Reproductive Technology Accreditation Committee Scheme

(RTAC Scheme)

Requirements for bodies providing audit and certification to the Code of Practice for Assisted Reproductive Technology Units

Combined Australia, New Zealand and International Edition

May 2016
## Contents

0  Introduction ........................................................................................................................................ 4  
0.1  Background .................................................................................................................................... 4  
0.2  Foreword .......................................................................................................................................... 4  
1  Scope .................................................................................................................................................. 4  
2  Normative references .......................................................................................................................... 5  
3  Terms and definitions ............................................................................................................................ 5  
4  General requirements ............................................................................................................................. 7  
4.1  Legal and contractual matters ............................................................................................................. 7  
4.1.1  Certification agreement .................................................................................................................. 7  
4.1.2  Use of license, certificates and marks of conformity ........................................................................ 8  
4.2  Confidentiality ................................................................................................................................... 8  
4.3  Publicly available information ........................................................................................................... 9  
5  Structural requirements .......................................................................................................................... 9  
6  Resource requirements ........................................................................................................................... 9  
6.1  Certification body personnel ................................................................................................................ 9  
6.1.2  Management of competence for personnel involved in the certification process ....................... 9  
6.1.3  Contract with personnel ................................................................................................................ 10  
7  Process requirements ............................................................................................................................. 10  
7.1  General .............................................................................................................................................. 10  
7.2  Application ....................................................................................................................................... 10  
7.3  Application review ............................................................................................................................... 10  
7.4  Evaluation ......................................................................................................................................... 11  
7.5  Certification decision .......................................................................................................................... 13  
7.6  Certification documentation ............................................................................................................... 13  
7.7  Surveillance ...................................................................................................................................... 13  
7.8  Records ............................................................................................................................................ 14  
7.9  Complaints and appeals ..................................................................................................................... 14  
8  Management system requirements ......................................................................................................... 14
Introduction

0.1 Background

In 1986, the FSA promoted a set of standards in the form of Guidelines for Centres using Assisted Reproductive Technology (ART) in Australia and New Zealand, and in 1987, RTAC was established.

The guidelines were amended from time to time and, in 2002, became the Code of Practice for Assisted Reproductive Technology Units. The purpose of the Code is to set minimum standards for clinics or centres offering assisted reproductive technology, and to encourage continuous improvement in the quality of care offered to people accessing fertility treatment in Australia and New Zealand.

The New Zealand standard, NZS 8181, Fertility Services, was developed to be consistent with the requirements of the 2005 version of the RTAC Code of Practice. NZS 8181 and its associated Fertility Services Audit Workbook cover all the requirements of the present Code of Practice, although in a different format and to a different level of detail.

In 2014, an international version of the Code was also released for use outside Australia and New Zealand.

0.2 Foreword

This scheme was developed by the RTAC Scheme Technical Committee contains the requirements for certification bodies (CBs) seeking JAS-ANZ accreditation to audit assisted reproductive technology (ART) organisations and certify that the ART organisation satisfies the applicable code of practice identified in the normative references to this scheme.

This Scheme contains requirements that supplement, but do not diminish, the requirements of ISO/IEC 17065.

For ease of cross reference, the section headings of this scheme are aligned with the related section headings of ISO/IEC 17065 with the term ‘product’ replaced by the term ‘service’.

The clauses of this scheme are prefixed with the character ‘R’ to allow the user to easily differentiate references to ISO/IEC 17065 from references to the associated clauses of this scheme.

The term ‘shall’ indicates a mandatory requirement.

The term ‘should’ indicates a recognised way to meet a requirement of the scheme. CBs must demonstrate how they comply with these requirements, but may do so in an equivalent way provided this can be demonstrated to JAS-ANZ.

1 Scope

Certain assisted reproductive technology units in Australia and New Zealand have also been designated as training units for the subspecialty of reproductive endocrinology and infertility. The additional requirements for those units are beyond the scope of this Scheme.
Certification under the RTAC Scheme shall not imply that the ART organisation has met legislative requirements, which will vary according to the jurisdiction in which it operates. Responsibility for legislative compliance always rests with the ART organisation. If there is a conflict between applicable legislative requirements and the Code, the applicable legislative requirement shall take precedence and these differences shall be immediately reported in writing to the RTAC via the contact details for the FSA included on page 2 of this Scheme.

2 Normative references

The following references are indispensable for the proper application of this Scheme:

The Code of Practice (CoP), meaning:

- RTAC Code of Practice for Assisted Reproductive Technology Units (August 2015) or as subsequently amended for ART Units requiring full RTAC accreditation and licensing.

- RTAC Code of Practice for Assisted Reproductive Technology Units, International Edition, (March 2014) or as subsequently amended for ART Units outside Australia and New Zealand not requiring full RTAC accreditation and licensing.

- NZS 8181:2007, Fertility Services; when combined with:

- ISO/IEC 17065:2012, Conformity assessment – Requirements for bodies certifying products, processes and services

- ISO 19011:2011 - Guidelines for auditing management systems

- Privacy Act (Australia) 1988, as amended.

- Privacy Act (New Zealand) 1993, as amended.

3 Terms and definitions

The following definitions also apply to the RTAC Scheme:

**ANZARD**

Australian and New Zealand Assisted Reproduction Database.

**ART**

assisted reproductive technology, which means clinical treatments and laboratory procedures that include the handling of human oocytes, sperm or embryos. This includes in vitro fertilization (IVF); gamete intrafallopian transfer; zygote intrafallopian transfer; intracytoplasmic sperm injection; embryo or gamete cryopreservation; oocyte, semen or embryo donation; blastomere or trophectoderm biopsy for pre-implantation genetic diagnosis; gestational surrogacy where legal; and intrauterine insemination (IUI).

**ART organisation**

an entity accountable for the delivery of services at one or more ART units.
ART unit: a facility that uses, collects, prepares or assesses human gametes and/or embryos for therapeutic service, or otherwise involves the treatment of patients with ART services including donated gametes or embryos, surrogacy and intrauterine insemination, across one or more sites of clinical activity. Where the collection of gametes/embryos takes place at a different site to the preparation, the two sites are considered to be a single unit.

Certification Body (CB): the certification body accredited by JAS-ANZ to assess compliance of an ART unit and an ART organisation with the CoP.

Close out: verification by a CB that corrective action has been implemented by an ART organisation to address a nonconformity.

Conflict of interest: a relationship between the CB, or a person working for the CB (paid or unpaid, staff or contractor), and an ART organisation or person, that threatens the impartiality of the CB. Such relationships apply to past, present or future involvement and include:

a) having worked with, or been a patient of, or consulted to the ART organisation in the last three years, or reasonable prospects of such work in the next three years
b) any financial interest in the ART organisation or relatives or friends with a financial interest in the ART organisation
c) being in competition with the ART organisation
d) any other commercial or voluntary arrangement or directorship with the ART organisation
e) having immediate family members employed by an ART organisation in any of the above situations

any personal bias or inclination which would affect decisions in relation to the ART organisation.

FSA: Fertility Society of Australia (the RTAC Scheme owner, in conjunction with JAS-ANZ). See: http://www.fertilitysociety.com.au

JAS-ANZ: Joint Accreditation System of Australia and New Zealand

Major nonconformity: the requirements of an item in the Critical Criteria section of the Code are not met, or the outcome is ineffective. A number of related nonconformities may also constitute a major nonconformity.

Nonconformity: the requirements of an item in the Good Practice Criteria section of the Code are not met, or the outcome is ineffective.

Patient: a user or participant in the ART service.

RTAC: Reproduction Technology Accreditation Committee, a committee of the
RTAC licence

a licence issued by RTAC to an ART organisation which indicates RTAC accreditation has been granted to one or more ART units accountable to that ART organisation by a Certification Body to carry out assisted reproductive technology.

Rules governing trade mark use

means the “Rules Governing Use of Trade Marks”, as amended by the FSA from time to time.

Therapeutic service

service aimed at treating patients; e.g. IVF, IUI. It does not include diagnostic procedures; e.g. semen analysis.

Trade marks

has the same meaning given to it in the Rules Governing Trade Mark Use.

4 General requirements

4.1 Legal and contractual matters

4.1.1 Certification agreement

4.1.1.1 The certification agreement shall:

a) extend to all the ART units and sites covered by the scope of certification

b) require the ART organisation to make available to the CB the records of all communications and action taken in relation to the requirements of the Code. This includes correspondence, recommendations and actions documented by RTAC or FSA; or correspondence with any other ART organisation, other organisation or person relating to complaints about the ART organisation seeking certification.

c) require that the ART organisation does not offer gifts or inducements of significant value to the CB or representatives of the CB.

Note: It is recognised that in many economies it is culturally normal to offer small or token gifts. Such practices should not be abused.

4.1.1.2 The certification agreement shall also require the ART organisation to inform the CB and RTAC of:

a) changes to the location of an ART unit

b) relocation of any of the sites at which an ART unit operates

c) changes in the scope of treatment

d) changes to key personnel as defined in Attachment 1 to the Code

e) adverse events as specified in Critical Criterion 4 of the RTAC Code of Practice.
4.1.1.3 The certification agreement shall also require units accredited against the full RTAC Code of Practice, Australian and New Zealand version, to provide specified cycle treatment data to the Australian and New Zealand Assisted Reproduction Database (ANZARD).

4.1.2 Use of license, certificates and marks of conformity

4.1.2.1 A CB or any certified ART organisation may use the FSA mark as defined in the Rules Governing the use of the Trademark, available from the FSA, and any relevant deeds between the FSA and the CB or ART organisation.

4.1.3 Transfer of Certification

4.1.3.1 When a certified ART organisation wishes to transfer from one CB to another the receiving CB shall require the clinic to provide to it copies of the clinic’s:
   a) Current RTAC licence/s
   b) Current CB RTAC certificate/s
   c) Most recent CB RTAC audit report/s including a list of any non-conformities, both open and closed
   d) Evidence of any actions that may affect their ongoing certification with RTAC or any other relevant regulatory body

4.1.3.2 When a certified ART organisation wishes to transfer from one CB to another the relinquishing CB shall, when requested, provide, to the nominated new CB copies of the clinic’s:
   a) Current CB RTAC certificate/s
   b) Most recent CB RTAC audit report/s including a list of any non-conformities, both open and closed
   c) Evidence of any actions that may affect their ongoing certification with RTAC or any other relevant regulatory body

4.2 Confidentiality

4.2.1 The CB shall treat all information about an ART organisation, comprising documentation, records, data either in hard copy or electronic format, or verbal information that comes into the possession of a CB or any of its representatives in accordance with the laws that are applicable to the jurisdiction where the services are being provided. In Australia, this will include the Privacy Act and any relevant state or territory legislation.

4.2.2 The CB shall return or dispose of any patient information supplied by the ART organisation, or any personal staff information, such as training and competency records.

4.2.3 Patient names shall not be communicated with patient information outside an ART organisation without specific, written patient consent.

4.2.4 The CB shall clearly explain levels of confidentiality and how they are applied to every participant in the audit, including but not limited to:
   a) ART organisation staff and management
   b) patients.
4.3 Publicly available information

4.3.1 CBs shall include the following in public information about the RTAC Scheme:

a) a description of the complaints and appeals handling process, including the right of ART organisations to complain to JAS-ANZ if not satisfied with the outcome of the CB’s complaints and appeals processes

b) the process for transferring certification, which shall be in accordance with clause 4.1.3.2 above.

5 Structural requirements

No additional requirements

6 Resource requirements

6.1 Certification body personnel

6.1.2 Management of competence for personnel involved in the certification process

6.1.2.1 All auditors and audit team leaders shall have demonstrated ability to apply the knowledge and skills described in ISO 19011, clauses 7.2.3 and 7.2.4 as applicable. They shall also have current knowledge and understanding of:

a) the legislative and regulatory requirements applicable to ART organisations, including the Code

b) the issues for consumers of healthcare services including the concepts of patient rights, dignity, privacy and confidentiality

c) management practices and quality systems in a healthcare setting.

6.1.2.2 The team member that audits the clinical element of the Code shall have a clinical qualification and have been employed in a senior clinical role (such as medical, nursing, counselling or scientific) or have been providing relevant clinical consultancy for such a role in an ART unit and have gained a detailed understanding of the administrative, technical and regulatory requirements that are applicable to an ART organisation.

6.1.2.3 The team member that audits the clinical element of the Code shall be able to demonstrate current (not more than two years old) participation in relevant professional development recognised by the RTAC.

6.1.2.4 All audit teams shall include an audit team leader of Lead Auditor status.

6.1.2.5 The audit team may be one person, providing that person satisfies all of the above requirements.

6.1.2.6 The CB’s procedures for monitoring the performance of its personnel shall include all audit team members, including contracted personnel and technical experts, and address any performance management issues that may arise. Procedures shall include on-site observation. The CB shall establish the frequency of observation to take account of the criticality and volume of the work.
being undertaken, the experience and performance history of the audit team members and any data obtained from other types of monitoring activity such as review of audit reports and feedback from ART organisations.

6.1.3 Contract with personnel

6.1.3.1 The contract with personnel involved in RTAC Scheme certification audits to the Code of Practice shall require that, if an ART organisation or unit, or their representative, offers a gift or inducement, it shall be immediately reported to the CB to determine its acceptability.

Note: It is recognised that in many economies it is culturally normal to offer small or token gifts. Such practices should not be abused.

7 Process requirements

7.1 General

7.1.1 If an explanation is required for the consistent application of this scheme or the Code, it shall only be acceptable if approved by RTAC and JAS-ANZ.

7.2 Application

7.2.1 The CB shall provide for the transfer of JAS-ANZ-accredited RTAC Scheme certifications in accordance with IAF MD2.

7.2.2 The CB shall require the ART organisation to supply the following information:
   a) a completed application form (Supplement 1), available from the FSA
   b) a copy of its current Deed of Agreement with FSA which requires the ART organisation to abide by the Code of Practice
   c) the proposed scope of certification, by listing the specific ART treatments offered.

7.2.3 RTAC requires the ART organisation requesting full accreditation to the Australian and New Zealand Code of Practice to sign a new Deed of Agreement annually, as part of the process to renew its licence. The CB shall confirm that a Deed of Agreement has been signed.

7.2.4 The CB shall ensure that the applicant ART organisation has applied for certification to cover every ART Unit including each site that is attached to each ART Unit for which the ART organisation is responsible; i.e. it is not acceptable to offer certification to only some of the ART units / ART unit sites.

7.3 Application review

7.3.1 The CB shall have documented procedures for reviewing applications. As part of the review process, the CB shall:
   a) review the outcomes of observations and discussions during any pre-audit on-site visits
   b) confirm the availability of the required audit team competencies
c) plan its sampling of an ART organisation with multiple sites according to IAF MD1.

7.4 Evaluation

7.4.1 The CB shall establish and implement documented systems to ensure that audits of ART organisations are performed in accordance with ISO 19011.

7.4.2 The audit team shall inform the CB, prior to the audit, of any potential, current or perceived conflict of interest they have in conducting the audit.

7.4.3 The CB shall inform the ART organisation of the names of the members of the audit team who will carry out the audit, with sufficient notice to appeal against the appointment of any team member. The CB shall seek the ART organisation’s agreement to the audit plan before conducting the audit.

7.4.4 The CB shall follow up at audit any matters referred to it by RTAC or FSA that relate to conformity with the Code and provide any relevant information to RTAC/FSA if requested. If FSA is or becomes aware of circumstances or practices which may have significant consequences from a legislative or regulatory perspective or with respect to clinical care, it has the right, through RTAC, to require the CB to conduct an exceptional circumstances audit of the ART organisation.

7.4.5 The CB shall perform the initial audit in a 2 stage process. The CB may conduct the stage 1 audit remotely. During the stage 1 audit, the CB shall:

a) review the ART organisation’s policies and procedures for complying with the Code

b) confirm that the ART organisation has implemented an effective internal audit and review program covering its compliance with all the requirements of the Code.

7.4.6 The CB shall document stage 1 audit findings and communicate them to the ART organisation before the stage 2 audit, identifying any areas of concern that could be classified as nonconformities during the stage 2 audit.

7.4.7 The stage 2 audit shall not proceed until the ART organisation advises the CB that they are ready to proceed and the CB agrees. In determining the interval between stage 1 and stage 2 audits, the CB shall ensure that any significant findings are sufficiently addressed to enable evaluation of implementation where applicable during the stage 2 audit.

7.4.8 The CB shall conduct the stage 2 audit at the site(s) of the ART organisation, against the critical criteria and all sections of good practice criteria as applicable to each ART unit within the ART organisation.

7.4.9 For newly-established ART organisations, the CB shall audit and certify the ART organisation prior to first gamete collection for therapeutic service.

7.4.10 CBs shall audit donor and surrogacy treatment cycles against the Code. As specified in Critical Criterion 12 of the Australian & New Zealand Code of Practice, an organisation must supply to the Certifying Body audit team a list of all file codes involving donation divided according to sperm, oocytes and embryos, and surrogacy, in the previous calendar year. The CB will select 3 (where available) from each category for full audit on the day.
7.4.11 CBs shall audit multiple pregnancy rates against the Code. CBs shall check that trends in an ART unit’s multiple pregnancy rates decrease multiple pregnancy rates over time while they remain above 10%.

7.4.12 At the closing meeting, the audit team shall summarise any audit follow-up activities and the available avenues for resolving complaints and appeals including via JAS-ANZ.

7.4.13 The CB’s procedures shall ensure that if a major nonconformity (i.e. against a critical criterion) is raised:

a) the CB shall require the ART organisation to present a corrective action plan within 5 days of the date of issue of the major nonconformity. The CB shall require the ART organisation to take corrective action sufficient to allow the CB to close the major nonconformity within a maximum of 30 calendar days of the date of issue, based on the magnitude of the risk

b) any major nonconformity related to a high risk activity must be corrected or addressed immediately. High risk includes, but is not limited to, patient safety, patient identification or traceability

c) the CB shall sight evidence of corrective action to close out a major nonconformity; normally at an on-site follow-up audit within the 30 days. The CB shall be able to justify circumstances where it did not conduct a follow-up on-site audit to close out a major nonconformity.

7.4.14 The CB’s procedures shall ensure that if a nonconformity (i.e. against a good practice criterion) is raised:

a) the CB shall require the ART organisation to present a corrective action plan within 5 days of the date of issue of the nonconformity. The CB shall require the ART organisation to take corrective action sufficient to allow the CB to close the nonconformity within a maximum of 30 calendar days of the date of issue, based on the magnitude of the risk

b) the CB shall either sight evidence of corrective action to close out a nonconformity, OR rely on the ART organisation’s corrective action plan, in which case it shall review the corrective action at the next audit.

7.4.15 The content of all final written audit reports shall include:

a) a summary of all major nonconformities and nonconformities raised during the audit, and the proposed corrective actions to be taken by the ART organisation

b) the specific report information required by RTAC as detailed in Supplement 2, available from the FSA

c) recommendation(s) regarding granting certification (initial / primary audits) or continuing certification (surveillance audits), on which RTAC can base its licensing decisions.

7.4.16 In an audit that covers more than one type of certification standard (e.g. combined audit to ISO 9001 in addition to the Code of Practice), the audit plan shall clearly illustrate the standards that each audit team member is auditing to demonstrate that all relevant Code of Practice requirements are audited by the audit teams members conform to the requirements of this scheme.

7.4.17 The CB shall provide a written report to the ART organisation within 10 working days of completing the on-site component of the audit or, in the case of a multi-
sited organisation, within 10 working days of completion of all sites. The report shall outline major nonconformities and nonconformities and timeframes for proposed corrective actions where applicable.

7.4.18 Once the ART organisation has met all the requirements of the audit and the CB has closed out any major nonconformities or nonconformities, the CB shall provide the final written report to the ART organisation and RTAC within 10 working days.

7.4.19 Where applicable, reports of surveillance or follow-up audits shall document close-out of each major nonconformity revealed during the previous audit.

7.4.20 The CB shall prepare stand-alone reports of any follow-up audits, outlining any major nonconformities or nonconformities and clearly documenting the evidence provided to support decisions to close out major nonconformities or nonconformities. It is not acceptable to report follow up activity as an amendment to the original audit report.

7.5 Certification decision

7.5.1 ‘Certification decision’ includes the decision on initial certification after the initial (primary) audit, and the decision to renew or extend certification after each surveillance audit.

7.5.2 The CB shall ensure that the dates of certification and certification expiry always align with the RTAC licence period. The CB shall not certify an ART organisation that does not have a valid RTAC licence, or allow certification to continue if RTAC withdraws the licence.

7.5.3 The CB shall not certify an ART organisation until there is sufficient evidence to demonstrate that the arrangements for internal audit as specified in the Critical Criteria have been planned, and implemented.

7.5.4 The CB’s procedures shall ensure that all major nonconformities and nonconformities are closed out before certification or renewal/extension of certification.

7.5.5 The CB shall immediately advise RTAC of each recommendation to award certification and with reasons for any decisions to vary, suspend or withdraw certification, together with a copy of the certification document(s).

7.5.6 The entity, which may be an individual, which takes the decision to grant, maintain, extend, suspend or withdraw certification, shall satisfy the requirements for audit team leader and the competencies at clauses 6.1.1.1 and 6.1.1.2.

7.6 Certification documentation

7.6.1 Certification documents shall include the JAS-ANZ symbol and the trade-marked RTAC symbol. The latter must be used in accordance with the Rules Governing Trade Mark Use available from the FSA Secretariat

7.7 Surveillance

7.7.1 In the RTAC Scheme, ‘surveillance’ means surveillance audits of an ART organisation at least once every 12 months, before certification expires, or at least once every two years for ART organisations operating outside Australia and New Zealand, unless local legislation requires a shorter period. Where an ART unit operates for fewer than six months a year AND that unit is part of a larger
ART organisation, the interval between surveillance audits for that ART unit may be more than 12 months but at least every 36 months, at the discretion of the CB.

7.7.2 The CB shall plan surveillance audits so that ART organisations have sufficient time to address any potential major nonconformities or nonconformities before certification expires.

7.7.3 The surveillance process shall be in accordance with initial (primary) audit process as applicable, except that the CB need not repeat the stage 1 audit.

7.7.4 Surveillance audit activities shall include auditing as applicable to each ART organisation:

a) For Australian & New Zealand clinics wishing full RTAC accreditation and licensing:
   (i) all of the Critical Criteria
   (ii) at least one third of the Good Practice Criteria such that all of the Good Practice Criteria are covered over the three year surveillance period
   (iii) the effectiveness of internal audits plus a minimum of one-third of the quality management system (QMS), such that all of the QMS is covered over the three year surveillance period

b) For units wishing accreditation against the International Code of Practice:
   (i) all of the Critical Criteria
   (ii) all of the Good Practice Criteria
   (iii) the effectiveness of internal audits

c) use of marks and/or any other reference to certification or licensing.

7.8 Records

7.8.1 The CB’s records shall include the following information:

a) clear, up to date documentation of the supporting information and rationale for all decisions to sample ART organisations with multiple ART units and sites

b) sufficient information to trace all on-site audit durations, the basis for the calculations and justification for the durations arrived at.

7.8.2 The CB shall maintain certification records for at least 8 years.

7.9 Complaints and appeals

7.9.1 The CB shall copy matters referred to it by RTAC or FSA into its complaints system and action them according to its procedures for handling complaints.

8 Management system requirements

No additional requirements