



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

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0 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*, (the FSA Guidelines) and in 1987, RTAC was established.

The FSA Guidelines were amended from time to time and, in 2002, became the first version of the *RTAC Code of Practice for Assisted Reproductive Technology Units* (the Code).

The New Zealand standard, NZS 8181:2007, *Fertility Services*, was developed to be consistent with the 2005 version of the Code. NZS 8181 combined with SNZ HB 8181, *Fertility Services Audit Workbook*, are consistent with the 2005 version of the Code.

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.

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, which is a steering committee established by the FSA to represent all significant parties for the development and maintenance of the Certification Scheme. It contains the requirements for certification bodies (CBs) seeking JAS-ANZ accreditation to audit assisted reproductive technology (ART) Units/organisations and certify that the ART organisation satisfies the applicable code/s of practice as identified in the normative references to this scheme.

This Scheme contains requirements which 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 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

The scope of this document is to specify the requirements for the accreditation of bodies that certify ART units. This document also specifies the criteria that ART units must meet for certification purposes. Certain ART 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:

- Fertility Society of Australia, Reproductive Technology Accreditation Committee (RTAC), Code of Practice for Assisted Reproductive Technology Units (October 2017)
- Fertility Society of Australia, Reproductive Technology Accreditation Committee (RTAC), Code of Practice for Assisted Reproductive Technology Units, International Edition, (October 2018)
- ISO/IEC 17065:2012: Conformity assessment – Requirements for bodies certifying products, processes, and services
- ISO 19011:2018: Guidelines for auditing management systems
- IAF MD 2:2017: IAF Mandatory Document for the Transfer of Accredited Certification of 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:

<u>ANZARD</u>	Australian and New Zealand Assisted Reproduction Database.
<u>ART</u>	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 (GIFT); zygote intrafallopian transfer (ZIFT); intracytoplasmic sperm injection (ICSI); embryo or gamete cryopreservation; oocyte, semen or embryo donation; blastomere or trophoctoderm biopsy for preimplantation genetic diagnosis; gestational surrogacy where legal; and intrauterine insemination (IUI); as defined in the Code of Practice.
<u>ART organisation</u>	an entity accountable for the delivery of services at one or more ART units.
<u>ART unit</u>	a facility that uses collects, cryopreserves, stores, 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; as defined in the Code of Practice.
<u>Certification Body (CB)</u>	the certification body accredited by JAS-ANZ to assess compliance of an ART unit and an ART organisation with the Code of Practice.
<u>Closeout</u>	verification by a CB that corrective action has been implemented by an ART organisation to address a nonconformity.
<u>Conflict of interest</u>	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: <ul style="list-style-type: none"> a) having worked with, or been a patient of, or consulted to the ART organisation in the last two years, b) any financial interest in the ART organisation of relatives c) competing 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 f) any personal bias or inclination which would affect decisions concerning the ART organisation.
<u>FSA</u>	Fertility Society of Australia (the RTAC Scheme owner, in conjunction with JAS-ANZ). See: http://www.fertilitysociety.com.au



<u>JAS-ANZ</u>	Joint Accreditation System of Australia and New Zealand
<u>Major nonconformity</u>	the requirements of an item in the Code are not met, the outcome is ineffective and there is a patient risk. Several related minor nonconformities may also constitute a major nonconformity.
<u>Minor nonconformity</u>	the requirements of an item in the Code are not met, the outcome is ineffective but there is no patient risk.
<u>Patient</u>	a user or participant in the ART service.
<u>RTAC</u>	Reproduction Technology Accreditation Committee, a committee of the FSA which developed and maintains the Code on behalf of the FSA.
<u>RTAC licence</u>	a licence issued by RTAC to an ART Unit/organisation which may belong and be accountable to an ART organisation by a Certification Body to carry out assisted reproductive technology.
<u>RTAC Code of Practice (the Code)</u>	means as applicable: <ul style="list-style-type: none"> - <i>Fertility Society of Australia, Reproductive Technology Accreditation Committee (RTAC), Code of Practice for Assisted Reproductive Technology Units, OR</i> - <i>Fertility Society of Australia, Reproductive Technology Accreditation Committee (RTAC), Code of Practice for Assisted Reproductive Technology Units, International Edition</i>
<u>Rules governing trade-mark use</u>	means the “Rules Governing Use of Trade-Marks”, as amended by the FSA from time to time.
<u>Therapeutic service</u>	service aimed at treating patients, e.g. IVF, IUI. It does not include diagnostic procedures, e.g. semen analysis.
<u>Trademarks</u>	has the same meaning given to it in the Rules Governing Trade-Mark use



4 General requirements

4.1 Legal and contractual matters

4.1.2 Certification agreement

4.1.2.1 The certification agreement shall also:

- a) be signed by an authorised representative of the ART organisation and 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 concerning 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 to the CB or representatives of the CB.

4.1.2.2 The certification agreement shall also require the ART organisation to inform the CB and RTAC within the timeframe as defined in the Code of Practice 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 the Code and provision of their CV upon appointment
- e) adverse events as defined in the Code.

4.1.2.3 The certification agreement shall also require units certified against the Code (excluding certifications to the International Edition of the Code), to provide specified cycle treatment data to the Australian and New Zealand Assisted Reproduction Database (ANZARD).

4.1.3 Use of license, certificates, and marks of conformity

4.1.3.1 A CB or any certified ART Unit/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.

4.2 Management of impartiality

No additional requirements to ISO/IEC 17065:2012

4.3 Liability and financing

No additional requirements to ISO/IEC 17065:2012

4.4 Non-discriminatory conditions

No additional requirements to ISO/IEC 17065:2012



4.5 Confidentiality

- 4.5.1 The CB shall treat all information about an ART Unit/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 following the laws that apply to the jurisdiction where the services are being provided. In Australia, this will include the Privacy Act and any relevant state or territory legislation.
- 4.5.2 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.
- 4.5.3 No identifying patient information to be used outside of the unit once the audit is complete
- 4.5.4 The CB shall clearly explain how confidentiality will be applied to every participant in the audit, including but not limited to:
- ART organisation staff and management, and
 - patients.

4.6 Publicly available information

- 4.6.1 CBs shall include the following in public information about the RTAC Scheme:
- a description of the complaints and appeals handling process, including the right of ART Units/organisations to complain to JAS-ANZ if not satisfied with the outcome of the CB's complaints processes
 - the process for the ART organisation moving from one CB to another CB shall be following IAF MD 2.

5 Structural requirements

No additional requirements to ISO/IEC 17065:2012

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 the ability to apply the knowledge and skills described in ISO 19011 clauses 7.2.3 as applicable. They shall also have current knowledge and understanding of:
- the Code,
 - legislative and regulatory requirements applicable to ART Units/organisations,
 - issues for consumers of healthcare services including the concepts of patient-centred care and cultural sensitivity,
 - management practices and quality systems in a healthcare setting.



- 6.1.2.2 The team member(s) who audits the clinical elements 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 applicable to an ART organisation.
- 6.1.2.3 The team member(s) who audit the clinical elements of the Code shall also be able to demonstrate participation in relevant professional development activities within the past two (2) years.
- 6.1.2.4 All audit teams shall include an audit team leader.
- 6.1.2.5 In all jurisdictions the audit team may be one person, providing that person satisfies all above requirements, providing:
- In Australia and New Zealand, where the audit team comprises a sole auditor, a Technical Expert (TE), of a complementary discipline, must also attend as part of the audit team within a 3-year cycle. A TE, who is not a trained auditor, must always work under the direct supervision of the Lead Auditor.
 - In countries other than Australia and New Zealand, a single auditor who is a TE is permissible. If an auditor is not a TE a TE must attend the audit.
- 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 Units/organisations.
- 6.1.3 Contract with personnel**
- 6.1.3.1 The contract with personnel involved in audits to the Code shall require that if an ART organisation or unit, or their representative, offers a gift or inducement, it shall be immediately reported in writing to the CB to determine its acceptability and to provide a record of the gift being reported.

Note: It is recognised that in many economies it is culturally normal to offer small or token gifts. Such practices should still be reported.

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 accepted if approved by RTAC and JAS-ANZ.

7.2 Applications

- 7.2.1 The transfer should be per 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,
 - c) the proposed scope of certification, by listing the specific ART treatments offered.
- 7.2.3 RTAC requires the ART Unit/organisation requesting certification to the Code 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
- a) In Australia and New Zealand it is not acceptable to offer certification to only some of the ART units in an organisation
 - b) In other countries; it is acceptable to first certify a main or head office, including other sites (which may sit in other countries), at subsequent visits on a scope extension basis.
- 7.2.5 For relocation of existing ART Units, a verification on-site audit is required during final fit-out but prior to commencement of the provision of services.

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

7.4 Evaluation

- 7.4.1 The CB shall establish and implement documented systems to ensure that audits of ART Units/organisations are performed in a manner that is generally consistent with the applicable Guidelines in ISO 19011.
- 7.4.2 The audit team shall inform the CB, before 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 adequate notice to allow for an 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 concerning 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 stage 1 remotely. During Stage 1, the CB shall:
- review the ART Unit/organisation's policies and procedures for complying with the Code, and
 - confirm that the ART Unit/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 findings and communicate them to the ART organisation before undertaking the Stage 2, identifying any areas of concern that could be classified as Major nonconformities or minor nonconformities during the Stage 2.
- 7.4.7 The Stage 2 shall not proceed until the ART Unit/organisation advises the CB they are ready to proceed, and the CB agrees. In determining the interval between Stage 1 and Stage 2, the CB shall ensure any significant findings are sufficiently addressed to enable evaluation of implementation where applicable, during Stage 2.
- 7.4.8 The CB shall conduct the Stage 2 at the site(s) of the ART Unit/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 Units/organisations, the CB shall audit and certify the ART organisation before first gamete collection for therapeutic service.
- 7.4.10 CBs shall audit donor and surrogacy treatment cycles against the Code. 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 a 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, Note: Complaints may be escalated to JAS-ANZ
- 7.4.13 The CB's procedures shall ensure that if a Major nonconformity is raised:
- the CB shall require the ART Unit/organisation to present a corrective action plan within 5 business days of the date of issue of the Major nonconformity. The CB shall require the ART Unit/organisation to take corrective action 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;
 - 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, and
 - the CB shall sight evidence of corrective action to close out a Major nonconformity; normally at an on-site follow-up audit within 30 calendar 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 minor nonconformity is raised:
- The non-conformities can be closed out and reviewed at the next audit
 - the CB shall either sight evidence of corrective action to close out a nonconformity; OR rely on the ART Unit's/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 summary of all Major nonconformities and minor non-conformities raised during the audit, and the corrective actions were taken by the ART Unit/organisation.
 - the specific report information required by RTAC as detailed in Supplement 2, available from the FSA, and
 - 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 which 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 each audit team member is auditing to demonstrate that all relevant Code of Practice requirements audited by the audit team members conform to the requirements of this scheme.
- 7.4.17 The CB shall provide a written report to the ART Unit/organisation within 10 business days of completing the on-site component of the audit, or in the case of a multi-sited organisation, within 10 business days of completion of all sites. The report shall outline all nonconformities and the timeframes for proposed corrective actions.
- 7.4.18 Once the ART Unit/organisation has met all the requirements of the audit and the CB has closed out any Major nonconformities, the CB shall provide the final written report to the ART Unit/organisation and RTAC within 10 business days.
- 7.4.19 Reports on surveillance or follow-up audits shall document close-out of each nonconformity.
- 7.4.20 The CB shall prepare stand-alone reports of any follow-up on-site audits, outlining any Major nonconformities or minor nonconformities and documenting clearly the evidence provided to support decisions to close out Major nonconformities or minor nonconformities. It is not acceptable to report follow up activity as an amendment to the original audit report.

7.5 Review

No additional requirements to ISO/IEC 17065:2012

7.6 Certification decision

- 7.6.1 The CB shall not certify an ART organisation that does not hold a valid RTAC licence or allow certification to continue if RTAC withdraws the licence unless the certification is an initial audit.
- 7.6.2 The CB shall not certify an ART Unit/organisation until there is sufficient evidence to demonstrate the arrangements for internal audit have been implemented, are effective and are being maintained, and that one complete internal audit and review program covering all processes of the ART organisation's management system has been conducted.



- 7.6.3 The CB's procedures shall ensure all Major nonconformities are closed out before certification or renewal/extension of certification.
- 7.6.4 The CB shall immediately advise RTAC of each recommendation to award certification and provide reasons for any decisions to vary, suspend or withdraw certification, together with a copy of the certification document(s).
- 7.6.5 The entity, which may be an individual, deciding to grant, maintain, extend, suspend, or withdraw certification, shall satisfy the requirements for an audit team leader and the competencies at clauses 6.1.2.1 and 6.1.2.2.

7.7 Certification documentation

- 7.7.1 Certification documents shall include the JAS-ANZ symbol and the trade-marked RTAC symbol. The latter must be used following the Rules Governing Trademark Use available from the FSA Secretariat.

7.8 Directory of certified products

Not applicable

7.9 Surveillance

- 7.9.1 In the RTAC Scheme, 'surveillance' means surveillance audits of an ART organisation at least once every 12 months, or as otherwise defined by the CoP, before certification expiry.
- 7.9.2 For ART units operating outside of Australia and New Zealand, RTAC may authorise a CB to undertake certification on a less frequent basis if legislation within that country allows for less frequent certification, however, if legislation is silent on this matter certification will be annual. Copies of local legislation shall be provided if that legislation is being used to seek RTAC approval for less frequent surveillance
- 7.9.3 CBs may only offer certification to Units/organisations which abide by the appropriate Code of Practice.
- 7.9.4 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.
- 7.9.5 The CB shall plan surveillance audits so that ART Units/organisations have adequate time to address any potential Major nonconformities or minor nonconformities before the certification expires.
- 7.9.6 The surveillance process shall be per the initial (primary) audit process as applicable, except that the CB need not repeat the Stage 1.



- 7.9.7 Surveillance audit activities shall include auditing as applicable to each ART organisation:
- a) For Units undergoing annual RTAC certification surveillances and licensing:
 - (i) all Critical Criteria.
 - (ii) at least one-third of the Good Practice Criteria, such that all the Good Practice Criteria are covered over the three-year surveillance period, and
 - (iii) the effectiveness of internal audits plus a minimum of one-third of the quality management system (QMS), such that all the QMS is covered over the three-year surveillance period.
 - b) For Units/organisations undergoing biennial certification (selected international units):
 - (i) all the Critical Criteria.
 - (ii) all the Good Practice Criteria, and
 - (iii) the effectiveness of internal audits.
 - c) use of marks and/or any other reference to certification or licensing.

7.10 Changes affecting certification

No additional requirements to ISO/IEC 17065:2012

7.11 Termination, reduction, suspension, or withdrawal of certification

No additional requirements to ISO/IEC 17065:2012

7.12 Records

7.12.1 The CB's records shall support the justification for on-site audit durations.

7.12.2 The CB shall maintain certification records for at least eight (8) years.

7.13 Complaints and appeals

7.13.1 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 to ISO/IEC 17065:2012