

Reproductive Technology Accreditation
Committee

CERTIFICATION SCHEME
(RTAC Scheme)

Fertility Society of Australia

(October 2010)

Rev 1





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PART 1 – GENERAL INFORMATION FOR ART UNITS AND CERTIFICATION BODIES

1. References

- 1.1. *Code of Practice for Assisted Reproductive Technology Units*
- 1.2. NZS 8181:2007, *Fertility Services*
- 1.3. ISO/IEC Guide 65: 1996 – *General requirements for bodies operating product certification systems.*
- 1.4. International Accreditation Forum, IAF GD5 - *Guidance on the Application of ISO/IEC Guide 65:1996*
- 1.5. ISO 19011:2002 – *Guidelines for quality and/or environmental management systems auditing*

2. Transition Policy

- 2.1. All new applicant RTAC certification bodies will be required to demonstrate compliance with the October 2010 issue of the RTAC Scheme before accreditation is granted.
- 2.2. Existing applicant RTAC certification bodies and accredited RTAC certification bodies that are due to be assessed on or after 1 July 2011, may be assessed against the August 2008 issue and shall be assessed against the October 2010 issue of the RTAC Scheme. Any findings against the additional requirements of the October 2010 issue of the RTAC Scheme may be raised as observations.
- 2.3. All accredited RTAC certification bodies are required to fully comply with the October 2010 issue of the RTAC Scheme by 1 July 2011. All accreditation assessments of applicant RTAC certification bodies or accredited RTAC certification bodies performed on or after 1 July 2011, shall be assessed against the October 2010 issue of the RTAC Scheme and any deficiencies shall be reported as nonconformities or major nonconformities.

3. Definitions

- 3.1. **Assisted Reproductive Technology (ART)** - involves 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 biopsy for preimplantation genetic diagnosis; gestational surrogacy where legal and intrauterine insemination (IUI).



An ART Unit is a facility with a laboratory collecting or preparing human gametes and/or embryos for therapeutic service, possibly across a range of sites of clinical activity. When clinical activity covers more than one site, the CB will determine what auditing needs to be performed at each site.

An ART Organisation is an entity with accountability for the delivery of services at one or more ART units.

- 3.2. **Nonconformity** – In the context of the RTAC Scheme, the definition of a nonconformity as defined in IAF GD5 shall be: any deviation from specified requirements related to the service or service requirements defined by the Code of Practice. The Certifying Body is free to define different grades of deviations and areas for improvement (e.g. major or minor nonconformities, observations, etc). However, all deviations which lead to any doubts about the conformity of the service to specified requirements should be dealt with as set out in IAF GD5, G.12.6.

Nonconformities that relate to items identified in the Critical Criteria section of the Code of Practice shall require immediate corrective action and notification to RTAC.

- 3.3. **RTAC Licensing** – the issuance of a licence from RTAC to an ART unit.
- 3.4. **RTAC Certification** – the issuance of a certificate of conformity to an ART unit by a JAS-ANZ accredited Certification Body in accordance with the RTAC Certification Scheme.
- 3.5. **Technical Expert** – a recognised expert with ART experience (as per section 13.1) engaged by a Certification Body if required.

Note: Refer to Annex E for additional definitions.



4. Abbreviations

ART unit	Assisted Reproductive Technology Unit
CoP	Code of Practice for Assisted Reproductive Technology Units
FSA	Fertility Society of Australia
JAS-ANZ	Joint Accreditation System of Australia and New Zealand
RTAC	Reproductive Technology Accreditation Committee
CB	A JAS-ANZ applicant or JAS-ANZ accredited Certification Body
RTAC TC	RTAC Technical Committee

Note: Refer to Annex E for additional abbreviations.

5. Background

- 5.1. 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.
- 5.2. 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 CoP is to set and maintain 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.
- 5.3. The New Zealand standard, NZS 8181, *Fertility Services*, was developed to be consistent with the requirements of the 2005 version of the RTAC CoP. NZS 8181 and its associated Fertility Services Audit Workbook cover all the requirements of the present CoP, although in a different format and to a different level of detail. Where this document refers to the CoP, it can also apply to the analogous section(s) of NZS8181.
- 5.4. The CoP and a list of accredited ART units can be downloaded from the FSA website.¹
- 5.5. The RTAC also developed a detailed Management Manual for the operation of the RTAC and licensing of ART units.
- 5.6. In 2007, the FSA decided to introduce independent (third-party) certification of ART units as the basis for considering the RTAC licence, and asked JAS-ANZ to assist in the development and delivery of an RTAC Scheme. The RTAC Management Manual and the CoP provided the technical content for this Scheme.

¹ <http://www.fsa.au.com> (accessed 16 December 2004)



- 5.7. This Scheme was developed by a JAS-ANZ / RTAC TC in accordance with ISO/IEC Guide 65, *General Requirements for Bodies Operating Product Certification Systems*, and the International Accreditation Forum (IAF) Guidance GD5:2006, and in particular, Annex 1 detailing the requirements for the certification of services.
- 5.8. The RTAC TC included appropriate representation by technically competent, and other significantly interested, parties.
- 5.9. At the review in September 2010, references to the transition between the former RTAC auditing system to the present systems were removed for simplicity.

6. Scope

- 6.1. This Scheme details the requirements and procedures for the certification of ART units against the CoP.
- 6.2. The CoP is to be observed in units involved in the treatment of patients with ART including donated gametes or embryos.
- 6.3. Certain ART units in Australia and New Zealand have also been designated by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists as training units for the subspecialty of reproductive endocrinology and infertility. The additional requirements of those units are beyond the scope of the RTAC Scheme.
- 6.4. In Australia, the *Research involving Human Embryos Act 2002* defines an accredited ART centre as follows:

accredited ART centre means a person or body accredited to carry out assisted reproductive technology by:

(a) the Reproductive Technology Accreditation Committee of the Fertility Society of Australia; or

(b) if the regulations prescribe another body or other bodies in addition to, or instead of, the body mentioned in paragraph (a)—that other body or any of those other bodies, as the case requires.

A 'person or body commits an offence (imprisonment for up to 5 years) if:

(a) the person intentionally uses, outside the body of a woman, a human embryo:

- (i) that was created by fertilisation of a human egg by a human sperm; and
- (ii) that is not an excess ART embryo; and

(b) the use is not for a purpose relating to the assisted reproductive technology treatment of a woman carried out by an accredited ART centre, and the person knows or is reckless as to that fact.

In New Zealand the HART Act 2004 governs the delivery of ART services. Fertility services are defined a *specified health or disability service*, which means they require their own standard. This is the New Zealand Fertility Services Standard, NZS 8181:2007. The Ministry of Health requires Designated Auditing Agencies auditing against the Fertility Standard to follow the RTAC Scheme.



- 6.5. ART units must also comply with relevant legislation and regulations. In rewriting the CoP, RTAC has attempted to align it with the regulatory and legislative requirements. However, there may be differences in detail between this CoP, National Health and Medical Research Council (NHMRC) guidelines, and the legislation and associated regulations relevant to ART that have been proclaimed by various governments. In such cases, as a general rule, national legislation overrides state legislation, and state legislation overrides regulation / guidelines.

7. Appeals, complaints and disputes

- 7.1. If a certification decision or matter arising from the certification process is disputed by an ART unit, the organisation, shall in the first instance, register a complaint with the CB and provide the CB with an opportunity to review the matter in accordance with their internal procedures. The organisation may also find it appropriate to appeal through the CB appeals process available from the CB. After following due process with the CB, if the CB's complaint handling procedures are found to be ineffective, the organisation may consider it appropriate to register a complaint with JAS-ANZ. Such complaints are then handled in accordance with JAS-ANZ's published complaints handling procedure.

8. Disclaimer

- 8.1. It is the responsibility of an ART unit seeking certification to the CoP to verify the accreditation status of the chosen CB, by searching the JAS-ANZ Register, which is available on-line at www.jas-anz.com.au or www.jas-anz.org.

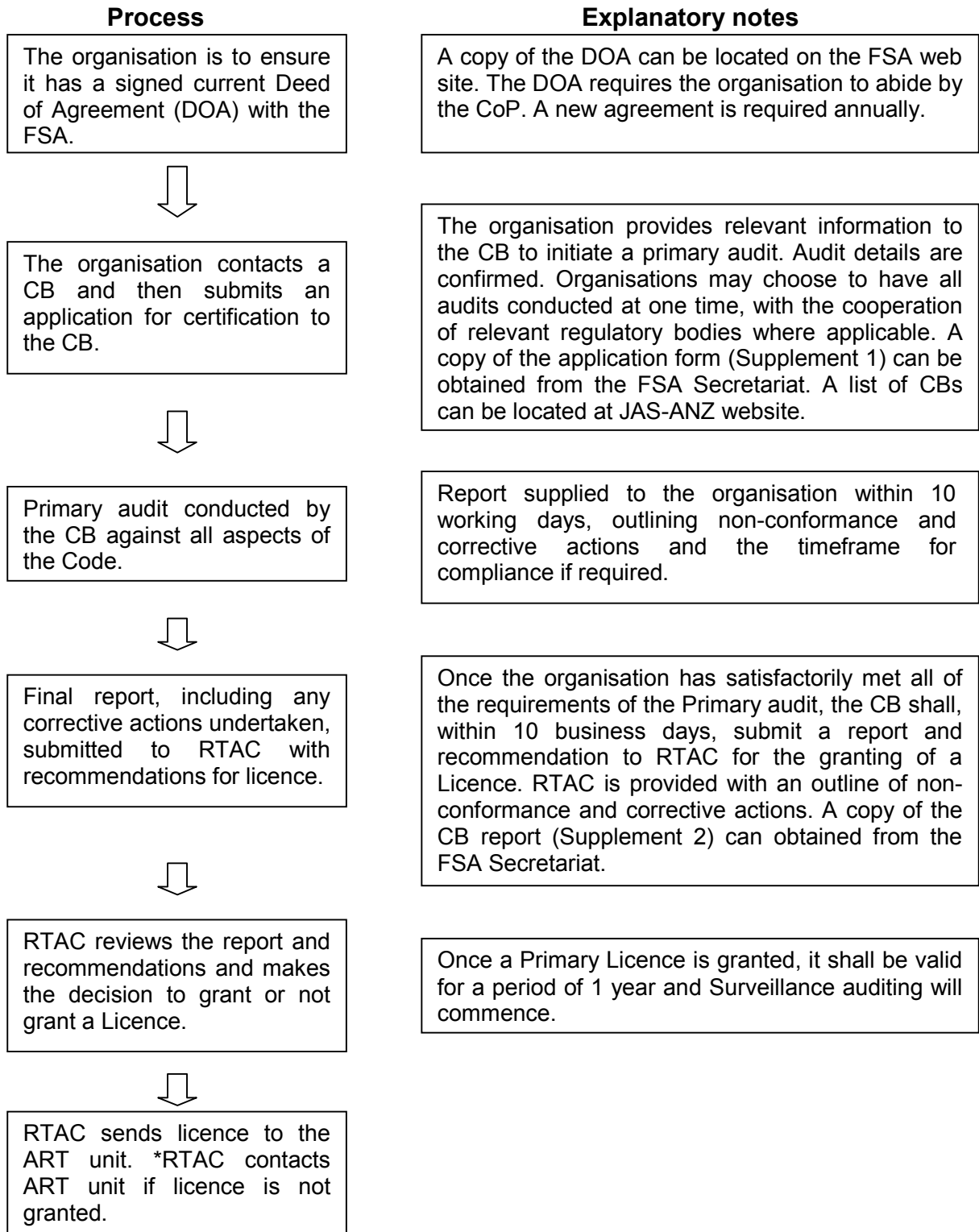
9. Process for Granting and Maintaining CB Certification and RTAC Licensing

- 9.1. Organisations must seek certification by a JAS-ANZ accredited certification body for all ART units to obtain an RTAC Licence for the operation of each ART unit.



PRIOR to commencing treatment, new ART Units must start from here:

Primary Audit: The first audit undertaken by a newly established ART unit





Surveillance Audit: Following the granting of a Primary Licence, surveillance auditing will commence on an annual basis. Each Surveillance audit will include all of the Critical Criteria and one third of the Good Practice criteria on an annual basis with the review of all areas of Good Practice criteria over a three year period.

Process

The organisation is to ensure it has a signed current DOA with the FSA.



The CB contacts the organisation to arrange annual surveillance audits.



Surveillance audit conducted against all aspects of Critical Criteria and 1/3 of Good Practice Criteria in the Code.



RTAC reviews the report and recommendation and makes the decision to continue or not continue a Licence.



Final report, including any corrective actions undertaken, submitted to RTAC with recommendations for ongoing certification.



RTAC sends licence to the ART unit. *RTAC contacts ART unit if licence is not granted.

Explanatory notes

A copy of the DOA can be located on the FSA web site. The DOA requires the organisation to abide by the CoP. A new agreement is required annually.

On request from the CB, the organisation provides relevant information to initiate surveillance audit. Audit details confirmed, including the 1/3 of Good Practice Criteria to be audited on the visit. A copy of the application form (Supplement 1) can be obtained from the FSA Secretariat.

Report supplied to the organisation within 10 working days, outlining non-conformance and corrective actions and the timeframe for compliance if required.

Once the organisation has satisfactorily met all of the requirements of the Surveillance audit, the CB shall, within 10 business days, submit a report and recommendation to RTAC for the granting of a Licence. RTAC provided with an outline of non-conformance and corrective actions. A copy of the CB report (Supplement 2) can be obtained from the FSA Secretariat.

If a continuation of the Licence is granted to the organisation, it shall be valid for a period of 1 year followed by annual surveillance audits.



Changes to an ART Unit: scope of treatment; key personnel; relocation of a unit

When an organisation wishes to change its scope of treatment, it shall advise the RTAC and the CB. The CB shall determine what information it needs and if a partial audit is required before extending the scope of treatment.

When an organisation changes any of its key personnel as defined in Attachment 1 of the RTAC Code of Practice, it shall advise RTAC and the CB. The organisation should provide the CB with sufficient information for it to assess the education, training and expertise of the new appointment against the requirements in Attachment 1. The CB shall determine if a partial audit is required.

When an organisation changes the location of a unit, or relocates any of the sites at which a unit operates, it shall advise RTAC and the CB. The CB shall determine what information it needs and if an appropriate audit is required before extending the scope of treatment.

Transition period when RTAC Code of Practice or Scheme changed

Unless specifically stated, new or changed provisions in the RTAC Code of Practice or Scheme take effect from six months after publication of the new Code of Practice or Scheme on the FSA website.

To help organisations comply with new or changed provisions, CBs may audit against the new RTAC Code of Practice and/or use the new Scheme. During the six month transition period any gaps related to the new or changed provisions will be raised as opportunities for improvement rather than non-conformances.

Exceptional Circumstances Audit:

Should an exceptional circumstance arise concerning an ART unit or organisation and related to compliance with the CoP, the FSA Board retains the right, through RTAC, to require an ART unit to undergo an additional Primary or Surveillance audit conducted by a CB.



PART 2 – SPECIFIC GUIDANCE TO ISO/IEC GUIDE 65 FOR THIRD-PARTY CERTIFICATION BODIES

10. Application of ISO/IEC Guide 65 and IAF GD5

- 10.1. For the purposes of this Scheme, CBs shall comply with all of the requirements of ISO/IEC Guide 65 and the IAF Guidance GD5 (GD5), to the extent that where there are additional requirements identified in this Scheme, the requirements in this Scheme take precedence.
- 10.2. The clause numbers from ISO/IEC Guide 65 have been added to the following clauses of the RTAC Scheme to facilitate cross-referencing, noting that this Scheme shall be read in conjunction with ISO/IEC Guide 65 and GD5.

11. General Provisions (G65, Clause 4.1.3)

- 11.1. If an explanation is required for the consistent application of this Scheme or reference standards, such explanatory requirements shall only be acceptable if approved and published by the RTAC TC.

12. Conditions and Procedures for Granting, Maintaining, Extending, Suspending and Withdrawing Certification (G65, Clause 4.6)

- 12.1. Certification shall not be granted to the ART unit until there is sufficient evidence to demonstrate that the arrangements for internal audit have been implemented, are effective and are being maintained, and one complete internal audit and review program covering all processes of the ART management system has been conducted.

13. Records (G65, Clause 4.9)

- 13.1. Copies of CB certification records shall be maintained for at least the current JAS-ANZ accreditation cycle plus the immediately previous JAS-ANZ accreditation cycle where applicable.
- 13.2. Patient names shall not be communicated with patient information outside of the ART unit, except where subject to written and specific patient consent.
- 13.3. Privacy Legislation requires the RETURN or DISPOSAL of any patient information supplied by the ART unit, or any personal staff information, such as training and competency records.



14. Certification Body Personnel (G65, Clause 5)

- 14.1 ISO/IEC Guide 65 requires CBs to ensure that personnel are competent for the functions they perform. The following specific requirements shall also apply:
- a. certification bodies shall retain records to demonstrate that for every on-site audit, all auditors satisfy the auditor requirements of ISO 19011 and at least one member satisfies the audit team leader requirements and is assigned as the audit team leader. These records must also demonstrate that all auditors (including the lead auditor) have current knowledge of:
 1. the issues for consumers of healthcare services including the concepts of patient rights, dignity, privacy and confidentiality; and
 2. management practices and quality systems in a healthcare setting.
 - b. team members with appropriate technical expertise shall be directly involved in auditing the clinical elements of the CoP. To gain sufficient technical expertise, such team members shall have been employed in a senior clinical role (including medical, nursing, counselling or scientific) in an ART unit and have gained a detailed understanding of the administrative, technical and regulatory requirements that are applicable to an ART organisation.
 - c. the assessment team may be one person, providing that person satisfies all of the requirements of this clause.
- 14.2 The CB must be able to demonstrate that it has verified the scope of the technical areas to be covered by each audit team member and confirmed that the audit team has sufficient collective knowledge and experience to evaluate the application of the CoP by the ART organisation.

15. Application for Certification (G65, Clause 8)

- 15.1. In addition to the requirements of ISO/IEC Guide 65, applications shall include the specific information required by RTAC as detailed in Supplement 1, which is available from the FSA.

Note: the contact details for the FSA are at the front of this document.

- 15.2. The application shall identify the proposed scope of certification by listing specific treatments offered from those listed in section 3.1.
- 15.3. Applications for transfer of certification shall be treated in accordance with Annex A.
- 15.4. The CB shall require the ART organisation to notify the CB and RTAC of any changes to key personnel, change in location or planned change in scope of treatment

16. Preparation for Evaluation (G65, Clause 9)

- 16.1. Personnel assigned to the evaluation shall not have a conflict of interest. A person is considered to have a conflict of interest with an ART Organisation if:



- i. he/she is, or has (within the past three years) been, employed by or contracted to the ART Organisation; or
- ii. he/she has a current financial interest in the ART Organisation; or
- iii. he/she is currently employed by, or contracted to, an organisation with a financial interest in the ART Organisation.

Note: Having a financial interest in or being employed by a different organisation in the same state or similar locality as the subject ART Organisation or Unit is not normally considered to present a conflict of interest.

- 16.2. The CB shall submit audit plans to the organisation prior to conducting the audit. The audit plans shall include the name(s) of the audit team members, and shall provide sufficient notice for the organisation to appeal against the appointment of any particular auditors or technical experts if required.
- 16.3. The CB shall seek the organisation's agreement to the audit plans prior to conducting the audit.

17. Evaluation – Primary Audit (G65, Clause 10)

- 17.1. The initial audit of the organisation under the CoP must include the critical criteria and all sections of good practice criteria as applicable within each ART unit.
- 17.2. Newly established ART units will undertake the primary audit and be granted an RTAC licence prior to first gamete collection for therapeutic service.
- 17.3. The CB shall then convey the findings and any recommendations to the organisation. The organisation shall respond to the findings, where applicable, within a required timeframe.
 - a. Critical Criteria – agreed corrective action within a timeframe negotiated with the CB based on the magnitude of the risk, up to a maximum of 30 calendar days; evidence of compliance is required. Any non-conformance related to a high risk activity must be corrected or addressed immediately. This includes but is not limited to:
 1. Patient safety
 2. Patient identification
 3. Traceability
 - b. Good Practice Criteria – agreed corrective action within a timeframe negotiated with the CB based on the magnitude of the risk, up to a maximum of 30 calendar days; evidence of compliance, or a documented corrective action plan for correction to be reviewed at next audit, is required.

16.4 Upon satisfactory correction of any non-conformances, the CB will make a recommendation to RTAC to grant a licence.



18. Evaluation - Surveillance (G65, Clause 13)

- 18.1. The organisation and ART units shall be subjected to a surveillance audit at least once in each 12 month period. Where an ART unit operates for fewer than six months a year AND that unit is part of an organisation which has an annual surveillance audit, the interval between surveillance audits may be more than 12 months but at least every 36 months at the discretion of the CB,
- 18.2. The scope of these audits as applicable to each ART unit shall cover:
 - a. all of the Critical Criteria; plus
 - b. a minimum of one-third of the Good Practice Criteria such that all of the Good Practice criteria are covered at each unit over the three year surveillance period.
 - c. a 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 to the extent applicable at each unit over the three year surveillance period.
- 18.3. The CB shall then convey the findings and any recommendations to the ART unit. The ART unit shall respond to the findings, where applicable, within a required timeframe as prescribed in clause 16.3.
19. 17.4 Upon satisfactory correction of any non-conformances, the CB will make a recommendation to RTAC to grant a licence.

Evaluation Report (G65, Clause 11)

- 19.1. On completion of a surveillance visit, the CB shall, within 10 business days, provide a written report and recommendation(s) regarding the continuation of certification, and submit this report to RTAC for the purposes of considering the continuation of the RTAC Licence. The report must include all non-compliance issues and the corrective actions undertaken.
- 19.2. In addition to the requirements of ISO/IEC Guide 65, reports shall also include the specific report information required by RTAC as detailed in Supplement 2, which is available from the FSA.

Note: the contact details for the FSA are at the front of this document.

20. Decision on Certification (G65, Clause 12)

- 20.1. The entity, which may be an individual, which takes the decision to grant, maintain, extend, suspend or withdraw certification, shall incorporate a level of competence sufficient to satisfy the lead auditor and associated competencies detailed at item 13.1 above.
- 20.2. When the CB has made a certification decision, it shall provide a written report and recommendation(s) to RTAC within 10 business days, regarding the granting of an RTAC licence.



21. Use of licences, certificates and marks (G65, Clause 14)

- 21.1. Any CB or any ART organisation that has been awarded an RTAC licence may use the FSA mark as defined in the Rules Governing the use of the Trademark. A copy is available from the FSA Secretariat.
- 21.2. The CB responsibilities include:
- a. issuing, monitoring, suspending and withdrawing certificates and licences to use the CB mark and JAS-ANZ symbol;
 - b. informing RTAC of the (planned) audit schedule every THREE months to enable the supply of ANZARD data to the CB by RTAC.
 - c. immediately advising RTAC on every occasion that an RTAC certificate and/or licence to use the CB mark is suspended or withdrawn; and
 - d. monitoring the use, and controlling and reporting the misuse, of Certificates and all associated marks including the CB's, JAS-ANZ's and FSA's marks.
 - e. auditing donor treatment cycles against the CoP. Sample size outlined in (o).
 - f. auditing multiple pregnancy rates against the CoP. Trends in an ART unit's multiple pregnancy rates are to follow compliance to decreasing multiple pregnancy rates over time.
 - g. notifying RTAC without delay, of matters that may affect the capability of the management system to continue to fulfil the requirements of the standard used for certification.

20.3 The RTAC responsibilities include:

- h. issuing, suspending and withdrawing of RTAC licences.
- i. withdrawing licences if ART units have not signed a current DOA or the unit has not paid its annual fees to FSA.
- j. immediately advising CB and JAS-ANZ on every occasion that an RTAC licence is suspended or withdrawn.
- k. ensuring that ART units are undertaking audits and that reports have been received and licences issued.
- l. regularly reviewing the CoP.
- m. maintaining records of non-compliance activities for Quality Assurance review and to assist in the revision of the CoP.
- n. ensuring a DOA for adherence to the CoP is obtained annually.
- o. supplying a CB with identification numbers for gamete & embryo donors from the ANZARD database. Sample size is 30% of annual donor treatments to a maximum often performed by an ART unit.
- p. technical advice as requested by a CB.
- q. maintaining a register of CBs undertaking audits with specific organisations/ART units.



- r. direct (if the FSA Board has determined that an exceptional circumstance has arisen concerning an ART unit or organization) an ART Unit to undergo an additional Primary or Surveillance Audit conducted by a CB.

20.4 The organisation's responsibilities include:

- a. Adhering to the RTAC Deed of Agreement.
- b. Notifying RTAC without delay of matters that may affect the capability of the management system to continue to fulfil the requirements of the standard used for certification



PART 3 - ANNEXES

(Normative Annex)

A Transfer of Certification

1. Definition

1.1. Transfer of Certification

The transfer of certification is defined as the recognition of an existing and valid RTAC Scheme certification, granted by one JAS-ANZ accredited RTAC Scheme certification body, (hereinafter referred to as the “issuing CB”), by another JAS-ANZ accredited RTAC Scheme certification body, (hereinafter referred to as the “accepting CB”) for the purpose of issuing its own certification.

2. Minimum Requirements

2.1. Accreditation

Only RTAC Scheme certifications which are covered by a JAS-ANZ accredited RTAC Scheme certification shall be eligible for transfer.

2.2. Pre-Transfer Review

A competent person from the accepting CB shall carry out a review of the certification of the prospective organisation. This review shall be conducted by means of a documentation review and should, normally, include a visit to the prospective organisation.

Reasons for not conducting a visit shall be fully justified and documented and a visit shall be conducted if no contact can be made with the issuing CB. The review should cover the following aspects and its findings shall be fully documented:

- a. confirmation that the organisation’s certified activities fall within the accredited scope of the accepting CB.
- b. the reasons for the organisation seeking a transfer.
- c. that the existing certification covers all ART units of the organisation wishing to transfer certification. If practical, the validity of certification and the status of outstanding nonconformities should be verified with the issuing CB unless it has ceased trading. Where it has not been possible to communicate with the issuing CB, the accepting CB shall record the reasons.
- d. a consideration of the certification audit and subsequent surveillance audit reports and any outstanding nonconformities that may have arisen from them.



- e. if the certification or surveillance audit reports are not made available or if the surveillance audit is overdue then the organisation shall be treated as a new client.
- f. complaints received and action taken.
- g. any current engagement by the organisation with regulatory bodies in respect of legal compliance.

2.3. Certification

2.3.1 Normally, only valid JAS-ANZ accredited RTAC Scheme certification should be transferred. In cases where the certification has been granted by a CB which has ceased trading or whose accreditation has expired, been suspended or withdrawn, the accepting CB may consider such a certification for transfer at its discretion. In cases where a CB is acquired by another CB, the acquiring CB should, where practicable, fulfil the obligations of the acquired CB.

2.3.2. Certification which is known to have been suspended or under threat of suspension shall not be accepted for transfer. If the accepting CB has not been able to verify the status of the certification with the issuing CB, the organisation shall be required to confirm that the certificate is not suspended or under threat of suspension.

2.3.3. Outstanding nonconformities should be closed out, if practical, with the issuing CB, before transfer. Otherwise, with accepting CB will determine an appropriate time for close out. .

2.3.4. If no further outstanding or potential problems are identified by the pre-transfer review, a certification may be issued following the normal decision making process.

2.3.5 Where doubt continues to exist, after the pre-transfer review, as to the adequacy of a current or previously held certification, the accepting CB shall, depending upon the extent of doubt, either:

- treat the applicant as a new client
- OR
- conduct an audit concentrating on identified problem areas.

The decision as to the action required will depend upon the nature and extent of any problems found and shall be explained to the organization and the justification for the decision shall be documented and the records maintained by the CB.



(Informative Annex)

B The Reproductive Technology Accreditation Committee (RTAC)

Note: Further information can be found in the RTAC Terms of Reference issued by FSA.

RTAC includes FSA expert representatives from all specialty areas of ART, including reproductive medicine, nursing, counselling and reproductive biology. It also includes representation from the fertility consumer organisation ACCESS.

Membership of RTAC is as follows:

- Chair (appointed by the FSA Board)
- Deputy Chair (appointed by the FSA Board)
- Nominee of ACCESS
- Nominee of Australian New Zealand Infertility Counsellor's Association (ANZICA)
- Nominee of Fertility Nurses of Australia (FNA)
- Nominee of IVF Medical Director's Group.
- Nominee of Scientists in Reproductive Technology (SIRT)

The RTAC chairperson is appointed by the FSA Board of Directors for a term determined by the board, but not exceeding two terms of three years. The chairperson is an ex-officio member of the FSA Board and reports regularly to the FSA board, but RTAC licensing decisions remain independent of the FSA board and FSA subcommittees.

RTAC reports annually on certification of organisations to the FSA board.



(Informative Annex)

C The RTAC Technical Committee (RTAC TC)

Note: Further information can be found in the RTAC Terms of Reference issued by FSA.

The RTAC TC is a standing committee established by the FSA to represent all significant parties for the development and maintenance of the Certification Scheme.

Membership of the RTAC TC is as follows:

- Chair: FSA President
- Chair of RTAC
- A representative invited from each of the following:
 - IVF Medical Director's Group
 - SIRT
 - ANZICA
 - FNA
 - ACCESS / Fertility NZ
 - Australian Private Hospitals Association
 - Australian Medical Association
 - National Health and Medical Research Council
 - Royal Australian and New Zealand College of Obstetricians & Gynaecologists
 - Australian Health Insurance Association
 - Joint Accreditation System – Australia and New Zealand
 - Australian Association of Certification Bodies
 - New Zealand Conformity Assessment Bodies
 - Australia Department of Health and Ageing
 - Victorian Assisted Reproductive Treatment Authority
 - WA Reproductive Technology Council
 - SA Council of Reproductive Technology
 - Body administering the New South Wales Assisted Reproductive Technology Act 2007
 - NZ Ministry of Health



(Informative Annex)

D Review and Amendments

At the direction of the FSA, the RTAC Technical Committee (RTAC TC) shall review this Scheme at least every three years, and propose revised or additional criteria where it considers it appropriate.

The review process includes consultation with the FSA subcommittees and other stakeholders and ratification by RTAC and the FSA Board of Directors before release to the general community.

In every case, the FSA shall advise JAS-ANZ of all proposed changes to any of the requirements and the appropriate period of time for ART units to fully adopt any revised or additional criteria. The applicable transition policy is published in Part 1, Section 2 of this document.



(Informative Annex)

E Additional definitions and abbreviations

Note: Refer to Part 1 for the key definitions and abbreviations.

ANZARD	Australian and New Zealand Assisted Reproduction Database
ANZICA	Australian and New Zealand Infertility Counsellor's Association
Appoint	When the Organisation employs, hires, contracts with, chooses, or arranges for a particular individual to provide a certain role.
ART Unit	A facility with a laboratory collecting or preparing human gametes and/or embryos for therapeutic service, possibly across a range of 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.
Artificial Insemination	The controlled and planned ART process by which sperm is introduced into the female genital tract with or without hormonal stimulation.
Audit	A systematic independent examination and a review to determine whether actual activities and results comply with planned arrangements.
Authority	The proper powers to carry out an action whether granted directly or delegated.
Certification	A third party assessment of the quality system of the service provider with respect to published quality system standards and any supplementary documentation required under the system (for example ISO 19011:2002).
Competent	Having the required ability, knowledge or authority.
Deed of Agreement	Signed agreement with the FSA to comply with the RTAC Code of Practice. New agreement required annually.
Exceptional Circumstances Audit	An audit requested by the FSA Board that arises from an exceptional circumstance with respect to compliance with the CoP.
Facility	The physical location, site or building within or from which the service is provided.
FNA	Fertility Nurses of Australasia
Governance	Taking responsibility for the overall direction of the organisation, including determination of the purpose and goals of the service.
Integration	When the Organisation involves, assimilates, incorporates or amalgamates individuals into its day to day activities.
Management	Implementing the policy determined by the governing body and coordinating the day to day service activity which achieve the purpose and goals of the organisation.
Must	Where it is mandatory in every circumstance to perform the required task with no exception.
New owners	The addition of any new company directors with financial shareholdings



	in the organisation.
New unit New unit (cont)	An ART Unit that is newly established with no previous accreditation. This includes Units that are additional to the number of accredited Units for which an Organisation is already accountable but excludes Units that are only a relocation of an existing accredited Unit.
Organisation	An entity that is accountable for the delivery of services at one or more ART Units.
Ovulation Induction	The controlled and planned ART process whereby hormonal stimulation is employed to induce the process of ovulation.
Patient	A user or participant in the service.
Policy	Overall intentions and directions of an organisation.
Primary Audit	The first audit undertaken by a newly established ART unit or the first audit undertaken by an established unit after the introduction of the 2008 RTAC CoP.
Procedure	A procedure is a specific way to carry out an activity.
Process	A set of interrelated or interactive activities which are planned and carried out under controlled conditions.
Quality Policy	Overall intentions and direction of an organisation related to quality as formally expressed by top management.
Records	A description of the healthcare provided for an identifiable patient/donor. May be a single file, multiple files, hard copy or electronic and is held by an organisation, service provider or the patient/donor themselves.
Relocation	Established ART organisation or unit which relocates premises.
Review	A formal process of updating, amending, or replanning, based on evaluation outcomes.
Risk	The chance of something happening which will have an adverse impact on objectives.
Risk management	The culture, processes and structures that are directed towards realising potential opportunities whilst managing adverse effects.
Service provider	An individual who is responsible for providing the service either independently or on behalf of an organisation. This includes all staff and management who are employed, self employed, visiting, honorary, sectional, contracted or volunteer.
SIRT	Scientists in Reproductive Technology
Stakeholders	Person or group having an interest in the performance or success of an organisation.
Supervision	An activity that aims to enable the supervisee to achieve, sustain and develop a high quality practice through the means of focused support and development.
Surveillance Audit	All audits following the Primary Audit.
Therapeutic Service	Service aimed at treating patients i.e. IVF, IUI. It does not include



	diagnostic procedures e.g. semen analysis.
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