How can ISO 9001 Quality PLUS Clinical Standards help improve your health service?

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How can ISO 9001 Quality PLUS Clinical Standards help improve your health service?

Areas Covered:

• Background
• What are the changes to legislation?
• What do the changes mean to you?
• What is ISO 9001 Quality Management System?
• What are the benefits ISO 9001
• Who is SAI Global
• Excellence in Healthcare: Tier 1 and Tier 2
• How can ISO 9001 quality plus Clinical Standards help improve your health service?
Background

- Safety & Quality Council established by State, Territory and Federal Health Ministers in 2000 in response to community concerns about safety in Australian hospitals.
- S&Q Council review of current health service accreditation schemes recommended changes.
- S&Q Commission established in 2006 expanded the review of accreditation schemes and developed a new model.
- The new model to be endorsed by Health Ministers implemented July 2011.
- July 2011 S&Q Commission established as permanent body.
A Model National Scheme for Safety and Quality Accreditation

Health Ministers

Regulators
- Includes States, Territories and Commonwealth
- Mandate the Standards and participation in the accreditation scheme
- Oversee accreditation program content
- Receive relevant accreditation data
- Be responsible for an escalating response where the Standards are not met

A program of national coordination in ACSQHC
- Develops and maintains standards
- Advise Australian Health Ministers Council on the scope of health service accreditation
- Approves accrediting agencies
- Receives relevant accreditation data
- Liaises with regulators
- Reports to Health Ministers

Health Service Organisations
- Select an approved accrediting agency
- Meet the Standards

Approved Accrediting Agencies
- Maintain JASANZ/ISQua accreditation
- Provide data on the Standards
- Cooperate on methodology / assessment development

Reports on assessment outcome
Assess & report
National Safety and Quality Health Service Standards

- The Commission developed the Standards following extensive public and stakeholder consultation.
- The Standards are a critical component of the Australian Health Services Safety and Quality Accreditation Scheme endorsed by the Australian Health Ministers in November 2010.
- The Standards provide a nationally consistent and uniform set of measures of safety and quality for application across a wide variety of health care services.
- They propose evidence-based improvement strategies to deal with gaps between current and best practice outcomes that affect a large number of patients.

Source: ACS&QHC National Safety and Quality Health Service Standards June 2011
National Safety and Quality Health Service Standards

The Standards

• Governance for Safety and Quality in Health Service Organisations
• Partnering with Consumers
• Preventing and Controlling Healthcare Associated Infections
• Medication Safety
• Patient Identification and Procedure Matching
• Clinical Handover
• Blood and Blood Products
• Preventing and Managing Pressure Injuries
• Recognising and Responding to Clinical Deterioration in Acute Health Care
• Preventing Falls and Harm from Falls

The Standards are designed to assist health service organisations to deliver safe and high quality care.

Source: ACS&QHC National Safety and Quality Health Service Standards June 2011
Implementation Timeframe

- **July 2011** begin transition period through to December 2012
  During this period the Commission will release Guidance documents, finalise reporting requirements and continue to consult with key stakeholders
  Health Services *may choose* to be certified to the new standards.
- **January 2013** Full implementation and Health Services must be certified to the new standards *at their next certification*
Proposed coverage

- The model national accreditation scheme proposes that all health services that pose high risk of harm to patients should participate in accreditation and be assessed against the Standards. **High-risk health services are those that undertake 'invasive' procedures into a body cavity or dissect skin while using anaesthesia or sedation.**
- Most high-risk services are hospitals and procedure centres, many of which are currently accredited. These services would continue to participate in an accreditation program.
- Other high-risk Health Service Organisations would now also be required to participate in an accreditation program, meaning they now also cover:
  - public and private hospitals
  - day procedure and day hospitals
  - practitioner rooms where high-risk activities can occur, *for example cosmetic surgery, endoscopy and dentistry.*
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*
Standards make an enormous and positive contribution to most aspects of our lives.

- Standards ensure desirable characteristics of products and services such as quality, environmental friendliness, safety, reliability, efficiency and interchangeability - and at an economical cost.

- When products and services meet our expectations, we tend to take this for granted and be unaware of the role of standards. However, when standards are absent, we soon notice. We soon care when products turn out to be of poor quality, do not fit, are incompatible with equipment that we already have, are unreliable or dangerous.

- When products, systems, machinery and devices work well and safely, it is often because they meet standards. And the organization responsible for many thousands of the standards which benefit the world is ISO.

When standards are absent, we soon notice.
Why conformity assessment/Certification is important

• "Conformity assessment“/Certification means checking that products, materials, services, systems, processes or people measure up to the specifications of a relevant standard or specification. Today, many products require testing for conformity with specifications or compliance with safety, or other regulations before they can be put on many markets.

• ISO guides and standards for conformity assessment represent an international consensus on best practice.

• Their use contributes to the consistency of conformity assessment worldwide and so facilitates trade.

• Standard 17021 provides requirements for auditor competencies including selection and training.
What is ISO 9001:2008

• The ISO 9000 family of standards represents an international consensus on good quality management practices. It consists of standards and guidelines relating to quality management systems and related supporting standards.

• ISO 9001:2008 is the standard that provides a set of standardized requirements for a quality management system, regardless of what the user organization does, its size, or whether it is in the private, or public sector. It is the only standard in the family against which organizations can be certified.
What are the benefits of ISO 9001?

The Standard

• International standard - applicable to all industries
• Broad Perspective – benefit from input into standards development & maintenance from all industries and Global perspective.
• Clinical standards used in ISO certification process are national standards developed by industry specialists and are fully congruent with the new National Health Service Safety & Quality Standards owned by the S&Q Commission.
What are the benefits of ISO 9001?(cont)

System Approach
• ISO assessments are undertaken on a process basis so that a single process that might cover multiple departments will be followed and assessed by the same auditor.

Auditor Expertise
• Auditors undertaking assessment of compliance to international/national standards receive comprehensive training (6mths) in audit methods
• Other Industry Experience: brings experience from across other relevant industry & Health sector
What are the benefits of ISO 9001?(cont)

The Certification Journey
• The lead auditor makes contact with the client upon receipt of application.
• Lead auditor remains the contact for the client throughout the ‘continual improvement journey’ from pre-audit through surveillance audit and re-certification in 3 years.

The Audit Report
• Audit report must be provided within 5 working days with recommendations subject to clearance of all non-conformances and decision from the certification authority.
• The client will be notified in writing by the lead auditor that action to clear non conformances is appropriate who may be required to return to the client to validate the actions.
What are the benefits of ISO 9001?(cont)

**Non-conformance**

- ISO auditors are required to advise the client of non-conformances at the exit meeting.
- Must provide all non-conformances within 24 hours of completion of the audit.
- All non-conformances must be closed within 60 days with Certification awarded within 3 months.

**Regularity of Measurement & reliance**

- ISO certification requires the inclusion of surveillance audits undertaken by the same team that undertook the certification audit and these are usually annual but may be 6 monthly if deemed necessary by the audit team or certification authority.
- The surveillance audits will usually focus on areas of concern or particularly high risk.
What are the benefits of ISO 9001?(cont)

Pricing

• The cost of ISO certification is usually 10-15% lower than ACHS for example, even though auditors are employees and not volunteers.

Resources

• There may be an initial cost to establish compliance to ISO standards but these are ‘one off’ and almost certainly will be things such as document control that represents good business practice,
What do clients report as the key issues when transferring from current health service accreditation?

• The ISO approach requires greater involvement of staff at all levels of the organisation and therefore ‘quality’ is much more embedded across the organisation.

• Greatest effort is in document management – “finding all the documentation that sits on individuals computers and ensuring policies are current, approved and reviewed”.
Example Section from ISO 9001 Standard

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

- documented statements of a quality policy and quality objectives,
- a quality manual,
- documented procedures required by this International Standard,
- documents needed by the organization to ensure the effective planning, operation and control of its processes, and
- records required by this International Standard (see 4.2.4).
Example Section from ISO 9001 Standard

4.2.3 Control of documents

Documents required by the quality management system shall be controlled.
Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed
• to approve documents for adequacy prior to issue,
• to review and update as necessary and re-approve documents,
• to ensure that changes and the current revision status of documents are identified,
• to ensure that relevant versions of applicable documents are available at points of use,
• to ensure that documents remain legible and readily identifiable,
• to ensure that documents of external origin determined by the organization to be necessary
• for the planning and operation of the quality management system are identified and their distribution controlled, and
• to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.
Who is SAI Global?

SAI Global (ASX:SAI) provides organisations around the world with information services and solutions for managing risk, achieving compliance and driving business improvement.

- Listed on the Australian Stock Exchange in December 2003
- Market capitalisation of (approx) $A629 million as at 31 May 2010
- Offices in 25 countries across Asia-Pacific, Europe and North America
- 1,400+ employees worldwide

SAI Global is the major provider of certification services in Australia

*The “five ticks” StandardsMark™ brand has an 82% recognition*
SAI Services

SAI Global is a publicly traded (ASX: SAI), global company with revenue of around $500m AUD. We have offices in 25 countries and we provide organisations around the world with service and solutions for managing risk, achieving compliance and driving sustainable performance through continuous improvement.

PUBLISHING

Standards Legislation
Database

COMPLIANCE

Newsfeeds & Alerts Obligation Registers
Risk & Compliance Incident & Event Mgt Whistle Blowing Service Board Management

ASSURANCE

Business Excellence Business Sustainability Certification Self-Assessment Programs Training Excellence Programs Improvement Programs

PROVIDE INFORMATION

APPLY BUSINESS SOLUTIONS TO REGULATORY AND COMPLIANCE OBLIGATIONS

ACHIEVE, AUDIT & ASSESS SUSTAINABILITY
SAI Global is highly credentialed, carrying multiple accreditations in several geographic locations.
Excellence in Health program

SAI Global has been among the first to respond to the changes in the health sector accreditation environment by developing a new accreditation program using a unique 2 tiered approach.

**Tier 1 – Quality in Health**
Incorporates all of the requirements of ISO 9001 and the Core Standards for Safety and Quality in Healthcare.
*Quality in Health develops operational efficiency & effectiveness*

**Tier 2 – Excellence in Health**
Incorporates all of the requirements of ISO 9001, the Core Standards for Safety and Quality in Healthcare and in addition brings in key and sector relevant elements from the Business Excellence Framework.
*Excellence in Health develops organisational efficiency & effectiveness*
A sample of health organisations that SAI Global has registered

- **Hospital Services** – Western NSW LHN, Wesley PH Sydney
- **Disability Services** – Achieve Australia Ltd, Endeavour Foundation, Karingal Inc. and Yooralla Society of Victoria
- **Specialist Services** – Royal Alexandra Hospital for Children Westmead, Queen Elizabeth Hospital Adelaide, Royal Perth Hospital
- **Health Services** – Calvary Silver Circle, McKesson, Aged care and Housing Group, Integrated Living, Chemtronics (Cabrini), Cabrini Linen.
- **Agencies/peak bodies** – Aged Care Standards & Accreditation Agency National Childcare Accreditation Council, Royal Australasian College of Surgeons, Royal College of Nursing Australia
- **Note:** SAI Global has significant experience in health sector certification throughout the world including some 70 hospitals in Indonesia
Positioning Business Excellence

Aspirational Quality

Values

Motivation

Compliance Quality

Rules

Low

High

Organisational Capability

Business Excellence

Quality Management Systems
ISO 9001-2008
Five Stage Model

1. Develop a conceptual understanding
2. Identify the current state with strengths and opportunities
3. Determine the necessary tools
4. Design a change strategy
5. Manage the transition
Achieving Sustainable Excellence Model
A roadmap for improvement
Systems Thinking
A Discipline for Seeing the Whole Organisation

Stakeholders
- Communities
- Owners
- Governments
- Employees

Inputs

Outputs

Processes

Value-Adding

Relationships

Vision

Mission

Values

Feedback

All enterprises are part of a larger system. All enterprises consist of a number of sub-systems

From Senge
Example – Systems View

Mont Albert North Nursing Home

VALUES - Trust, Respect, Integrity, Care

MISSION - To maximise quality of life for senior citizens and their families
At December 2005, we see:
- Facilities for an extra 40 residents
- Our processes flowcharted and continuously improved
- Partnerships in place with our key suppliers
- Staff turnover dramatically reduced

VISION -

SUPPLIERS
- Federal Government
- ACSA
- Mont Albert Pharmacy
- Accreditation Agency
- Professionals

INPUTS
- Policy
- Funds
- Standards
- Food
- Medicines
- Medical Care

CUSTOMERS
- Residents
- Families
- Potential Residents

OUTPUTS
- Housing
- Nutrition
- Nursing Care
- Recreation
- Personal Care
- Advice

OTHER STAKEHOLDERS
- Other Aged Care Facilities
- Unions

RELATIONSHIPS
- Within the Team
- Team with the Clients
- Team with Suppliers
- Team with other Stakeholders

OUR PEOPLE
- Staff
- Volunteers
- Management

RESULTS MEASURES
- Staff perception
- Client perception
- Financials
- 85% satisfied
- 90% delighted
- 300K surplus

PROCESSES
- Nursing
- Hotel
- Marketing and Sales
- Recreation

PROCESS MEASURES

FEEDBACK

TARGETS
The Business Excellence Framework
Criteria to assess your capability
The Assessment Dimensions - ADRI

**Approach**

Thinking and Planning
Identifies the organisation’s intent for the Item, the thinking and planning it does to design the strategies, processes and infrastructure to achieve the intent.

**Deployment**

Implementing and Doing
Identifies the activities actually happening.

**Improvement**

Learning and Adapting
Shows how the process of review and improvement of the Approach and its Deployment are occurring.

**Results**

Monitoring and Evaluating
Demonstrates how measures or achievements associated with the Approach are monitored.
BE & Management Systems

BEF & integrated leadership & management systems

Quality Mgmt
Environmental
Governance, Risk & Compliance
IT & HR Systems
OH&S

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A typical client journey

1. Fix the basics
2. Align the System
3. Focus on value
4. Sustainable Performance
Lean Implementation Event

Planning for the Lean Implementation Event

Step 1: Initial assessment and scoping
- Selection of Lean Project
- Establishment of core team & support team
- Agreement on path forward

Step 2: Lean Event Planning
- Establishment of clear objectives
- Define Plan
- Schedule support resources
- Plan for immediate results

Step 3: Conduct 5 Day Lean Event

Day 1
- Lean Training
  - Basic training - Introduction to Lean

Day 2
- Process Definition
  - "As is" process identified through direct observation
  - Define goals and measurements for process improvement

Day 3
- Process Design & Lean Application No. 1
  - Brainstorm & design "to be" process #1
  - Test & measure iteration #1 through applying lean tools

Day 4
- Process Design & Lean Application No. 2
  - Review results; repeat - Brainstorm; iteration 2 of process
  - Test, define and measure new process

Day 5
- Implement & Measure Process
  - Observe new process in action and gather data
  - Team final presentation to management
  - Team debriefs and follow up - review lean event, consolidate learnings and identify future opportunities for improvement

Results of Lean Implementation Event

- Lean tools applied to an actual process to immediately remove waste & duplication
- Staff equipped with knowledge of lean tools and application
- Additional opportunities for future improvement identified
- Knowledge gained applicable across other processes
- An optimised workplace to deliver the new process
- Reduced operational costs, increased customer satisfaction and motivated staff

SAI GLOBAL
Case Study – Domiciliary Care SA

Situation / Driver:
- Processes not optimised
- Admissions process taking on average 35 days

Solution:

Benefits Achieved:
- Service delivery (admissions) process optimised to reduce average to 3 days
- Annualised cost savings of $264,000
Benefits to Patients / Residents
- Less lost clothing through improving the Laundry process
- Higher satisfaction on survey
- Aggressive behavior in the Dementia Unit has been reduced significantly
- Improved quality of life experienced
- Increased quality personal care time by approximately 75%
- Improved medication process

Benefits to Staff
- Staff morale has increased and they are in more control
- Improved staff satisfaction
- Staff are beginning to understand their role in the context of the wider organization
- Personal improvement plans now work
- Staff members who previously were reluctant to be involved now line up to be part of it
- The staff have more confidence in using feedback systems
- Communication and awareness has increased by more than 90%
- Better use of RN time
SAI Global Improvement Solutions
A roadmap for improvement Achieving Sustainable Excellence Model

1. Understand the System
   - Review Improvements
   - Common understanding of the system and priorities agreed i.e. system outcomes

2. Lead and Manage the Change
   - System Thinking
   - OFI’s from other sources

3. Understand the Business Excellence Framework and Principles
   - Approval to implement and accountability assignment

4. Clarify Strengths and Opportunities for Improvement
   - Allocation of resources for working on the System

5. Apply Improvement Techniques
Positioning Business Excellence

Aspirational Quality

Compliance Quality

Values

Motivation

Rules

Organisational Capability

Business Excellence

Quality Management Systems
ISO 9001-2008
The Excellence in Health Program: Getting Started

1. GETTING STARTED
   - PURCHASE RELEVANT MANAGEMENT SYSTEM STANDARDS
     Management system standards are available for purchase at www.saiglobal.com/shop.
   - UNDERTAKE TRAINING (OPTIONAL)
     SAI Global offer training courses from understanding the standard to documenting and internal Auditing of the standard. Training information can be obtained from our website. Note: Please be aware that it will not be easier or cheaper to achieve certification with SAI Global if you attend our course.
   - IMPLEMENT THE STANDARD
     Apply the standard within your business.

2. APPLYING FOR CERTIFICATION
   - CALL SAI GLOBAL’S SALES TEAM
     Call SAI Global’s dedicated sales team on 1300 360 314 to discuss your business. Once we have acquired the relevant knowledge of your organization, we can then quote timeframes, costs involved to become certified and provide you with a formal proposal.
   - ACCEPTANCE OF PROPOSAL
     Once you have accepted the proposal, return to SAI Global with the application fee.
   - BOOK AUDIT DATES
     Once the application is received, an SAI Global scheduler will contact you to book in the Stage 1 Audit date. The earlier you book, the more likely you will be able to choose dates that suit you.

3. CERTIFICATION
   - STAGE 1 AUDIT
     The Audit team will assess your documentation, readiness of your management system for Stage 2 Audit and provide a Stage 1 Audit Report.
   - REVIEW THE STAGE 1 AUDIT REPORT
     Address any issues that may have arisen in the Stage 1 Audit.
   - CERTIFICATION AUDIT
     Our Audit team will assess how you have implemented your system and will verify any issues outstanding from the Stage 1 Audit. When all outstanding issues are addressed, you will be recommended for Certification and after a positive decision of the independent SAI Global Certification Authority, you’ll be issued with a certificate.

4. MAINTAINING CERTIFICATION
   - ONGOING MAINTENANCE AUDITS
     You will need to ensure your system is kept up-to-date. Part of your certification is that you will be required to undergo Surveillance Audits. Surveillance Audits are usually conducted every 6 or 12 months.
   - RE-CERTIFICATION AUDITS
     Your certification expires within 3 years and a re-certification Audit will be conducted prior the expiry date to ensure that your Management System is still maintained.

CONTACT SAI GLOBAL
Whether you are looking for certification against an International Standard, assessment to your own goals and commitments, supplier assessment, or training, SAI Global has a solution.
www.saiglobal.com/assurance
1300 360 314
assurance@saiglobal.com
So how can ISO 9001 Quality PLUS Clinical Standards help improve your health service?

- ISO 9001:2008 that is based on an international consensus on good quality management practices and is regarded as ‘the best practice’ quality management system.
- And the new National Safety & Quality Health Service Standards that provide a nationally consistent and uniform set of measures of safety and quality for application across a wide variety of health care services. They propose evidence-based improvement strategies to deal with gaps between current and best practice outcomes that affect a large number of patients.

By complying and becoming certified to both ISO 9001:2008 and the National Safety and Quality Health Service Standards you will have provided your health service with evidence based best practice quality improvement opportunities and will be well placed to achieve the objective of operational efficiency and effectiveness.
Where to from here?

• Talk to SAI Global about the most efficient and effective way to respond to the new accreditation requirements.
• SAI Global can undertake a Gap audit that will provide a detailed report highlighting the gaps between your current Quality Management System (QMS) and the internationally recognised ISO 9001:2008
• Attend an SAI Global training session on Demystifying ISO or arrange for an ‘in house’ course.
How can ISO 9001 Quality PLUS Clinical Standards help improve your health service?

Question
How can ISO 9001 Quality PLUS Clinical Standards help improve your health service?

Thank you

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