Basics of a Quality Management System

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Definition

- ‘A quality management system (QMS) is a set of policies, processes and procedures required for planning and execution (production/development/service) in the core business area of an organization. (i.e. areas that can impact the organization's ability to meet customer requirements.)’

Put more simply

- A quality management system is made up of everything which has put in place to ensure provision of a high class service
- Its made up of multiple processes and sections
- No 2 QMS's will ever be totally identical
- Every lab has had a QMS for many years although they may not have called it that!

What is the Quality Management System?

- The Laboratory
- The Staff
- The Procedures
- The Protocols
- Spotting errors / mistakes
- Learning from errors / mistakes

What makes up a QMS

QMS HIERARCHY

- It’s not a complex has it looks
- Honest!

Why?

- Its not enough to do think we are doing the right thing
- We now need to provide evidence that the right thing is done
  - *Today*
  - *Yesterday*
  - *Tomorrow*
- Inspections against established standards

Paperwork

- All labs have lots of paperwork
  - Staff Records
  - Policies
  - Equipment records
  - Audits
  - Cold Chain
  - Incident reporting
  - Etc

All this makes up part of the QMS

Staff records:

- Staff records includes:
  - Induction records
  - Training records
  - Competency records

  - All are designed to show you are suitably trainined and competency checked to do your role

Policies

- ISO 15189 accreditation requires a number of policies and protocols to be in place
  - Trust policies –
    - example Transfusion Policy
  - Divisional polices which apply to all laboratories
    - example Health and safety policy
  - Departmental policies
    - example annual leave policy
  - Section policies
    - Example sample acceptance policy

Equipment records

- There are lots of records associated with equipment
  - Installation Records
    - Installation Qualificaiton
    - Operational Qualificiation
    - Performance Qualification
  - Staff Training records
  - Maintenance records
    - Trend analysis/investigation of breakdowns

Protocols

- How we do something
  - SOPs
  - Training records
  - Competency records

Includes Quality Control and Quality Assurance!

Audits

- There are different types of audit
  - Clinical (is a policy or guideline being adhered to)
  - Examination (progess v SOP)
  - Vertical (follows process from start to finish)
  - Horizontal (examines 1 part of a process in multiple settings)

Audits cont

- Most important thing to remember about audits
  - Learn from them
  - Note failings
  - Develop an action plan
  - Ensure you follow up on the action plan in a reasonable time frame!

Audits cont

- Should be an on going process
- Should cover all areas and sites
- Should be part of routine day
- Objective, not judgmental
- Maybe National, regional, local

Cold Chain

- A good cold chain is a key part of a transfusion service
- The parts of the QMS we've talked about must be part of a good cold chain
  - Training/Competency
  - Equipment records
  - Validation
  - etc

Incidents

- Incidents are key
- Report and investigate own incidents
- Report and assist with investigations of incidents in other areas affecting own area
- Investigate incidents reported by other areas

Incidents continued

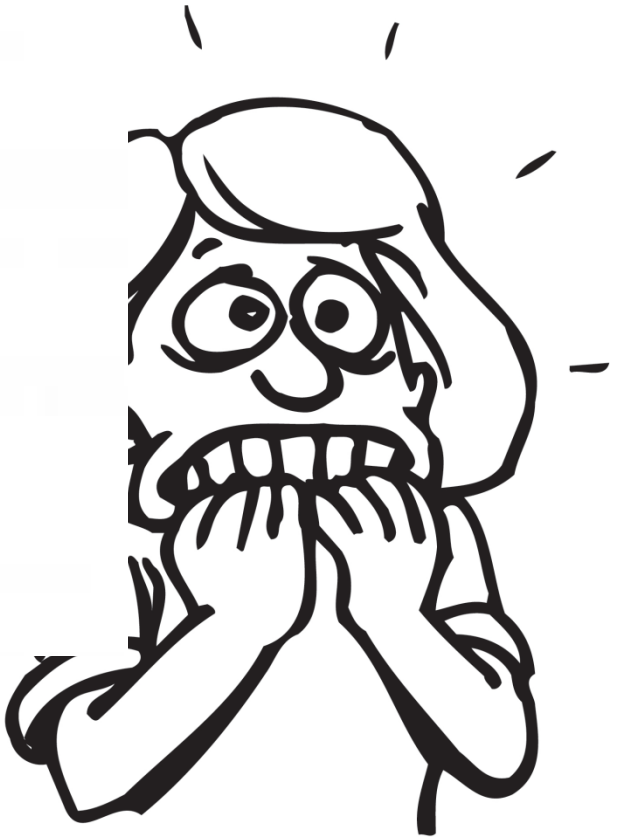
- Clinical teams are usually quick to report an incident related to transfusion
- Important:
  - Learn from incidents
  - Some may require an action plan
  - Remember to ensure your action plan is completed!

Who?

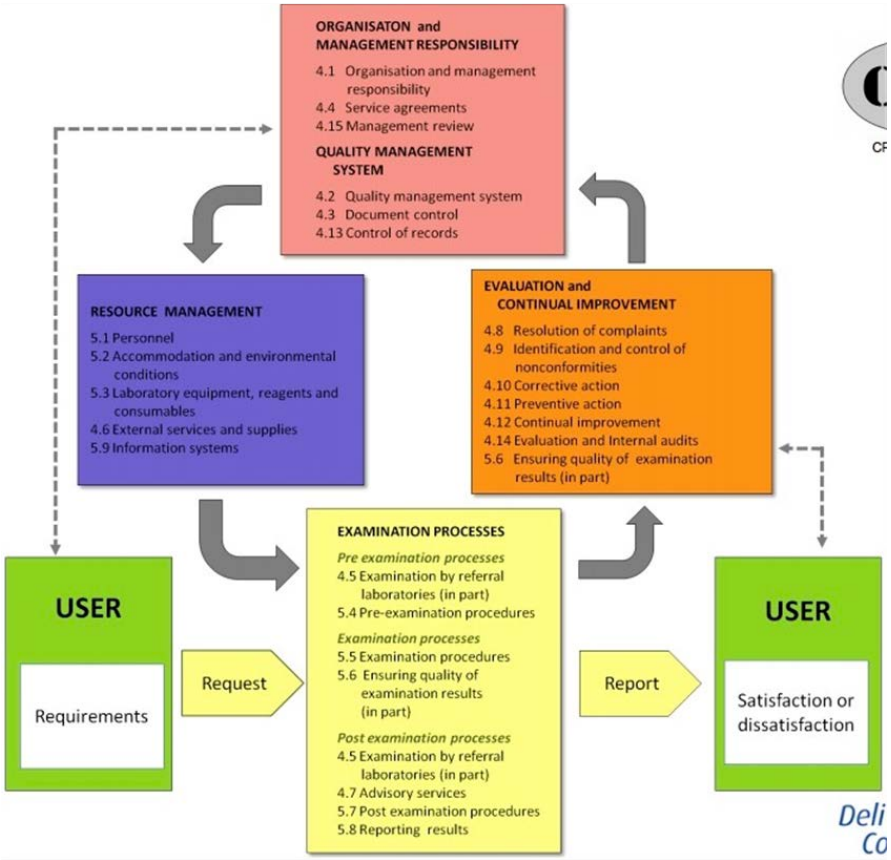
- Laboratories will have a quality lead
  - This may be shared with other laboratories
  - They will lead and encourage quality

  - But the QMS – is everyone's responsibility

Assessing your QMS?



Inspections – ISO 15189



Potential problem?

- Time
- Labs are busy
- There isn't time to get everything done!
- QMS is important
- It's the evidence that things are being done correctly

Summary

- Quality management is complicated (it may seem so)
  - A lot is good laboratory practice
- It is however time consuming
  - So you do need to make time for it
- No 1 person's job – its part of everyone's role

Thank You


this is how I finish a presentation:
Soo...
uhh
...yeah.
SCHOOL.FAILBLOG.ORG