

A Quality Service

Implementing EN ISO 13485:2003

By

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Background

- Sterile Services Technician/internal auditor for NHS Argyll and Clyde
- Seconded to Health Protection Scotland Decontamination Team - to write a report on CSSD Contingency Planning for Scotland and then to look at difficult to clean instruments
- Seconded to NHS Grampian as CSSD Deputy Manager
- NHS Grampian Decontamination Quality and Training Manager
- Healthcare Science Ltd Decontamination Technical Officer

Standard

- All Sterile Service Departments in Scotland have to be compliant with EN ISO 13485:2003
- A copy of the standard was essential
- A copy of the TR (EN ISO 14696)
- A copy of the Medical Devices Directive (93/42/EEC)

Support

- Full support from top management
- Funding
- Facilities
- Staff support and involvement

What was needed?

- Gap analysis – what did we need to conform to EN ISO 13485 and the MDD?
- Staff and management training
- Reassessment of CSSD procedures
- Time
- External audit from Notified Body

It would have also have been beneficial to have had a second gap analysis by the Notified Body.

The Process Approach

How did we carry out each job?

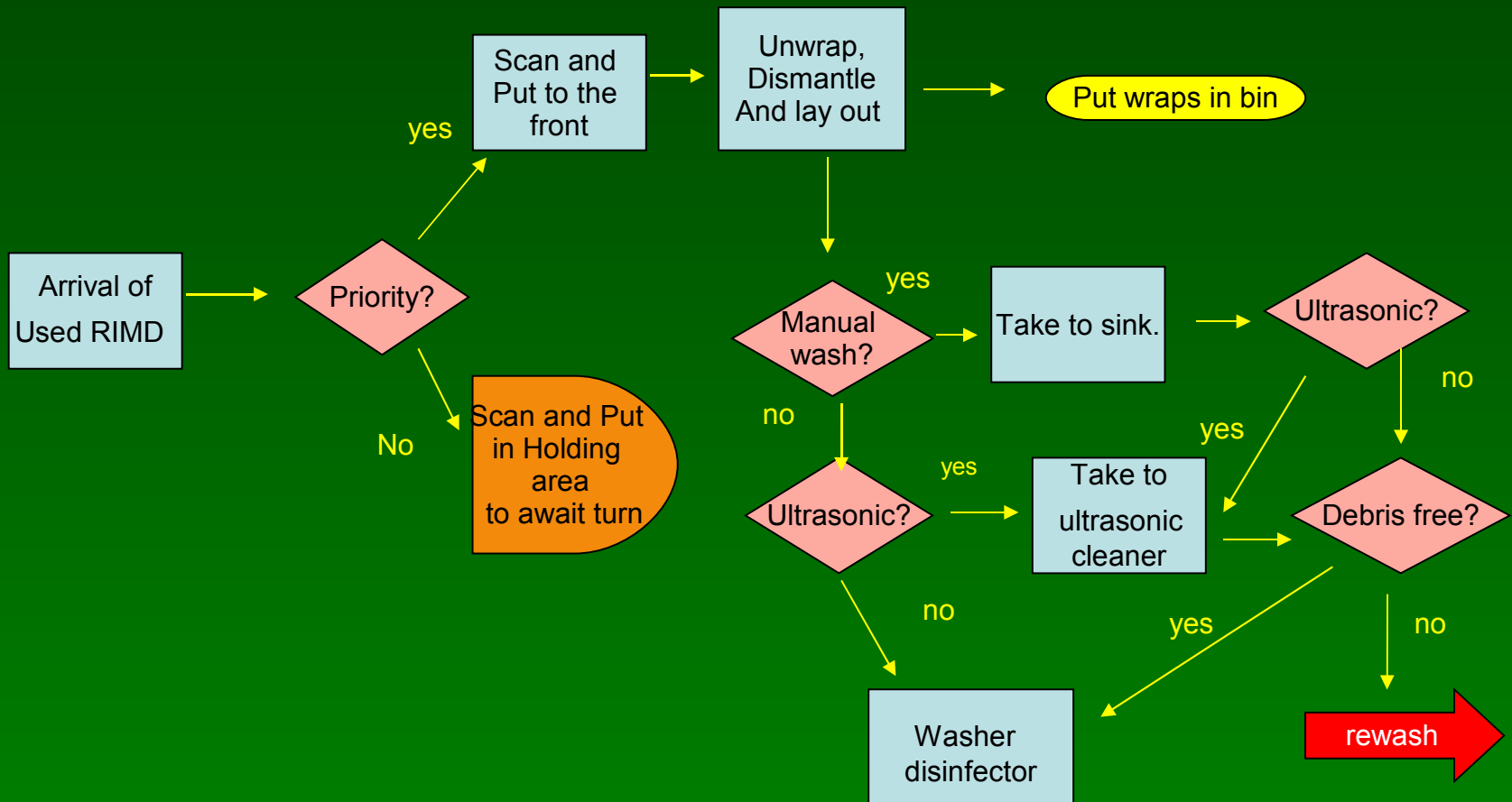


Other Quality Tools

- Analysis charts
- Quality circle
- Priority lists
- Customer feedback questionnaires
- Brainstorming sessions
- Networking
- Process mapping

Example Process Map

Priority Tray Process Map



Manual Washing

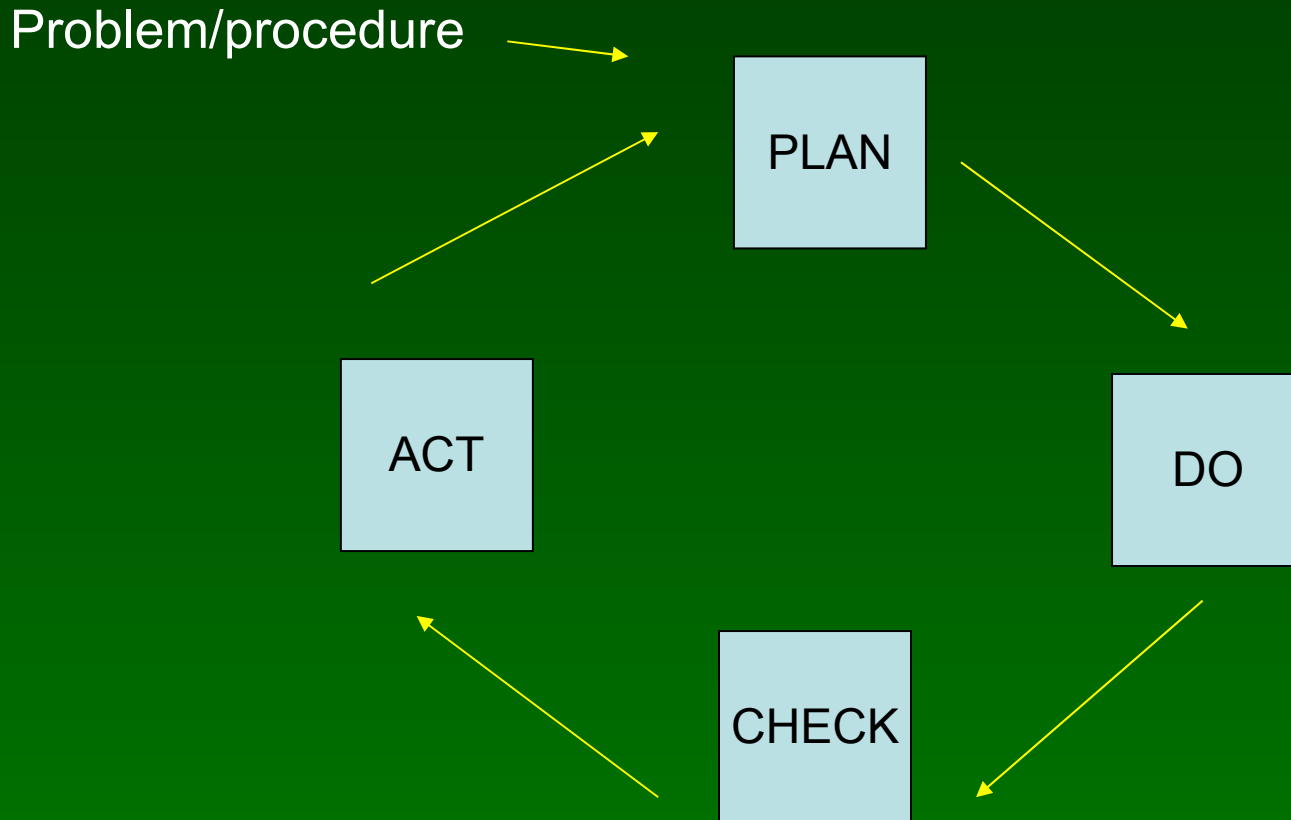
We looked at:

- PPE
- Manual wash facility
- Detergent
- Water
- Ventilation
- Wash methods
- Wash accessories
- Training
- Record Keeping/Traceability

For each change we had to:

- Define what we needed to change
- Define the required outcome of the change
- Consult with the relevant staff
- State how changes were to occur
- Train staff on changes
- Implement the change
- Analyse the records – Did we achieve what we set out to do?
- Revisit each change – Can we further improve?

Deming Cycle



ALWAYS TRAIN FIRST IMPLEMENT SECOND

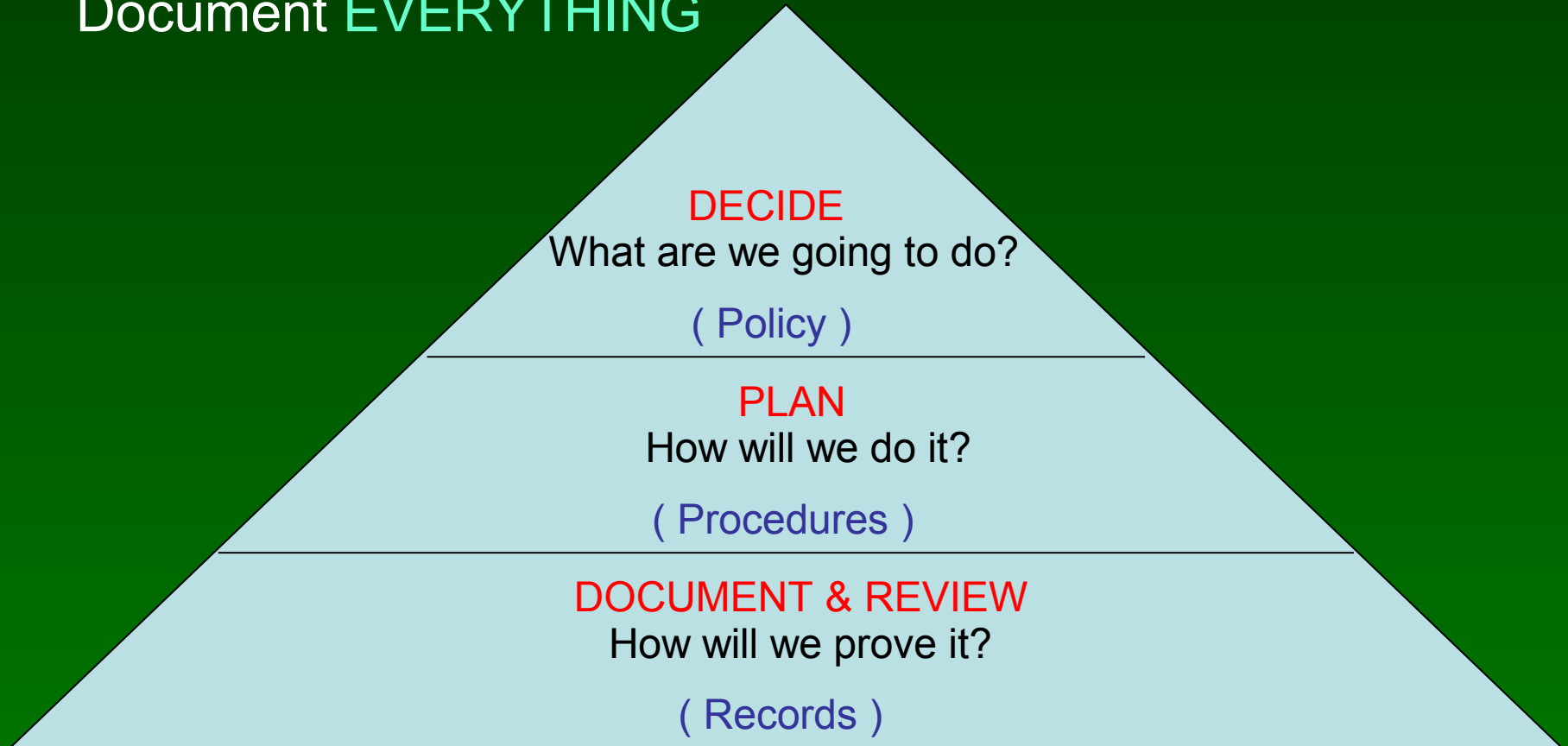
Organising Change

Everything eventually changes and every part of the quality manual was revisited approximately once a year.



Documentation

Document **EVERYTHING**



Procedures

All procedures have standard headings:

- Document Title
- Document Number
- Revision Number
- Authorising Signature and Title
- Authorisation Date
- Implementation Date
- Review date
- Page Number
- Purpose
- Application
- References
- Procedure
- Definitions

Quality Management Review

To conform with EN ISO 13485 it was also essential to have a Quality Management Review that included top management. EN ISO 13485 section 5.6.2 is specific on what this review should cover while 5.6.3 covers output.

5.6.2 Review Input

The input to management review shall include information on:

- a) results of audits,
- b) customer feedback,
- c) process performance and product conformity,
- d) status of preventive and corrective actions,
- e) follow-up actions from previous management reviews,
- f) changes that could affect the quality management system,
- g) recommendations for improvement, and
- *h) new or revised regulatory requirements.*

5.6.3 Review Output

- The output from the management review shall include any decisions and actions related to
 - *a) improvements needed to maintain the effectiveness of the quality management system and its processes,*
 - b) improvement of product related to customer requirements, and
 - c) resource needs

External Audit

A date was arranged for an external audit by the Notified Body. We also found out:

- Who?
- What?
- When?
- How long?

Audit Preparation

Evidence was found of :

- Equipment commissioning, validation and testing
- Quality management review
- Internal audits
- Preventive action
- Corrective action
- Tracking and tracing
- Procedure records
- Staff training
- IAP room microbial testing
- RIMD risk assessments
- Batch Records
- Non Batch Records

Final Preparation

- Management meeting
- Staff meeting
- A dummy run!

On Day of Audit

At hand were:

- Preparation information
- Quality manual
- Technical file
- Adverse incident reports
- Auditor and/or microbiologist guide
- Management
- Any relevant quality staff
- Office space and equipment

Audit Result

- We failed.

There had been no advised secondary gap analysis by the notified body and a gap in the heat sealer records was discovered. This was a major non conformance.

Quality had to perform the agreed corrective action and a new date was set for another audit. This was an additional cost to the unit.

Finally

Another audit and

- SUCCESS!!!!!!
- The execution of audit minor non conformances was planned.
- The non conformance corrective action plan was sent to Notified Body for approval within the allotted time
- We started preparation for NEXT external audit in six months time!

What were the Benefits?

- Reassurance for patients
- Reassurance for service users
- Lower non conformances
- Fewer cancelled/delayed operations
- Money saved
- Enhanced unit/service user relations
- Enhanced management/staff communication
- Compulsory organised training
- High staff moral
- Enhanced funding

Níl mórán Gaeilge agam, ach
...Go raibh maith agaibh!