, in case the use of cardiopulmonary bypass is required. The Perfusionist should be present in the operating room throughout the procedure.
3. A circuit should be available or set up in the operating room, in case an emergency arises necessitating the institution of cardiopulmonary bypass.
4. The procedure should be fully documented and recorded.

### **9.10 Extra-corporeal Life Support (ECLS)**

1. Extracorporeal Life Support is a method for providing life support to patients with cardiac and/or respiratory disease. The support is generally provided for patients with reversible conditions; however it can also be used as a bridge to organ transplantation.
2. Patients will either be categorised as ambulatory or non-ambulatory, depending upon the type of device inserted. The patients may have to meet certain institution-based criteria before ECLS can be instituted.
3. Priming of all extracorporeal circuits should be carried out by a Perfusionist.
4. For all patients, a Perfusionist should:
  - a) be involved in the decision to offer ECLS;
  - b) be responsible for the setting up and institution of the ECLS device;
  - c) be an integral part of the management of the patient;
  - d) be responsible for the training of appropriate personnel in the management of the patient on ECLS.
5. Spare pumps and disposable equipment should be available at all times and emergency kit for change out of failing components.
6. A Perfusionist should accompany the transport of any patient on ECLS.
7. Patients on ECLS in the operating theatre require an appropriately trained and experienced Perfusionist to supervise the ECLS circuit.

### **9.11 Ventricular-Assist Devices (VADs)**

1. *Description.* Ventricular-assist devices provide support to patients with decreased cardiac function. The specific device will be selected on the basis of whether the support is intended to be short term (i.e. days to weeks), intermediate to long term (i.e. weeks to months), or permanent (i.e. destination therapy).

2. *Device Selection.* The device selected for support of these patients will be at the discretion of the Surgeon, and will be dependant on the patient's pathology and prognosis.
3. *Bridge to Recovery.* If the pathology is reversible, the device may be used to support the patient until heart function recovers.
4. *Bridge to Transplant.* If the pathology is irreversible and the patient is a suitable candidate for transplantation the device may be used to support the patient until a suitable organ becomes available.
5. *Destination Therapy (Alternative to Transplant).* If the patient has irreversible pathology and is deemed to be unsuitable for transplantation the device may be used to support the patient permanently.
6. General principles.
  - a) For all patients, a Perfusionist should assist in the priming and setting up of the driver and in the institution of ventricular support.
  - b) Perfusionists should be an integral part of the management of the patient and the VAD.
  - c) Perfusionists should be responsible for the training of personnel for the management of the equipment
  - d) Spare equipment should be available at all times and an emergency kit for change out of failing components.
7. *Transport of Patients on VAD.* For some VAD's, the presence of an appropriately trained Perfusionist to accompany the device during transport is required.
8. *Non-Cardiac Surgical Procedures on VAD patients.* Patients on VAD in the operating theatre require an appropriately trained Perfusionist to operate the VAD.