



**Asia-Pacific
Economic Cooperation**

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Quality Systems - The New Zealand Experience

Submitted by: New Zealand Blood Service (NZBS)



**Policy Dialogue and Workshop on Attaining a
Safe and Sustainable Blood Supply Chain
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Quality Systems the NZ experience

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Scope





- Standards
- Organisational management
- **Documentation**
- **Training**
- **Assessment**

NZBS statistics

- NZ Population: 4.5 million
- NZBS Sites:
 - 9 collection sites
 - 4 processing sites
 - 2 donor testing sites
 - 6 hospital blood bank sites
- Collections: approx 150,000 per annum
- FTE: approx 500

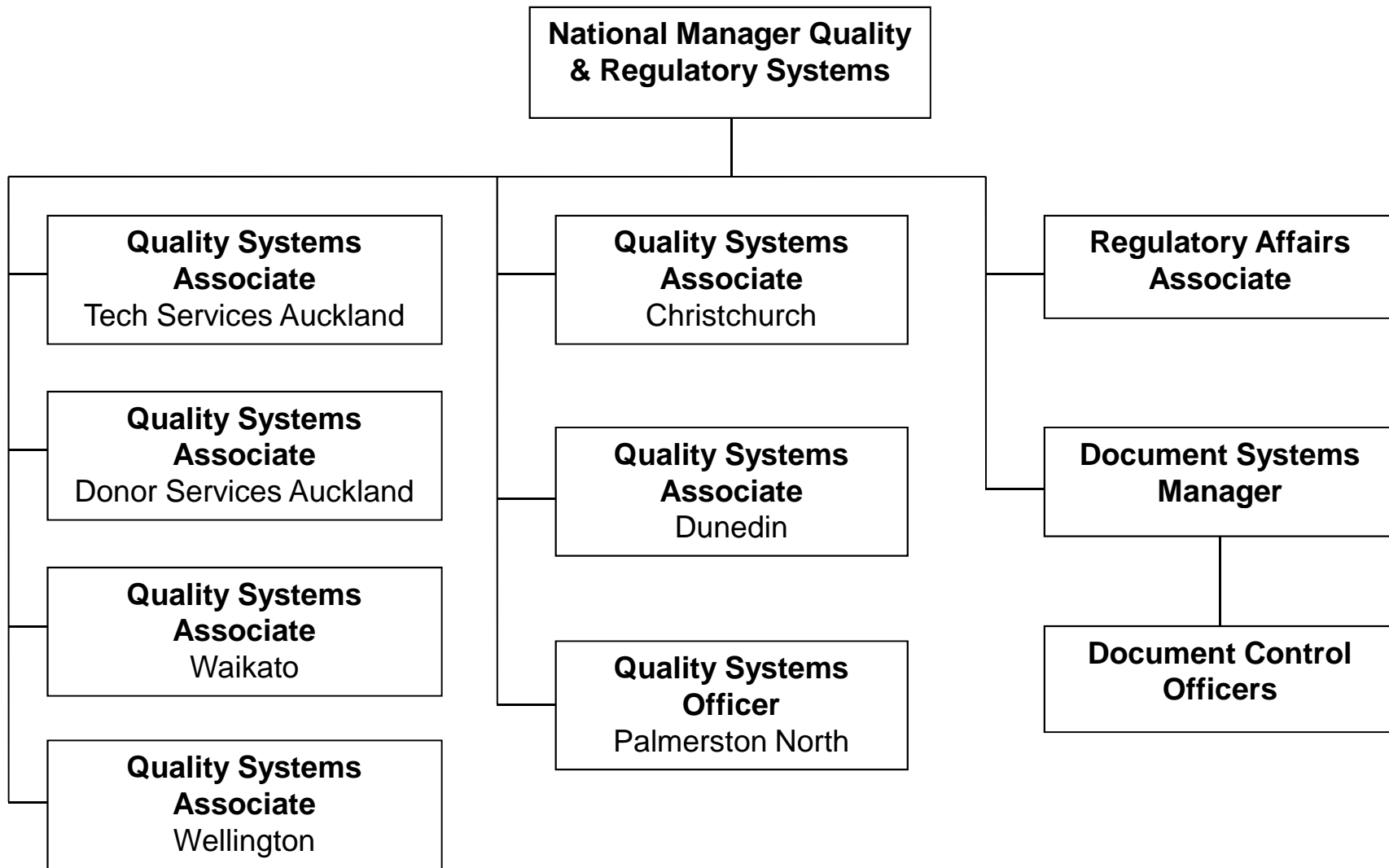
NEW ZEALAND



-  Collection
Blood Processing /HPC
Tissue Banking
Donor Testing /Ref Lab
Blood Bank
-  Collection
Blood Processing / HPC
Tissue Banking
Blood Bank
-  Collection
Tissue Banking
Blood Bank
-  Collection

What has worked at NZBS?

- Single Quality System and National Quality Manager
- National Quality Team providing Quality resources across the country
- 6 x QSAs plus 1 QSO working as partners with operational staff at six sites



NZBS – What has worked?

- Starting with simple systems and refining and improving them over time
 - e.g. progressively adopting electronic tools
- Operational staff understanding their role in
 - Equipment calibration & maintenance
 - Validation & change control
 - Responding to corrective actions
 - Conducting training
 - Writing procedures

Documentation

- Documentation structure
- Document content
- Document control
- Recordkeeping
- Records management



What has worked? - Documents

- Dedicated Document Management team
- Structured system - defined document types
- SMEs develop document content

What has worked? - Documents

- National IT infrastructure
- National electronic quality management system since 2005:



- Documents
- Corrective actions
- Change control & validation
- Equipment
- Audits
- Training
- Suppliers

Document Control Systems

Paper based system

- Unmanageable for large numbers of documents
- Hard copy signatures
- Complex to manage versions and tracking of copies
- No process for managing drafting
- Long term storage issues with archived copies and difficult to retrieve

Electronic system

- Simple to manage large numbers of documents
- Electronic signatures
- Simple to manage versions and tracking of copies
- Controls the whole document lifecycle
- Archived copies stored electronically and easily retrieved

What has worked? - Records

- Culture of recording everything
- Establishing rules for record completion
- Paper AND electronic records
- Developing records management skills:
 - retention and disposal schedules
 - systems for archiving systematically

Training

- Task based training
- Quality systems training
- Training plans, material & records



What has worked? - Training

- Training material
 - Developed by National Training & Development Coordinators
 - National consistency
 - Mix of paper based and electronic training material

What has worked? - Training

- Training delivery
 - Workplace trainers
 - In service training sessions
 - Competency assessments
- Training records
 - Completion of each training event and competency assessment tracked in Q-Pulse

Assessment

- Auditing
- Error management
- Process monitoring
- Management Review
- QAPs
- Haemovigilance
- Process & equipment validation
- Equipment management



What has worked? - Auditing

- Scheduling and managing audits in Q-Pulse
- Training for auditors
- Involving operational staff in audits
- Fosters understanding of quality expectations in operational staff

What has worked?

Error management

- Focusing on the system, not the individual
- Root cause analysis on serious errors
- Classification system for errors to enable trending

What has worked?

Process monitoring

- Specifications for finished product
- Testing plan for process control testing
- Statistical process control
- Regular review of results

Assessment

- Management Review
- QAPs
- Haemovigilance
- Process & equipment validation
- Equipment management

Conclusion

- Robust quality systems are fundamental to the production of safe blood
- Quality must be adequately resourced
- Documentation and training systems are fundamentals that must be established early
- Assessment systems are essential for ensuring ongoing quality improvement

