

**Qualcon 2005**

**Risk based ISO9001 model for Hospitals and Day Surgeries**

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## **ABSTRACT**

ISO9001 is a well proven compliance and business improvement framework. Whilst is well established in the traditional markets (manufacturing, consulting and engineering based services), in the health sector in Australia, ISO9001 is new and is making in-roads.

Whilst this creates a new window of opportunity for the quality movement, we need to understand the drivers of this new market, and particularly in supporting the regulatory and funding models.

In the health sector the word “certification” is very much mixed with “accreditation”, and it is one of the confusing aspects of working in this environment. But we need to adapt, understand and innovate.

The paper includes:

- Review of the history of ISO9001 in the health sector
- Key players in the market
- Current and more traditional accreditation framework
- Key differences with ISO9001
- Expectations of stakeholders
- User feedback
- Threats and opportunities
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Future directions (as the health sector become more and more complex and specialised, there are new markets where compliance activities will be needed).

## **PART 1: BACKGROUND FRAMEWORKS**

One needs to understand that ISO9001 is a new tool in the health industry.

Whilst in other parts of the world (Europe or Singapore for example) ISO9001 has been extensively used in health, in Australia it was not until the mid 1990's that ISO9001 started to be recognised and used.

To a large extent, this was a result of the emergence of Day Surgeries, or Day Only Hospitals: typically these are very small facilities, with 5 to 15 staff members, working (doing procedures) in some cases 1 to 5 days a week, single theatre, and in many cases single procedure.

Until ISO9001, there were few Accreditation/Certification frameworks. Their implementation was typically driven by:

- Regulators (Departments of Health)
- Funding providers (Health Funds, private or public) or
- Internal governance requirements (Board, Medical Advisory Committees)

The main Accreditation model was ACHS (Australian Council for Healthcare Standards). [www.achs.org.au](http://www.achs.org.au). The model is based around the Equip Standard (s), and is now being expanded to new areas.

In this case ACHS:

- Write the Standard
- Develop the audit/certification/accreditation tools

- Deliver the audits and make decisions on accreditation
- Trains and authorises the audit team.
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In the ISO9001 framework there is a clear separation of roles:

- ISO (International Standard Organisation) develops the Standard
- JASANZ decides who can accredit
- RABQSA recognise the auditors
- Certification Bodies like Global-Mark develop and deliver audits and make certification decisions.
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The above framework offers the benefits of each party specialising in their field of expertise (Standards development, personnel credentialing, Accreditation and Certification). It also offers the hospitals a choice of provider: to win the business, the certification body needs to be better, faster, and competitive with the other one.

On the other hand, the layers of “overheads” would tend to increase cost: instead of supporting 1 organisation, the market needs to support 4 (or more). However, market feedback tends to show that the ISO9001 framework is financially very competitive. Part 2: Understanding the unique conditions of the health sector

## **STAKEHOLDERS: WHO ARE THEY AND WHAT ARE THEIR EXPECTATIONS?**

The following concept is not unique to the health sector however perhaps it is more obvious than in many other sectors in that:

Who is the customer (as presented in the Standard)?

- Is it the Patient?
- The Patient carer/family?
- The Community?
- The funding provider?

One could also see that in the case of a private hospital or day surgery the Doctor also has to be “cared” for.

This is a very important concept, and one that the normal ISO9001 practitioner needs to come to terms with and understand. Hospitals, their staff and Doctors are often under very conflicting pressures.

### **Limits of ISO9001**

Whilst the ISO9001 Standard as a document has been much improved with the 2000 version, it is still a “product realization” thinking model. Patients are not “products”; care is not a “service” etc.

Furthermore the regulation of the ISO9001 framework (under JASANZ in Australia and NZ) and in particular of competence and experience of some of the ISO9001 auditors have been less than fully satisfactory over the years.

Whilst we cannot generalize, the “worth” auditor is the one who will be remembered, and they will bring everybody into disrepute.

As a result of some generalized concerns, the Health Funds and the Commonwealth decided to develop a new set of Accreditation Standards (or minimum requirements that all

accreditation frameworks in Australia should meet): these were called 2<sup>nd</sup> Criteria, now called “Private Sector Quality Criteria”. This criteria covers:

- The Certification body (like Global-Mark)
- The Certification process
- The skills and competences of the auditor
- Some criteria also cover the hospital and day surgery

### **Limiting Our Scope to ISO9001**

As you know, within the “ISO framework” there are QMS standards, Environmental standards, local OHS standards, and Risk Management standards. By default this means that ISO9001 does not include OHS, Environmental or risk issues.

However ISO9001 also refers to “all applicable requirements” which in this case include Legislation, Regulations, Codes of Practices and the Standards called for in these.

So where do we draw the line, and who should draw it? This is a very good question.

Clearly patient safety (included in OHS standards) should be considered as an integral part of a Quality Management System. So to an extent so are environmental controls as they can also affect the patient or staff of the hospital. At the same time, full OHS or Environmental Certification would be broader and more extensive in its coverage of such issues.

Many quality practitioners will take a “holistic” view of the standard and the norm is different and we need to find a “meaningful” line between QMS, OHS and EMS.

### **Typical Problems**

Some of the problems we have found with Hospitals migrating to ISO9001 include:

- Calibration
- Document Control (maintaining procedures and policies, no more memos)
- VMO application
- Employee records (HR, competence recognition)
- Systems and process approach to running a hospital
- Making it part of day to day life, hence making it work
- Internal auditing, as a concept and as a practice

Once understood, we have found that hospital management and staff welcome the ISO9001 framework.

### **PART 3: BENEFITS OF ISO9001 MODEL**

Hospitals and other stakeholders can expect to see the following benefits from certification and a well maintained ISO9001 system.

- Business/workflow/patient path oriented management system and processes
- Ability to choose and transfer Certification company (subject to strict rules)
- Better compliance (audits on a frequency of 6 to 12 months maximum, with full 3 yearly re-certification),
- Early identification of problems (typically change of personnel, change of ownership)

- A structure from which to build other compliance programs (OHS, Governance, Environmental etc)
- Internationally compatible and recognised standard and framework: locally supported and adopted

## **PART 4: THE NEXT FRONTIER: RISK BASED AUDITING**

### **Risk Management, “of course”**

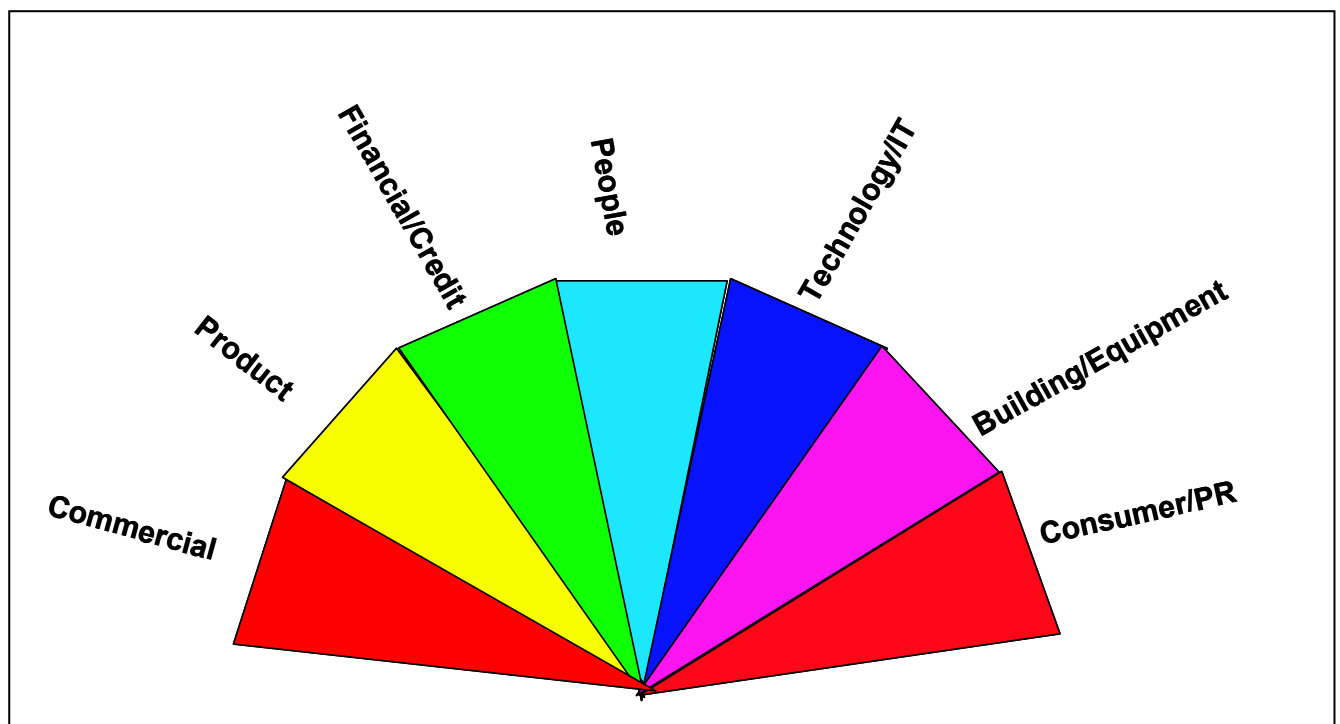
In most industry sectors, Risk Management has been a big driver for the last 5 to 10 years, though the ISO9001 standard does not formally call for it.

In Australia we have 2 key standards/guides that we need to make reference to:

- AS/NZS 4360 Risk Management
- GB158-2004: A guide to the use of AS/NZS 4360 Risk Management within the internal audit process.

Whilst the last document talks about the “internal” audit process, a lot of the approaches and concepts can be used within any audit process.

### **Defining the Context of Risk Management:**



Along the same lines we could look at:

- Patient care
- OHS, Environmental impacts and aspects.

**Risk Management within an external auditing context: concepts that the auditor needs to have, see or use.**

*Dealing with risks (the 4 T rules):*

- Terminate

- Tolerate
- Treat
- Transfer

*Dealing with events, the Control Suite:*

- Eliminate
- Substitute
- Isolate
- Engineer a solution
- Administration/management
- Protection (PPE)
- Emergency planning (ERP)
- Rehabilitate (once it has happened)
- Recovery (to get back into normality)

Please note that the last 2 steps of the control suite are not often called for hence assume that the event/risk will not occur.

*For Managers the Control Suite:*

- Audits
- Reviews
- Inspections
- Supervision
- Tests/Trials/Drills

Please note that all the above points are “included” in ISO9001.

*Measurements and fundamentals*

GB158 mentioned (based on Table 1):

<b>Likelihood rating</b>	<b>Likelihood guide</b>	<b>Likelihood periodicity</b>
<b>1</b>	Rare	10 yearly
<b>2</b>	Unlikely	5 yearly
<b>3</b>	Possible	Yearly
<b>4</b>	Likely	Monthly
<b>5</b>	Almost certain	Daily

GB158 mentioned (based on Table 2):

<b>Consequence rating</b>	<b>Consequence guide</b>	<b>Consequence periodicity</b>
<b>1</b>	Minor, less than \$50k	Minor injury to 1 individual
<b>2</b>	Major impact on 1 aspect of 1 process.	Minor injury to more than 1 individual

	No impact on corporate objective. Between \$50k and \$100k	
<b>3</b>	Impact on more than 1 aspect or more than 1 process. Minor impact on corporate objective. Between \$100k and \$500k	Injury to several individuals
<b>4</b>	Impact on lesser corporate objective, Significant impact on corporate objective. Between \$500k and \$1000k	Serious injury
<b>5</b>	Critical impact on corporate objective. Greater than \$1000k	Avoidable death

### Risk Management within a certification context

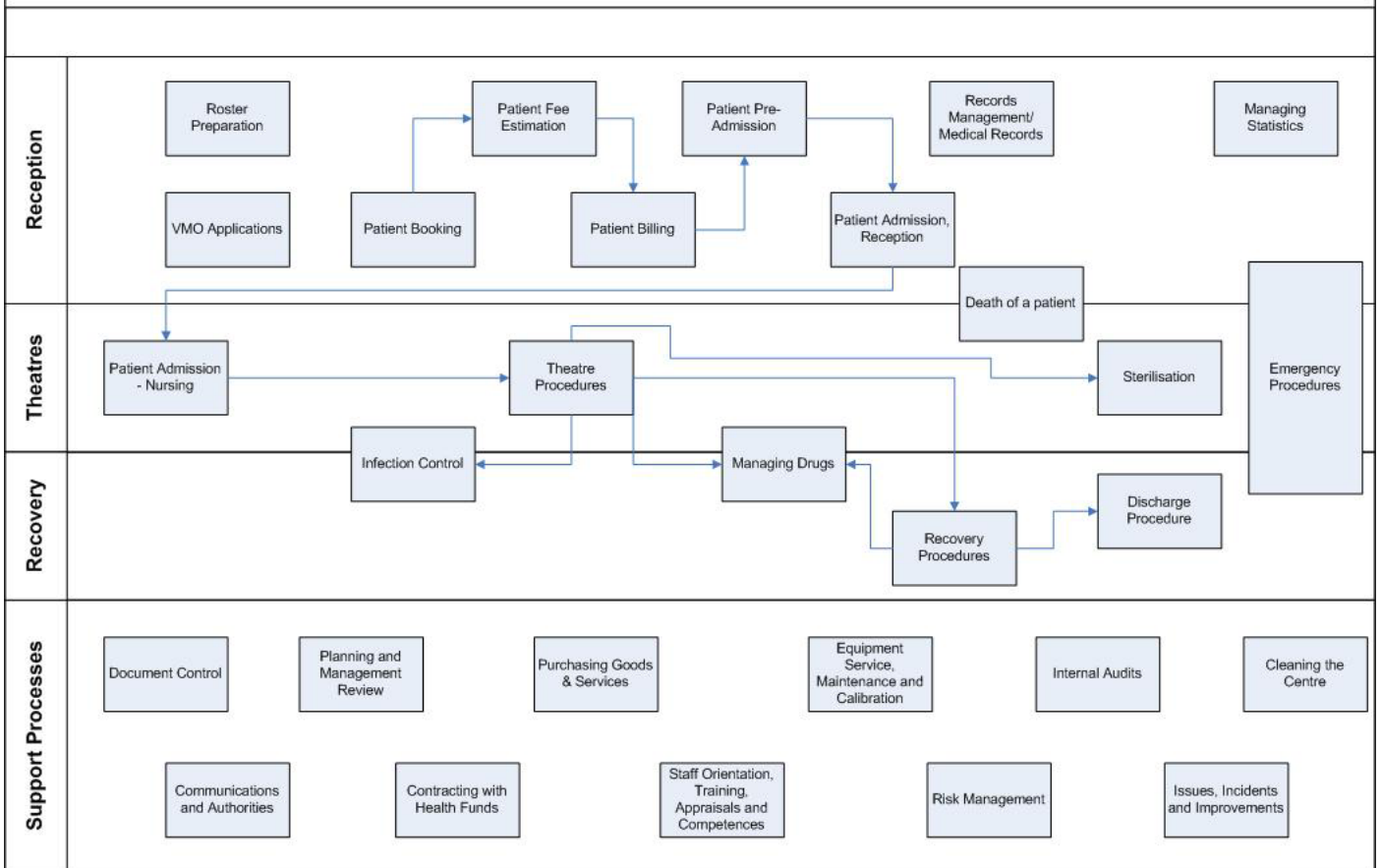
AS/NZS 4360/ Context	Event/Hazard	Consequence	Likelihood	Risk
<b>OHS</b>	Hazard	Consequence	Likelihood	Risk
<b>Environment</b>	Aspect	Impact	Probability	Significance
<b>Quality</b>	Non-conformance/ Defect	Loss	Frequency	Cost
<b>ISO9001 Certification in Health</b>	Deviation Non-compliance Lack of awareness	Patient safety Staff safety Process or system stability	Likelihood Other patients Other staff Other processes	Observation Improvement Request Non-Conformity

## PART 5: EXAMPLES: MAKING IT WORK

### Understanding the workflows

The following is a sample workflow for a day surgery

## Day Surgery Process Overview



## Understanding the document flows

The following are examples provided by the Westmead Rehabilitation Hospital and/or Peninsula Private Hospital.

The Client has structured its documents based on some core business units/areas and within each they have a Manual, with key processes represented. Each process then has a procedure and/or forms, flowchart etc as appropriate.



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**Patient**

**Admission**

**Continued**



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# **Patient Management**

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