VHQA Conference 2018

SAI Global Assurance Services

Version 2 of the NSQHS – Accreditation Requirements

7 May 2018

Introduction

- About SAI Global – Assurance Services
- Who/What is “ISO”?
- What is ISO 9001 – Quality Management Systems?
- NSQHS Version 2 – Overview and key changes
- Changes to the assessment/audit process
- The audit process
- Additional things to consider

SAI Global – Assurance Services

SAI Global provides organisations around the world with information services and solutions for managing risk, providing assurance (training and assessment/audit services), achieving compliance and driving business improvement.

SAI Global Assurance Services

- Offices in 25 countries across Asia-Pacific, Europe and North America
- 1,400+ employees worldwide
- JASANZ Accredited so also must comply with the related scheme rules and International Accreditation Forum requirements as well as Commission Requirements.
- Conducts Assessments/Audits against a range of International and Local Standards including:
  - Quality Management Systems
  - Occupational Health and Safety & Environment
  - Food; Products
  - Health; Disability and Human Services

SAI Global is the major provider of certification services in Australia

The "five ticks" StandardsMark™ brand has an 82% recognition

What/Who is ISO?

- ISO (International Organization for Standardization) is the world's ***largest developer*** and publisher of ***International Standards***, a **network** of the national standards institutes of **162 countries**, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system.
- A ***non-governmental organization*** that forms a bridge between the public and private sectors. On the one hand, many of its member institutes are part of the governmental structure of their countries, or are mandated by their government. On the other hand, other members have their roots uniquely in the private sector, having been set up by national partnerships of industry associations.
- Therefore, ISO enables a ***consensus*** to be reached on solutions that meet both the requirements of business and ***the broader needs of society.***

Because "International Organization for Standardization“ would have different acronyms in different languages ("IOS" in English, "OIN" in French for Organisation internationale de normalisation), its founders decided to give it a short, all-purpose name. They chose "ISO", derived from the Greek isos, meaning "equal".

Whatever the country, whatever the language, the short form of the organisation's name is always ISO.
Source: ISO website

What is ISO 9001

ISO 9001: Quality Management Systems – Requirements

- ISO 9001 is an International Standard. It defines requirements for a quality management system and how an organisation can consistently provide products and services that meet customer and applicable statutory and regulatory requirements.
- Key clauses of ISO 9001 include:
  - Context of the Organisation
  - Leadership
  - Planning
  - Support (resource, competence environment, monitoring, awareness, communication, documented information
  - Operation (planning, process controls, purchasing, supplier/external product and service providers; identification, traceability, control of changes, control of non conformances)
  - Performance Evaluation (monitoring, measurement, analysis, evaluation, internal audits, management review)

NSQHS - Overview of the 2nd edition

- The second edition addresses gaps identified in the 1st edition, including:
  - Mental health; Cognitive impairment; Health Literacy; End-of-life care; Aboriginal and Torres Strait Islander Health
- The 2nd edition has:
  - 8 standards; 148 Actions
- Approximately 65% of actions in the second edition relate directly to actions from the first edition. The remaining 35% of actions is new content related to the identified gaps.
- Similar or related actions have been merged together to reduce duplication and simplify compliance.
- There are 52 new actions in the second edition.

NSQHS - Overview of the 2nd edition

- All actions are now mandatory (core), i.e. no more developmental
- Met with Merit is no longer a rating
- New ratings are:
  - Satisfactorily Met
  - Not Met
  - Met with Recommendations (opportunities for improvement)
- Many of the actions have multiple clauses, e.g.:

  - Action 1.14 has clauses a – g; Action 3.3 has clauses a –c
- All clauses must be achieved before the action can be considered to be Satisfactorily Met.

NSQHS - Overview of the 2nd edition

- The Clinical Governance Standard and the Partnering with Consumers Standard set the overarching system requirements for the implementation of the remaining 6 standards
- The NSQHS Standards are designed to follow the patient journey and to be implemented in an integrated way
- Similar implementation strategies apply to multiple actions across the NSQHSS.
- Important to identify the links between actions to ensure that Safety and Quality systems are integrated and reduce duplication. E.g. if a gap in one area Is not identified can this lead to more issues in other areas (risk of sentinel event)?
- USER GUIDES are available from the Commission Web Site

Changes to the Assessment / Audit Process

Standardise assessment processes

- 3 Year Certification / Assessment Cycle (same as ISO 9001)

Option 1.

- 3 year audit cycle without mid cycle review

Option 2 (methodology still to be confirmed).

- Annual Audits covering the 8 standards over 3 years

PLUS:

- “Special” audits – outside normal audit cycle

Annual or 3 yearly assessments - Considerations?

3 Yearly:

- Get it done all at once

But:

- Large audit, time consuming (and cost)
- “Relaxing” between audits. E.g. risk of no work done between audits; “pop up” audits quickly done when an external audit is due; consultants in to fix systems before audits; change in management and potential impact on system maintenance.

Annual Audits:

- Align with ISO 9001 Quality Management System audits
- Encourages system maintenance through regular independent external reviews
- Smaller ‘bite size’ audits

But:

- Annual planning for external audits; ‘disruption’ for staff (or is it? – ideally audits should be seen as ‘system as usual)
- Focus on particular standards doesn’t stop assessors identifying gaps in other areas.

System Maintenance – Internal Audits/Self Assessments

Internal Audit Systems and Processes

- Are required by ISO 9001
- Regularly review system operations and performance is in line with planned arrangements. E.g. Do we really do what we think we are doing? Are our policies and procedures implemented?
- Are we conducting audits in line with our approved plans?
- Review of internal audit results and trends & reporting
  - Is 100% compliance good? (Are our processes robust enough? Are we really checking implementation of processes through review of records and evidence? Are we getting value from our audit processes?
- Essential if having one external audit every 3 years

Changes to the Assessment / Audit Process

- Timing for follow up of not met actions: a review in 4-6 months (timing TBC) to follow up NOT MET actions to make sure implementation of actions is ‘effective’ and ‘embedded’ into the organisation.
  - ISO 9001 “Corrective Action Processes”

- No extension to 3 year period (full audit or full coverage of Standards must be within the 3 year period)
  - Not Met (non conformity) closure before recertification 3 year certificate expiry date – *To be confirmed?*

Changes to the Assessment / Audit Process – Monitoring by the Commission

- Routine review of safety and quality data to indicate if performance is maintained.
- Additional Assessments may be required:
  - E.g. Significant not met actions; Commission Decisions; Performance Data; Discussions with Regulators
- 'Special' assessments could be done by accrediting agency/certification body or by a 'special' team which could include the Commission.

SO: 3 yearly audits: If good outcomes and performance.
This is seen as an incentive for organisations to perform better.

Changes to the Assessment / Audit Process

Standardisation of reports including summary format

- Health Service and ‘Public Information’.

In the longer term:

- Short Notice Audits (Pilot in Qld)
- Patient Journey Methodology
- Repeat Assessments if multiple NOT Met’s

Accreditation Agency/Certification Body requirements – Auditor Competence and Training

- The Commission has developed on line training modules
- Auditors ***MUST*** complete the training before being allowed to assess to NSQHS v2
- SAI Global (and other Certification Bodies) will have to be approved by the Commission to conduct audits for the 2nd edition

- NSQHS v2 Audits: Later in 2018 after auditor training completed and agencies approved.

Changes to the Assessment / Audit Process

Conflict of Interest

- Can't have consultants at assessments
- Relationship issues
- Transparency

Improve Communication about assessments and outcomes

- Standardised reporting and public reporting

Consumer Involvement

- More information for consumers via the organisation for individuals
- Interview consumers as part of process

The Audit Process

New Services:

- Stage 1 audit (systems and documentation – are you ready?). Can also do “gap audit” if required.

Then:

- Stage 2 / Certification Audit: Full audit to the NSQHS (can also include ISO 9001)
- Usually a team of assessors – depends on size of facility
- Certificate valid for 3 years

- ISO 9001 requires annual surveillance audits and also has a 3 year ‘recertification’ life cycle. (Full audit 3 yearly)

The Audit Process – The Audit Plan

GOOD PLANNING IS THE KEY TO A GOOD AUDIT

- Detailed audit plan – work with certification/accreditation body!
  - Who is doing what and when?
  - Executive, Staff and Operational Areas – who do we need to see to gather evidence?
  - Board involvement – when are they available?
  - Different Shifts and Handover Processes
  - Access to required documentation and records (evidence) to demonstrate conformance
  - Consumer involvement (Committee, Individuals, Patients).
  - Debrief regularly/daily debrief “NO SURPRISES”
  - Time to follow up queries and issues
  - Key contacts (follow up, questions, ‘chasing’ information)

The Audit Process – Evidence

Policy Documents, Procedures, Instructions, Guidelines, Pathways

- May exist for a single action, a number of actions, parts of one or more standards

Training Documents & Records; Staff Competence, Performance Review

- A risk management approach: what training is required for who and the frequency of training
- Includes orientation, education, training, attendance records, online training, external training, supervision, performance reviews etc.

Committee and meeting records

- Includes committee membership, Terms of Reference, Agenda, minutes or actions, dashboard reports, correspondence and reports.

The Audit Process – Evidence

Audit Results

- Risk management approach to determining what areas are to be audited, how often and how results will be used to improve safety and quality of health care for patients
- Includes survey instruments, forms and tools, analysis of data collected, reports on audits conducted, benchmarking of audits
- Audit Outcomes and Trends (Consider good results as well as issues/improvements)

Communication with the workforce, HSO or highest level of governance

- Includes reports tabled at meetings, intranet content or online message boards, correspondence such as broadcast emails, newsletters, posters

Discussion with Board Member(s) / Executive on Safety and Quality

- Board Induction, training, development
- Skills and competence of the Board
- Patient Feedback
- Is information provided up to date and accurate
- Information provided: trends, analysis, data, risks, issues

The Audit Process - Evidence

ISO 9001 Top Management Review

- Previous action items; customer feedback; objectives & targets; process performance and conformity; non conformities and corrective actions; internal audit results; monitoring and measuring results, performance of external providers; resources; effectiveness of actions on risks and opportunities; opportunities for improvement

NSQHS v2:

- Governing Body to sign off that they have met their responsibilities around safety and quality – and submit to Certification Body as part of assessment.

The Audit Process - Evidence

Operational Areas (Wards, ICU, Pharmacy, Theatre, Engineering):

- The presence of a resource, such as signage, PPE equipment or guidelines
- Clinical Practices
- The inclusion of a specific tool or form in the healthcare records
- Patient Journey & related records

Consumer Involvement

- Consumer Committee; Patients; Available Information

Testing of High Risk Scenarios e.g. through:

- Reviewing examples / discussion with staff about “when it all goes wrong”,
- Review of Risk Register,
- Recruitment of ‘junior’ staff,
- Continuity of care across Locum’s etc.

The Audit Process - Evidence

Other Evidence

- What are some other key groups or types of evidence we can review?
  - Clinical indicators
  - Benchmarking
  - Education needs analysis
  - Healthcare Acquired Complications
  - Patient Reportable Outcome Measures
  - Staff feedback / staff culture

The Audit Process - Outcome

Audit Report

- Details evidence viewed against each action item (yes reports are long). If Integrated with ISO 9001, focus maintained on NSQHS with additional requirements documented in ISO 9001 section of report.
- Recommendations/Opportunities for Improvement – in report.

Not Met / Non Conformances

- Outlined in audit report and Non Conformance Report
- Action Plan to identify root cause and actions documented (on Non conformance report or can be submitted separately).
- Action Plan reviewed and accepted or returned for further detail
- Evidence reviewed (4-6 months) to close out Not Met actions at a follow up audit.

The Assessment / Audit Process

What happens if there is disagreement between organisation and auditor?

- Conflict is managed by the Certification Body not the S&Q Commission nor the Regulator (Although the Commission will seek feedback following audits/assessments)
- Certification Bodies must have complaint and dispute resolution process
- If dispute between client and auditor the auditor will seek advice from Program Manager
- If dispute remains unsettled then appeals process is instituted

Questions

Thank You

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