GOVERNANCE, RISK AND QUALITY MANAGEMENT SYSTEMS

AS/NZS4187:2014

ACIPC WORKSHOP

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DOES AS/NZS4187:2014 ARTICULATE GOVERNANCE OR IS IT IMPLIED?

- AS/NZS4187:2014 only mentions the word governance in the HSO definition.
- When you read it, the framework it alludes to is GOVERNANCE
- QMS and Risk Management are the major governance components it focuses on in each section

WHAT IS GOVERNANCE?

There are many definitions……..good *governance* is based on major characteristics that are linked to the core values. For the organisation.

Most major characteristics include:

1. Consistent management
2. Cohesive policies and guidance + Standards
3. Processes and decision-rights for a given area of responsibility
4. Proper oversight (follow the rules of the law)
5. Accountable systems
6. Transparent responses and actions
7. Consensus orientated decisions and leadership
8. Effective, efficient and equitable systems and processes

Your governance framework will be dependent on your organisation

These are all implied in AS/NZS4187:2014

WHAT IS CLINICAL GOVERNANCE

Clinical Governance is the term used to describe a systematic approach to maintaining and improving the quality of patient care within a health system.

It is about the ability to produce effective change so that high quality care is achieved.

It requires clinicians and administrators to take joint responsibility for making sure this occurs.

When Clinical Governance is effective, it has the potential to:

- Make positive changes you want to see happen;
- Improve the quality of care for patients; and
- Provide a better experience for staff.

AN EXAMPLE OF A GOVERNANCE FRAMEWORK (NSW)

The governance framework is summarised in the following diagram. At the centre depicts the key elements of effective governance which public health organisations are responsible for managing and in the outer circles are the key external governance requirements that apply to these organisations across all their activities.

QMS Program

Service Planning

Financial, management and delegations

Managing your workforce, including education

Understanding roles and knowing who are your stakeholders

Clinical Governance, patient safety

Compliance with Standards, policies, records management and legislation

Roles and responsibilities Performance reporting

AS/NZS4187:2014 GOVERNANCE – WHAT SHOULD IT LOOK LIKE?

- An organisation structure that shows clear lines of reporting and accountability. Staff should understand the reporting lines
- A reporting structure for gaps, actions, implementation, QMS, KPIs and plans for AS/NZS4187:2014 - committees
- Policies/procedures/guidelines to meet requirements for AS/NZS4187:2014. These require consultation and ratification processes. Implementation and education program
- Position descriptions for staff working in reprocessing – roles and responsibilities that are clear
- Follow legislative requirements for your jurisdiction eg WHS, Health Practitioners Regulation (NSW) – look for a list on health department website
- Leadership assigned for AS/NZS4187:2014 - roles and responsibility eg gaps, actions, implementation, QMS, KPIs, plans, reporting
- Action/implementation plan for AS/NZS4187:2014
- Quality management system that includes risk assessments, education and competency of staff, records management
- Risk management framework
- Clear outcomes from an effective and efficient reprocessing area

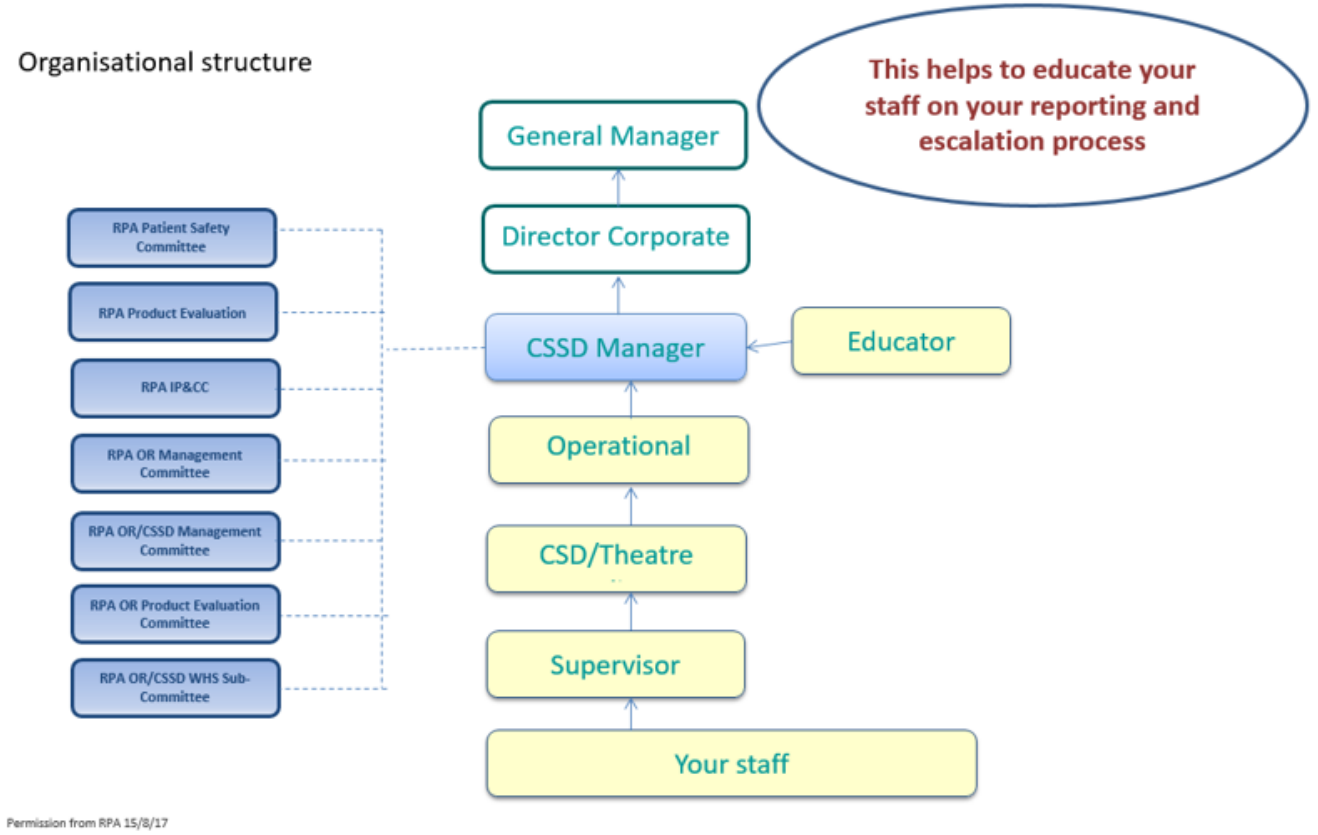
For all reprocessing areas – not just CSD or endoscopy!

HOW DO YOU DEMONSTRATE YOUR GOVERNANCE FOR ALL REPROCESSING AREAS?

- **Performance**—how the reprocessing area uses governance arrangements t contribute to its overall performance and the delivery of reprocessed RMDs services and quality programs

- **Conformance**—how the reprocessing area uses the governance arrangements to ensure it meets the requirements of the law, regulations, National Standards and community expectations of accuracy, accountability a openness (risks/incidents)

COMBINING ORGANISATIONAL STRUCTURE WITH COMMITTEE REPORTING - GOVERNANCE



UNDERSTANDING STAKEHOLDERS

The definition of a stakeholder is a **person who has an interest in or investment in something and who is impacted by and cares about how it turns out**.

Stakeholders all have a different level of interest, investment, influence or decision making in AS/NZS4187:2014 implementation

The implementation of AS/NZS4187:2014 (for all reprocessing areas)

If there are issues, barriers, lack of understanding or lack of decision making, you may need to draw a stakeholder map to enable everyone to understand who should:

- be involved
- engaged with
- consulted with
- considered
- who will support decisions
- who will influence decisions
- who should not be influencing decisions
- who needs to increase their level of interest
- who do you need to keep informed
- who will make decisions

How will you manage your stakeholders? Understanding stakeholders enables you to progress implementation in all reprocessing areas.

WHO ARE YOUR STAKEHOLDER INDIVIDUALS/GROUPS? WE NEED TO UNDERSTAND STAKEHOLDERS IN THE IMPLEMENTATION OF AS/NZS4187:2014. ISSUES I SOMETIMES/OFTEN SEE

Companies are seen as a KEY PLAYER. They are engaged and consulted regularly and are often asked to make key decisions regarding design, equipment purchases etc.

Companies play a vital consultation role – they are not the decision makers – they provide advice

Reprocessing staff/team leaders/managers are seen as INTERESTED.

Reprocessing staff/team leaders/mangers should be engaged and consulted regularly. Managers should be a KEY PLAYER

Engineering staff are seen as a KEY PLAYER. The provide the link between companies and reprocessing areas and preventative maintenance. They are a KEY PLAYER but all records must be accessible between reprocessing and engineering. Reporting and accountability.

Not all reprocessing areas are considered as 'they are not my responsibility'

They are a neglected stakeholder who are fending for themselves

WHAT IS A QMS?

- *A process based QMS enables the organizations to identify, measure, control and improve the various core business processes that will ultimately lead to improved business performance.*

Ref: ISO 9001 Quality Management System (QMS)

WHAT IS INCLUDED IN YOUR QMS?

Checking after every cycle

Non-conformance reports

TGA recalls/alerts, incidents, correction of errors

QI Projects

Competency assessments

Daily checks, tests and cleaning

Risk assessments eg difficult to clean RMD, WHS, waste reduction

How you manage your records

Gap analysis for AS/NZS4187

Policies, procedures or guidelines. Following IFUs

Audit program

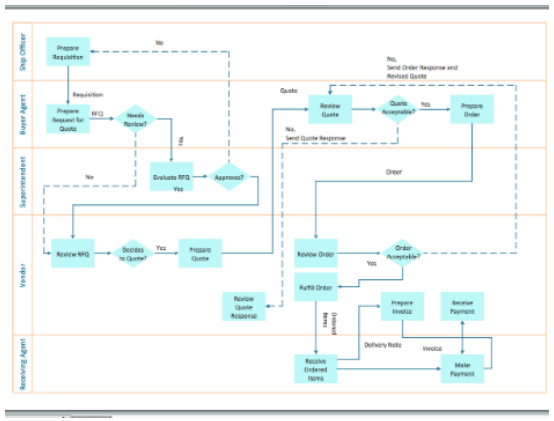
IQ, OQ, PQ

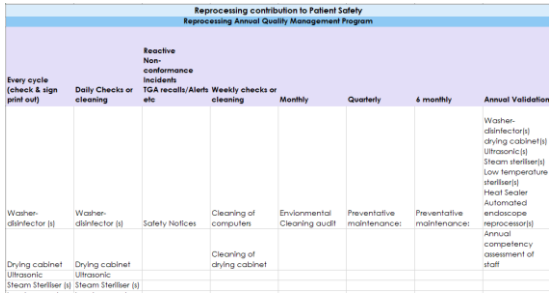
Preventative maintenance programs

Trials, assessments of equipment, chemicals, wraps etc

Desktop exercises

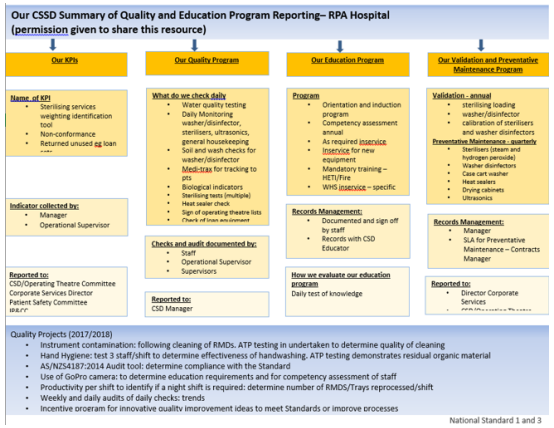
Documentation





Reprocessing contribution to Patient Safety
Reprocessing Annual Quality Management Program

Every cycle (check & sign print out)	Daily Checks or cleaning	Reactive Non-conformance Incidents TGA recalls/Alerts etc	Weekly checks or cleaning	Monthly	Quarterly	6 monthly	Annual Validation
Washer-disinfector (s)	Washer-disinfector (s)	Safety Notices	Cleaning of computers	Enviornmental Cleaning audit	Preventative maintenance:	Preventative maintenance:	Washer-disinfector(s) drying cabinet(s) Ultrasonic(s) Steam steriliser(s) Low temperature steriliser(s) Heat Sealer Automated endoscope reprocessor(s)
Drying cabinet	Drying cabinet		Cleaning of drying cabinet				Annual competency assessment of staff
Ultrasonic	Ultrasonic						
Steam Steriliser (s)	Steam Steriliser (s)						



HOW DO YOU DESCRIBE YOUR QMS?

Can you describe it?

Do staff understand that all the checks etc are part of the QMS?

Is it linked to patient safety?

QMS – AS/NZ4187:2014

- It should be about enhancing your existing QMS
- Keep your model simple
- Plan – Do – Study - Act
- Evaluate
- QI Projects require a simple plan

ACTIVITY TITLE:

BACKGROUND:

CURRENT RISKS:

CURRENT QUALITY ASSURANCE/AUDITING PROGRAM:

STAKEHOLDERS:

PROJECT SPONSOR:

PROJECT PLAN:

DATE	OBJECTIVE	MILESTONES/TASKS	RESPONSIBILITY
		•	
		•	
		•	
		•	
		•	
		•	
		•	

FINAL SUMMARY REPORT DATE:

COMMITTEE/GROUP:

WHAT IS RISK MANAGEMENT?

- *Risk Management is generally understood as coordinated activities to direct and control an organisation, with regard to risk.*

- The Australian Standards refer to risk management as including the "… *the systematic application of management policies, procedures and practices to the activities of communicating, consulting, establishing the context, and identifying, analysing, evaluating, treating, monitoring and reviewing risk*".

HOW DO YOU DEMONSTRATE YOUR RISK MANAGEMENT PROGRAM - EXAMPLES?

- Action/Implementation plan – risk rated
- Risk assessments
- Non-conformance reports – actions and outcomes. Trends
- Incidents – actions and outcomes. Trends
- Priority of QI projects – based on risks
- Recall procedure – has it been tested?

LETS RECAP

QMS and Risk are part of governance framework

AS/NZS4187:2014 is for all reprocessing areas – RMDs. Determine what is a RMD – check definition!

Documentation is essential – develop simple methods for documenting improvements, evaluations and reports

Keep track of action/implementation plan – set aside time every month (or more regular) to update

Report - committees and individuals. Determine what requires reporting – keep reports simple – one page. Link to NSs, evidence location, AS/NZS4187:2014 criteria etc

1.5.40 Medical device

Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of—

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(c) investigation, replacement, modification, or support of the anatomy or of a physiological process;

(d) supporting or sustaining life;

(e) control of conception;

(f) disinfection of medical devices;

(g) providing information for medical purposes by means of in vitro examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

[ISO 13485]

RISK/CRISIS COMMUNICATION – WHAT ARE THE ELEMENTS?

What we need to do

- Identify the risk
- Assessment of the risk – facts/evidence
- Report the risk – type of communication
- Control or mitigate the risk
- Determine risk level and risk category
- Escalate to the right person
- Document the outcomes

We are not so good at this?

- Crisis communication v's risk communication (things that go wrong versus what may go wrong)
- Risk communication – real-time
- Proactive v's reactive
- Identifying the correct level of risk – based on facts and evidence
- Communicating to the right person at the right time – not the scattergun method
- Documentation – risk assessment, report or other
- Reporting outcomes/evaluation to correct committee

PREPARING FOR ACCREDITATION

- Action/Implementation Plan – able to demonstrate that a gap analysis was completed, milestones are documented and progress tracked on actions
- Accessible records – electronic or paper
- Education of staff – competency assessments, QMS, risk identification, escalation and communication
- Policies, procedures or guidelines. Following manufacturers IFUs (location and accessibility)
- Description, documentation and evidence of tracking/traceability system – to the patient, procedure and RMD. Evaluation that it works
- Description of QMS program. These should be accessible.
- Summaries of QI Projects
- Validation – IQ,OQ.PQ – reported to committee (and action if required)
- SLAs and plans

Quality Improvement Project Report Summary

National Standard 3.xx | AS/NZS4187:2014 Section xx

Unit/Department: | Facility:

Date commenced: | Date completed:

PROJECT TITLE:

WHY DID WE DO THIS PROJECT?

WHO WAS OUR PROJECT TEAM LEADER AND TEAM MEMBERS?

WHAT METHODOLOGY DID WE USE FOR THIS PROJECT?

WHAT WERE OUR RESULTS?

WHAT WAS OUR OUTCOME FROM THE PROJECT?

HOW WILL WE SUSTAIN THE CHANGE FROM THE PROJECT?

REPORTED TO THE FOLLOWING COMMITTEES:

Evidence location for this project: Page

REFERENCES AND LINKS

- https://www.ukessays.com/essays/politics/principle-of-good-governance.php
- https://www.health.nsw.gov.au/policies/manuals/Publications/corporate-governance-compendium.pdf
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- AS/NZS4187:2014 Reprocessing of reusable medical devices in health service organizations
- Google images

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- https://www.health.nsw.gov.au/legislation/Pages/legislation-links.aspx