National Safety and Quality Health Standards (NSQHS) 2012 Recognition Booklet

BSI/AU/RB/NSQHS/09042015

Revision 2 (April 2015)

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Contents

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This recognition booklet is designed to assist your organisation/ acute care and sub-acute care organizations for Hospitals and Day Surgery units on the requirements for certification to the National Safety and Quality Health Standards (NSQHS) 2012. The Commonwealth Department of Health and the State departments of Health have specific regulatory framework around the National Safety and Quality Health Standards (NSQHS) implementation and compliance requirements.

1 Audit Cycle & Certification

The following section outlines the steps that apply during the BSI recognition process for the NSQHS 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.
- The nature and scope of the organisation's activities, structure and location(s), including any activities for which confirmation is being excluded; and
- The status of system documentation and implementation including organisational policies, objectives and targets.
- The shifts in your organisation, since each audit must include adequate evidence from all shifts to the extent required to determine whether the findings and recommendations are appropriate in the context of the hours of operation.

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 NSQHS 2012 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, every site of the organization is audited except where applicable legislative or regulatory requirements allow for an indicative sample to be taken. This will be determined on a case-by-case basis and approved by the Technical Specialist – Healthcare.
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
- To confirm that your organisation adheres to the applicable legislative and clinical guidelines and codes of practice
- To confirm that your system conforms with all the requirements of the scheme
- 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-conformity arising from this assessment. All Major Non-conformities are required to be closed out before certification can be recommended. The recommendation for certification is made by the Lead Auditor. The audit report is reviewed by an independent qualified report reviewer.

Your certificate will be issued electronically.

1.7 Surveillance Audits

For organisations with a current (or pending) certification to Core Standards:

- You will retain certification to the Core Standards until your organisation demonstrates full compliance with the ten NSQHS Standards by 31 December 2015.
- You will continue with your current cycle of certification audits and must demonstrate compliance with all 10 NSQHS standards at or before the next re-certification audit by the 31 December 2015.
- Each surveillance visit shall include NSQHS Standards 1, 2 and 3 and a selection of the Core Standards for Safety and Quality in Healthcare such that all specified items from the Table below are covered during the certification cycle

JAS-ANZ Core Standards for Safety and Quality in Healthcare	**Specified items additional to NSQHS Standards 1, 2 & 3, certification bodies shall assess:**
Core Standard 1, No. 3 Core Standard 1, No. 4	The Health Service shall have policies, protocols and procedures to facilitate effective management of: • fire systems • food administration, and • occupational health and safety • systems for maintenance of biomedical and general medical equipment
Core Standard 3, No. 1, 3, 4 & 5	Ensure compliance with best available practice guidelines including: 1. Quality use of Medicines 3. Falls Prevention 4. Blood product, tissue transplantation and prosthetic implants 5. Correct site surgery
Core Standard 4, No.3	The Health Service must have systems for ensuring: • Performance monitoring systems for non-clinical staff

For organisations with a current NSQHS certification

BSI will conduct at least one mid-cycle surveillance audit. The continuing assessment (surveillance) may be an annual event that may be completed in stages (if combined with ISO 9001 audits).

This will ensure your readiness for the re-certification audits completed within each certification cycle. Following areas will be covered in every surveillance audit:

- Standards 1, 2 and 3 must be assessed at each audit and a selection of applicable National Safety and Quality Health Standards (NSQHS) may be varied at each cycle. The Standards must be selected to ensure that all relevant standards are fully covered during the certification cycle.
- Any changes to the internal and external operating environment of the organisation
- Your organisation's awareness of changes in legislative requirements or recognised practices and their appropriate responses
- Any changes to the Quality Management System or clinical services
- Use of marks and any other reference to certification
- Records and processes relating to any customer or consumer
- A review of actions taken on nonconformities identified during the previous audits
- The effectiveness of the system with regard to achieving the organization's objective
- Each surveillance audit will be of a duration equal to half (50%) of the time spent at the initial assessment stage 1 and stage 2 total

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 your 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.

The purpose of your reassessment audit is to confirm the continued conformity and effectiveness of the NSQHS system and its continued relevance and applicability for your organisation's scope of certification.

The recertification audit will include the following aspects:

- The effectiveness of the NSQHS system in its entirety in the light of internal and external changes and applicability to the scope of certification
- Demonstrated commitment to maintain the effectiveness

- Improvement of the NSQHS system in order to enhance overall performance
- Where the operation of the certified NSQHS system contributes to the achievement of your organization's policy and objectives
- Reassessment audits will be of duration equal to 90% of the total of Stage 1 & 2 of the initial assessment and will replicate the requirements of the Stage 2 assessment

2 Reporting

At the conclusion of the audit, the audit team will prepare a written report on the audit findings and the audit team will present these findings to your organisation's senior management at the closing meeting. 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
- Observations for continual improvement
- Positive finding areas

If non-conformances, have been identified these will be communicated to you at the exit meeting and in writing through the audit report.

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-conformances 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-Conformances

All non-conformances must be closed out before certification is granted or expiry of certification.

Since some of these findings impact on funding arrangements of your organisation; system failures and responses must be treated as a matter of priority.

The following terms used to describe ratings: Met with Merit, Satisfactorily Met, Not Met and Developmental Met or not met.

This rating system is referred to as the 4 Point Ratings for the National Safety and Quality Health Standards (NSQHS).

Rating System	Definition
Met with Merit	In addition to meeting all the requirements to achieve a 'satisfactorily met' rating, measures of good quality and a higher level of achievement are evident
Satisfactorily Met	The required actions have been achieved at the base level. Evidence of a 'satisfactorily met' rating should be present, and best describes your organization's typical practice
Not Met	Requirements of the item have not been achieved. A "Not Met" is equal to a Major Non-conformance if it is a core action. This can be raised at any time during the assessment cycle

If your organisation has elected to be certified to the National Safety and Quality Health Standards (NSQHS) and have NOT MET criteria identified, these will be treated as major non-conformances.

In exceptional circumstances, a criterion or item may be rated as 'not applicable'.

Not Applicable Items
Those that are inappropriate in a service specific context or for which assessment would be meaningless.

Developmental Items
As per Advisory Note – A14/02, BSI must access all actions (core and developmental) and provide the health service organisations with a rating.
Progress towards meeting the developmental action must be demonstrated but will not prevent certification from being granted.

The NSQHS rating system is to be applied at the level of individual items in each Standard, but can also be applied to the overall Standard. The rating system allows accreditation outcomes to be evaluated on both a 'met or not met' scale, as well as providing a graduated scale for reviewing trends in quality improvement
An unsatisfactory outcome at assessment visits may impact on your certification.
Certification to the National Safety and Quality Health Standards (NSQHS) will not be granted until the full set of Standards as applied to your organisation has been met.

Critical Deficiencies/Issues
If the Assessor identifies a serious risk to patient safety, the Assessor shall discuss the issue with the General Manager – Compliance and Risk and the Sector Manager before informing the Client's Top Senior Management and if necessary they shall promptly inform the relevant regulator.

The General Manager of C&R will notify the relevant regulator within 48 hours.

3.1 Major Non-Conformances - Not Mets

Should a Major non-conformance be raised, your organisation will receive a Corrective Action Plan request at the time of the audit or within 24 hours. The completed Corrective Action Plans are to be returned to BSI within maximum 14 business days of the last day of the audit.
High risk issues (of significant clinical risk as described by the Australian Health, Safety and Quality Commission) may require more urgent attention; hence the timeframe could be more immediate than 14 days.
All Major Non-conformance (Not Met) reports require close-out with an onsite visit within maximum of 90 days. This is invoiced as one full auditor day for each assessor.
Where BSI is required to return to the site to close out or downgrade a Not Met/s, the additional duration must be agreed by your organisation.

3.2 Minor Non-Conformances

BSI does not raise Minor Non-Conformances in this scheme

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 approve issue of your NSQHS certificate.

5 Certificates

Following the satisfactory review and approval, your organisation will be provided a certificate stating compliance to NSQHS.

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

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.

Your organisation is 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.

Organisations holding a current NSQHS 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 following hyperlink - http://www.jas-anz.com.au/images/stories/Documents/Procedures/procedure03.pdf

7 Accreditation Status

Certification to this standard is accredited to ISO17021:2011
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 Australian Commission on Safety and Quality in Health Care.

8.1 Notification to the Standard Owner

BSI is required to advise the Commission at the following times;

- A list of all clients due for Initial/Surveillance/Re-certification audits to be provided every six (6) months
- Where a significant risk has been identified
- NOT MET Actions and all Compliance information monthly

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 NSQHS 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 (Services 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

11.1 Consumer Representative

BSI has a formalised relationship (contract) with a consumer representative to assist with monitoring the participation of consumers within applicant and certified health service organisations (if required)
Where there is concern about the effective participation of consumers within the health service organisation then BSI, in consultation with the health service, will include a Consumer Representative in the audit team for the relevant aspects of the audit. The cost of the Consumer Representative is additional to the audit fee.

11.2 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 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 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

Appeals against certification decisions and / or complaints against service delivery levels may be raised with your Client Manager. If you remain dissatisfied, contact the BSI General Manager Compliance and Risk in writing.

All complaints will be investigated and the originator of a complaint will be advised of the outcomes, as appropriate.

If your organisation's application for certification has been refused; or your certified organisation' certification has been suspended, withdrawn, or reduced in scope, you may appeal against the decision to a Review Committee constituted and operated as set out below:

The appellant shall, within 28 days of the disputed advice from BSI, lodge a notice of appeal with an affidavit as to the grounds of appeal with the BSI Group ANZ Pty Ltd's Managing Director in writing;

- The CEO or equivalent shall advise the BSI Group Regional APAC Executive within 14 days of receiving the appellant's notice;
- The Executive shall then establish a Review Committee upon payment of the fees set by the Executive for consideration of the appeal;

- The Review Committee shall consist of three persons considered as experts in the area of technology or business relevant to the appeal. The Review Committee shall be constituted as follows:
  - One person expert in the relevant area of technology or business appointed by the Board; and
  - Two persons selected by the appellant from a list of four persons nominated as eligible by the Board.
- The appellant shall represent himself and no legal representation will be allowed unless approved by the Review Committee; and
- The Review Committee will carry out investigations as are required, including assessment of information supplied by the appellant and, within a reasonable time, decide by majority vote whether or not to reverse the original decision. The Managing Director or equivalent shall give notification of the decision to the appellant within 14 days of the Review Committee decision.

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:

John Krnel
GM Sales and Marketing

Email: John.krnel@bsigroup.com
Phone: 1300 730 134