



Reproductive Technology Accreditation Committee (RTAC) Certification Guidebook

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Contents

1 Audit Cycle & Certification.....	3
1.1 Initial Inquiry	3
1.2 Application for Certification and Assessment	3
1.3 Client Contact	3
1.4 Gap Analysis (optional)	4
1.5 Initial Audit (Stage 1 Audit)	4
1.6 Certification Audit (Stage 2 Audit)	4
1.7 Surveillance Audits	5
1.8 Re-Assessment Audits	5
2 Reporting.....	5
3 Non-Conformities.....	6
3.1 Major Non-Conformances	6
3.2 Minor Non-Conformances	6
3.3 Observations	6
4 Certification Decision.....	7
5 Certificates.....	7
5.1 Scope of Certification	7
5.2 Refusal of Certification/Recognition	8
5.3 Suspension or Refusal of Certification	8
6 Use of Logos.....	8
7 Accreditation Status	8
8 Standard Owner Information.....	8
8.1 Notification to the Standard Owner	9
9 Confidentiality.....	9
10 Additional Process Requirements.....	9
11 Additional Obligations.....	9
12 Misleading Statements.....	10
13 Complaints and Appeals	10

This Certification Guidebook is designed to assist your organisation/Assisted Reproductive Technology (ART) Unit on the requirements for certification to the Code of Practice has been developed by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia (FSA).

1 Audit Cycle & Certification

The following section outlines the steps that apply during the BSI certification process for the RTAC scheme. BSI reserves the right to provide its clients and those that request quotations with marketing and technical information relating to standards, training and compliance services.

1.1 Initial Inquiry

BSI will respond to either verbal or written expressions of interest from organisations interested in one or more of our programs. If your organisation is located near one of BSI's offices, an advisory visit may be arranged to discuss your recognition requirements and how BSI can help your organisation achieve them. BSI will also, on request and receipt of a Request for Quotation, prepare a proposal tailoring our services to your organisation's needs.

1.2 Application for Certification and Assessment

Receipt of your organisation's Application form (or authorised acceptance of a valid BSI proposal), along with the accompanying payment of the non-refundable application fee (or invoicing instructions) together with this document forms the contract between your organisation and BSI.

Your requirements will be entered into our database and a Client Manager will be appointed to look after your certification or assessment requirements. The Client Manager will be your primary point of contact with BSI and is responsible for ensuring that our certification/assessment services are delivered to your organisation in the most effective manner possible.

1.3 Client Contact

As soon as practicable after receipt of your signed application/proposal, a BSI Client Manager (or nominated representative) will contact your organisation. The Client Manager will seek to establish a working relationship between your organisation and BSI, and to confirm your recognition requirements in terms of the certification or assessment services, standards or codes of practice, locations, and activities and/or products to be included in the scope of certification.

The Client Manager (or nominated representative) will seek to gain an appreciation of the structure of your organisation and the activities being conducted. In particular the Client Manager will:

- Seek an appreciation of the nature and scope of the organisation's activities, structure and location(s), including any activities for which confirmation is being excluded; and

- Determine the status of system documentation and implementation including organisational policies, objectives and targets.

If you are working with a consultant it is often useful for that person to be party to the communication process.

1.4 Gap Analysis (Optional)

A Gap Analysis approach often proves an invaluable tool in determining system implementation, particularly for new systems that are still in the early stages of development. This one-off assessment includes the identification of gaps against the requirement of the nominated Standard. At the conclusion of the Gap Analysis you will receive a report which highlights any gaps as well as options for next steps on your path to certification. The results of a Gap Analysis are not directly linked to any subsequent Certification Audits.

1.5 Initial Audit (Stage 1 Audit)

In order to gain certification to the RTAC scheme your organisation is required to have an initial audit followed by a certification audit. An initial audit determines your readiness for certification. BSI undertakes a review of your organisation's system documentation, including policy manuals, procedures and other relevant supporting documentation.

This step gives your organisation the opportunity to demonstrate that all documentation required by the relevant standard has been prepared, is controlled where necessary, and is monitored and updated as required.

The initial audit will be carried out by a qualified assessor. It is a requirement that the assessment be carried out at your site. If you have multiple sites not all of the sites are required to be included in this audit.

Your organisation will receive a written report which outlines the readiness for the Certification Audit. The findings from the initial audit must be satisfactorily addressed (closed out) prior to the certification audit.

At the Stage 1 assessment BSI will confirm that your organisation has conducted at least one self-assessment covering the relevant activities.

1.6 Certification Audit (Stage 2 Audit)

The certification audit must be conducted within four (4) months of the initial audit. If the certification audit is not conducted within this time the initial audit may need to be repeated.

The objectives of the Stage 2 audit are:

- To confirm that your organisation adheres to its own policies, procedures & objectives and practices the principals of continuous improvement;
- To confirm that the RTAC system conforms with all the requirements of the scheme and is achieving your organisation's policy objectives
- To verify that appropriate procedures, controls and guidelines are in place, and roles and responsibilities are defined.

Your organisation will be advised of any non-conformances arising from this assessment. All non-conformances are required to be closed out before certification can be recommended. The recommendation for certification is made by the auditor. The audit report is reviewed by an independent qualified report reviewer.

Your certificate will be issued electronically.

1.7 Surveillance Audits

Surveillance audits are carried out at 12 monthly intervals.

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.

Should an exceptional circumstance arise concerning an ART unit or organisation and related to compliance with the Code of Practice 2014, the FSA Board retains the right, through RTAC, to require an ART unit to undergo an additional Primary or Surveillance audit conducted by BSI.

1.8 Re-Assessment Audits

The re-assessment cycle for this program is 3 yearly. Your reassessment audit must be conducted within 3 years of the initial certification or last recertification. If not completed and processed within the required time frame, your certification is no longer valid.

The re-assessment audit must take place 3 months prior to the expiry date. Extensions on the re-certification dates are not permitted.

2 Reporting

At the conclusion of the audit, the audit team will prepare a written report on the audit findings and the audit team leader will present these findings to your organisation's senior management at the closing meeting.

Reporting will be done using the BSI E Report.

The audit findings include a summary of the overall compliance of your system with the requirements and provided to your organisation following each audit. The audit report will include the following information;

- An executive summary of the overall findings (conclusions) on the effectiveness of your system in meeting the requirements of the standard
- Each criteria including a statement of judgement as to the organisation's capability of systematically meeting the mandatory criteria
- Ratings of the non-conformances
- Suggestions for continual improvement
- Positive finding areas

Non-conformities will be discussed with your team during the auditor's visit and outlined at the exit meeting. Non-Conformities are categorised as Major, Minor and Observations.

If you are unclear regarding the meaning of anything in your report, please contact your BSI Client Manager.

It is your organisation's responsibility to respond to the non-conformities detailed in your audit report by the designated time frame. Failure to do so may result in suspension or cancellation of your certification.

3 Non-Conformities

All non-conformances must be closed out before certification is granted or expiry of certification. As some of these findings impact on funding arrangements of the facility; system failures and responses must be treated as a priority matter.

Specific audit findings are categorised as follows and are applicable during the certification and verification audit activities:

3.1 Major Non-Conformances

Major Non-conformances are audit findings that reveal system failure against the RTAC CoP and must be rectified before certification is granted.

Major Non-Conformances time frames are addressed according to severity of the deficiency. Depending on the urgency, it may be required to be submitted to the regulators within 24 hours, the auditor/s may have to return in a short space of time to address the corrective action or notify the state regulators. Where the major non-conformity does not place a person accessing the scheme at risk of significant harm BSI is required to close out or downgrade out the non-conformance following an on-site visit within three (3) months. Evidence of the corrective action plan is required to be sent to BSI within five (5) days of the assessment.

BSI is required to advise the RTAC secretariat of any major non-conformances and adverse events.

3.2 Minor Non-Conformances

Minor Non-conformances are audit findings that reveal an isolated incident of non-compliance that has no direct impact on the integrity of the product. Agreed proposed corrective action plans (CAPs) (detailing correction, cause identification and long term fix) must be received within two (2) weeks of the nonconformity being identified.

3.3 Observations

These are comments, which may include praise, opportunities for improvement, or comments that may be relevant for the next audit. Actions do not necessarily have to be taken for observations however; it is recommended that these have been considered as part of your continuous improvement process.

4 Certification Decision

After confirmation that any necessary corrective actions have been taken, which may involve a follow up visit by the BSI Assessor, the findings and recommendations made in the audit report are subject to an internal review process. Upon satisfactory completion of review, BSI will make a recommendation to RTAC to grant a licence.

5 Certificates

Following the satisfactory review and approval of the submission, the organisation will be provided a certificate stating compliance to RTAC Code of Practice.

The certificate will note that the system meets the requirements of the RTAC Code of Practice together with a description of the category of the healthcare facility scope.

Each site requires an independent certificate of compliance to the RTAC Code of Practice 2014.

BSI will make a recommendation to RTAC to grant a licence and provide the report to RTAC.

When copies or elements of the certificate are used in tenders or offered to potential or existing customers, the certificate should be accompanied by the scope of certification document (if issued separately) as it is important for them to understand the scope of activities for which certification has been granted (see 'scope' below).

Incorrect use of the certificate can result in a customer being misled as to the extent of your organisation's certification. Clients are obliged to ensure that BSI has been formally notified of the latest address, ownership, changes to key management responsibilities, major management system changes and capability information so that the certificate maintains its currency. Failure to do so may compromise your organisation's certification status.

All original certificates remain the property of BSI Group ANZ Pty Ltd and must be returned on request.

The reassessment cycle for this program is 3 yearly.

5.1 Scope of Certification

The scope of certification fully details the scope of your organisation's certification in terms of:

- Names and addresses of all locations covered by the certification;
- Achievement of certification to the relevant standard(s) or code(s) of practice;
- The capability statement (range of products, services, and activities) for each location covered by the certification; and
- Any specific exclusion from the scope of certification.

Clients are obliged to ensure that BSI has been formally briefed in a timely manner when any variations occur. Clients should not wait until the next scheduled assessment to notify BSI. Failure to do so may compromise the organisation's certification status.

5.2 Refusal of Certification/Recognition

In the event that your organisation is unable to comply with the requirements of the relevant standard, BSI may refuse to grant certification. The decision to refuse certification, and the grounds for that decision, will be communicated to your organisation in writing.

5.3 Suspension or Refusal of Certification

When an organisation's certification is suspended or refused, the organisation shall, for the period of suspension or refusal:

- Withdraw and cease to use any advertising or promotional material that promotes or advertises the fact that the organisation is certified;
- Ensure that all copies of certificates and scopes of certification are removed from areas of public display; and
- Cease to use the certification mark on stationery and other documents including media and packaging that are circulated to existing and potential clients, or in the public domain.

The organisation shall advise BSI in writing of action taken with respect to the requirements listed above;

- BSI shall advise the organisation in writing of the certification processes that will need to be completed to restore certification; and
- During the period of suspension the organisation shall continue to pay all fees levied by BSI

6 Use of Logos

You are entitled to use the appropriate BSI 'kitemark' and the JAS-ANZ logo whilst you maintain certification to this program with BSI. For a copy of the logo, visit our website at www.bsigroup.com

Use of the logo is subject to Condition and rules of its application.

ART units holding a current RTAC Certification issued by BSI are entitled to use the JAS-ANZ Accreditation Symbol. The rules for the use of this mark are governed by JAS-ANZ. The JAS-ANZ Accreditation Symbol may be used in conjunction with BSI Accreditation marks.

Specifications and use of the JAS-ANZ Accreditation Symbol are described in the JAS-ANZ Mark Use Guidelines document.

7 Accreditation Status

Certification to this standard is accredited to ISO17065:2012

This is a JAS-ANZ accredited scheme which is offered nationally. BSI is currently accredited to this scheme.

8 Standard Owner Information

The standard owner is the Fertility Society of Australia (FSA).

8.1 Notification to the Standard Owner

BSI is required to advise the RTAC Secretariat at the following times;

- Provide a list of all clients due for audit to the RTAC secretariat each year
- In case of major non-conformances and adverse events
- A report must be provided to RTAC within 10 working days to grant license after approval of certification by BSI

9 Confidentiality

BSI will treat all information in accordance with the Privacy Amendment (Enhancing Privacy Protection) Act 2012

10 Additional Process Requirements

Your organisation is required to keep a record of all known complaints relating to meeting the requirements of the RTAC scheme. These records must be made available to the audit team and BSI when requested.

Your organisation is required to demonstrate that you have taken appropriate action to address these complaints through investigation and correct any deficiencies found. These actions must be documented.

Your organisation is required to make all necessary arrangements to allow the evaluation and surveillance activities to take place. This includes but is not limited to; Equipment, Product, Locations, Personnel and Sub-contractors.

11 Additional Obligations

Following certification, there are a number of managerial responsibilities which your organisation will need to observe to maintain BSI's certification. These include:

- Continued compliance with the relevant standard(s) and scheme requirements at and the conditions of certification at all times;
- Compliance with the BSI Standard Commercial Terms and Conditions and obligations as specified in this document as well as other guidance documentation that may be specifically provided from time-to-time;
- Your organisation is required to implement appropriate changes as communicated by BSI in a time appropriate manner;
- Conduct of regular internal reviews of your system, with appropriate documentation of such reviews and of any subsequent corrective actions;
- Your organisation is required to advise BSI of any changes without delay to circumstances that may affect certification including significant changes in the structure (key responsibilities and management system), ownership and operations of your organisation to enable the impact of such changes on the certified ownership system to be evaluated;

Other examples of such changes include but are not limited to;

- Authorised Representative
- Business name (Legal entity) and Trading Name (where applicable), ABN
- Ownership
- Contact details

- Location, site addresses
- Business activity/ies, scope of certification (Products and Processes)
- System Management Number of employees, covering all shifts and sites
- Billing Details
- Notification to BSI of any litigation or serious events or matters that relate to the scope of your certification

Observers

From time to time BSI requires an Observer to be in attendance at an audit. This may be related to training of new staff and witness assessment of existing staff. It is a requirement of certification that your organisation allows these activities to occur.

Failure to allow this activity to occur may result in cancellation of your certification.

BSI will, at all times, ensure that the use of observers is kept to a minimum and your organisation will be advised prior to the assessment activity.

The Observer does not take an active part in an assessment.

12 Misleading Statements

Your organisation is not permitted to use its product certification in a manner that could bring the BSI into disrepute. This includes making misleading or unauthorized statements. If you are unsure if a statement could be misleading you are advised to contact BSI prior to making the statement. Statements include but are not limited to the use of the logo on non-certified product, advertising (including your website) and internal communication.

If your organisation is required to provide copies of their certification documents these must be reproduced in its entirety. Failure to do so may be misleading to the recipient as to the scope of certification.

13 Complaints and Appeals

BSI takes complaints relating to our service delivery seriously and all complaints will be investigated and the originator of a complaint will be advised of the outcomes, as appropriate.

BSI will also investigate legitimate documented complaints, relevant to operation of the system, from customers of your organization. Organizations shall, at all reasonable times, provide representatives of BSI with access to its premises and records for the purposes of investigating such complaints.

If your organization's application for certification has been refused, or your organization's certificate has been suspended, cancelled, or reduced in scope, you may appeal against the decision to a Review Committee.

Should you wish to appeal the certification decision your organization is required, within 28 days of the disputed advice from BSI, lodge a notice of appeal with your Client Manager in writing to initiate this process.

To raise a complaint or appeal against the service delivery by BSI or audit outcome please notify;

Stephanie Vincent
GM Compliance and Risk (ANZ)
Email: Stephanie.vincent@bsigroup.com
Phone: 1300 730 134

For other questions on this scheme, please contact:

Stephanie Vincent
GM Compliance and Risk (ANZ)
Email: Stephanie.vincent@bsigroup.com
Phone: 1300 730 134