Medicines & Healthcare products
Regulatory Agency

Capacity Planning

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The Good Practice Guide

1.2.2. The Quality System encompasses quality management, quality assurance, continuous quality improvement, **personnel,** premises and equipment, documentation, collection, testing and processing, storage, distribution, quality control, blood component recall, and external and internal auditing, contract management, non-conformance and self-inspection (Directive 2005/62/EC/Annex 1.1.2).

1.2.5. **Executive management has the ultimate responsibility** to ensure that an effective Quality System is in place and resourced adequately, and that roles and responsibilities, are defined, communicated and implemented throughout the organisation. Executive management's leadership and active participation in the Quality System is essential. This leadership should ensure the support and commitment of staff at all levels and sites within the organisation to the Quality System.

2.2. The organisation should have an **adequate number of personnel with the necessary qualifications and experience**. Management has the ultimate responsibility to determine and provide adequate and appropriate resources (human, financial, materials, facilities and equipment) to implement and maintain the Quality Management System and continually improve its suitability and effectiveness through participation in management review. The responsibilities placed on any one individual should not be so extensive as to present any risk to quality.

This underpins the fact that personnel are a central cog in the management of EVERY Quality Management System and as such the management has the ultimate responsibility for providing this resource that is fit for task to ensure business continuity through an adequate capacity plan.

To ensure adequate resource, relevant evidence needs to be provided so sufficient capacity is available to suit all situations so business continuity can be preserved..

Findings at Inspection

5 HBB had significant deficiency findings related to their operations and were escalated to the CMT. This is a significant increase over the previous year. Common deficiency groups identified from these inspections included:

- Senior management not fulfilling their responsibilities
- Non-conformances/incidents/events and CAPA implementation
- Change control management
- Self-inspection
- Resourcing and training
- Failure to complete previous commitments
- Data integrity failures

In some inspections, the number of systems found to be deficient indicated that there were insufficient resources to maintain an effective quality management system at the same time as ensuring service delivery. Further investigation identified failings such as:

- A quality manager who was available for less than 0.1 whole time equivalent (WTE) for transfusion
- A laboratory manager with overall responsibility for quality but insufficient time to fulfil this responsibility due to required time on the bench
- No resource plan to define the required resource levels to support operational delivery and the quality system

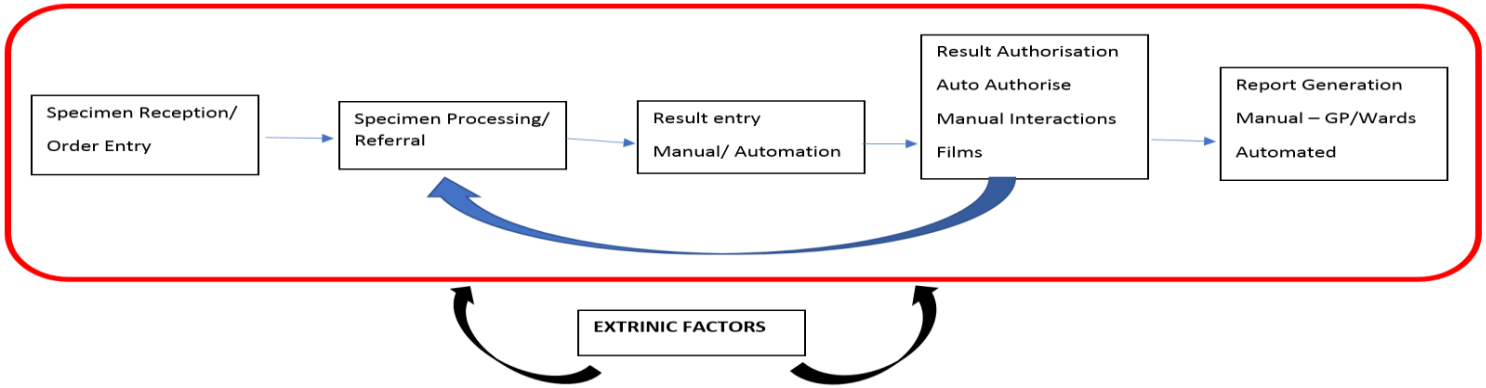
A capacity plan should be put in place to demonstrate that the staffing level is sufficient to cover the workload including out-of-hours working and effective implementation of the quality management system. Where a shortfall is identified, senior management should take action to ensure sufficient resource will be made available.

HOW TO ACHIEVE COMPLIANCE?

Evidence Based Requirements

Management buy in at ALL levels

Senior Management not fulfilling their responsibilities?



Is this all management see – A strategic view of the Pathology Business is not reflective of its business processes (Component Parts)

Look at the individual elements of the business process and capacity plan to ensure business continuity (IS IT WORKING) such as:

- Workload – daily, weekly, monthly, annually/ meetings/ quality management/ Out of hours
- Staff – Training/Competency/Associated roles (management/maintenance)/breaks/ Sickness/skill mix/Holiday/Morale – Critical, Major, Normal levels (what can and cant do with the numbers you have – triggers BCP)
- LIMS – Up to date/downtime/speed/rules/ fit for task/updates (validation)/management back up
- Automation/Technology – Maintenance/Validation/Downtime/middleware/interfacing

IS IT WORKING? IF IT IS NOT THEN WHY NOT -ACTION BASED ON EVIDENCE

Workload

Tracking activity

- Time of day
- Daily
- Weekly
- Monthly
- Annually
- KPI and TAT (Failures)

Future provisions - New Arrangements, i.e. GP Contracts

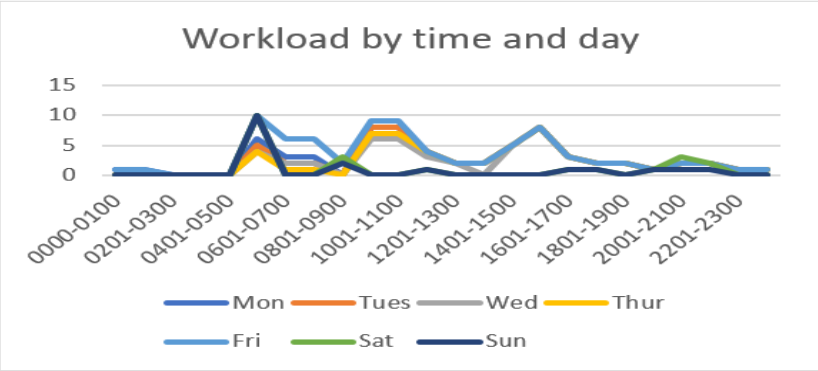
Increase – decrease – Analyse and audit

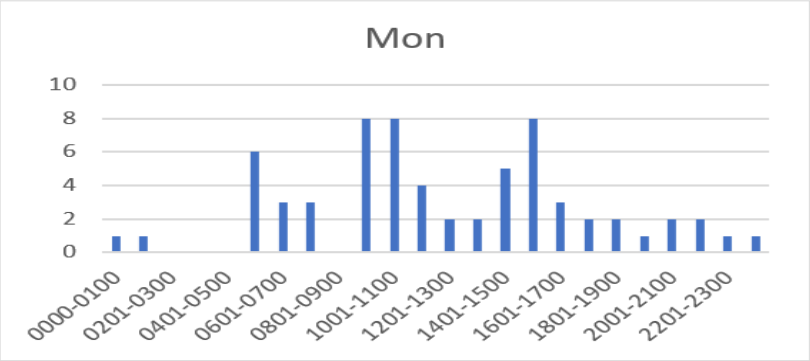
Tailor the staff to meet the demand – Part Time/On Call

Design a Shift system that meets your needs – NOT ON CALL

Skill mix to meet the demand – MLA/BMS??

Financials – Positive and Negative Impact on staffing





A Detailed View – Risk Status and Impact

Severity and Risk stauts against KPI								
QMS Support	KPI	Required Capacity WTE	Current Capacity WTE	Associated/ Curret Risks	itigation in pla	Detail of Mitigation	Current Score Vs Compliance	Impact
	Training and Competency	0.3	0.1	Currently only achieving 70% compliance and thjerefore unable to meet 100% KPI as staff cannot be released to train junior members. Senior BMS staff unable to be released for conferences, TADG	No	No mitigation in place as workload and staffing levels only allow for routine workload targets to be met		Unable to meet regulation 2.2 of the GPG as only 70% of staff are adequately trained and competency assessed at current staffing levels. Continuing at this level is increasing our SABRE reportable events, 2% increase in the last quarter all associated with ineffective and inadequate training of junior, new and locum staff. 2.2. The organisation should have an adequate number of personnel with the necessary qualifications and experience. Management has the ultimate responsibility to determine and provide adequate and appropriate resources (human, financial, materials, facilities and equipment) to implement and maintain the Quality Management System and continually improve its suitability and effectiveness through participation in management review. The responsibilities placed on any one individual should not be so extensive as to present any risk to quality.

Raise this issue as a major non compliance to the BSQR's at your hospital risk committee meeting

A true evidenced reflection of the current situation

Use the regulations to support your case

Record not just the issue but the actions and time frame for implementation and keep track

Add to your hospital risk register

Strategic KPIs have component parts i.e

Severity and Risk stauts against KPI			
QMS Support	KPI	Required Capacity WTE	Current Capacity WTE
	Training and Competency	0.3	0.1
	SOP Review	0.1	0.1
	IQC	0.1	0.1
	EQA	0.2	0.1
	Attendance at TADG, HTT, etc	o.3	0.1
	Internal Management Meetings	0.3	0.1
	Adverse Incident reporting	0.1	0.1
	Adverse Incident AUDIT	0.1	0.1
	Traceability	0.5	0.1
	IT Support	0.1	0.1
	Automation	0.1	0.1
	Staffing Levels including Holiday and Sickness		-0.3
	Change Control and Validation Projects	0.1	0.1
	Stock Management	0.1	0.1
	Overall Total and Score	**2.1**	**1**
		based on 37.5 hour week	**working at -1. WTE**

Staffing

Skill mix to meet the demand – MLA/BMS?? Inappropriate roles for non-qualified staff

Quality Management – Dedicated resource, Part Time or paying lip service

Training and Competency – Up to date, Audit - % complete, realistic, can it be expanded

Professional Training – Portfolios (Investing for the future), requirements

Error rates – Over working, insufficient cover for breaks, on call, more errors more time

Sickness/ Holiday Levels – Short Notice

Supportive/Supervisory Management – How much drain is this on others time (Not just the managers)

Managing distractions – Design and Ergonomics of the lab

Culture – Is it a nice place to work (morale),

Effective Communication – All levels are their gaps? Dictatorship does not work

Good Will – NOT TO BE USED AS AN EFECTIVE MEASURE OF A GOOD CAPACITY PLAN!!! – Log it

Work to Set goals – How have these changed and are changing and is your capacity keeping pace

Flexible Management – One size does not fit all, does your capacity allow for this (Part Time, allowing for everyday events)

Technology – Hindrance or Help

Transparent decision making

LIMS /Technology (Automation)

Up to date – Adequate and intuitive release notes – how often and how much validation

Back up and updates – How long does it take and does it interfere with routine work (speed)

Downtime – What is the effect on TAT and BCP, Why (Maintenance) and how often

Trending Errors – Common and impact

Data retrieval – How often

Loss/corruption of Data – How did it happen, impact on resource and reputation

Manufacturer Support – Critical/Major/ Observation (SLA) – Do you actually get it, what's in your SLA

Training time – intuitive (old technology), knowledge transfer/loss (retirement), staff turnover

Quality Control and calibration – How long, how many times

New Technology – Is it available, research and evidence a BC to succeed

Stability and Load – Can it cope

Impact on best practice – Does it Work? Algorithms.

Other Quality Management Non Conformances

Non-conformances/incidents/events and CAPA implementation

- How many have been raised by Self Inspection, External Audit (MHRA, CPA UKAS)
- Are they getting done – If not why not (Time, resource)
- Extensions – Why and how many (Be Specific)

Change control management

- Are they effective – Time to plan
- Resource committed to manage and effect the change – Are they available
- Do they reflect the business change – are they realistic
- Dedicated resource – Availability AND Expertise

Self-inspection

- Audit Calendar – Realistic and inclusive
- Fitted to resource instead of the business process – The correct way around
- Do they capture the realistic picture of what is happening or is a culture of ‘will be done by the time we are inspected so no need to worry now’?

Other Quality Management Non Conformances

Resourcing and training

- See above comments about staff
- Tick Box Exercise

Failure to complete previous commitments

- Action Plan – Honest and realistic
- Setting appropriate timelines – Be honest

Data integrity failures – SEE ABOVE

Extrinsic Factors

Internal Meetings – are these factored in, how many, are they needed

External Meetings/Conferences – Essential for networking for best practice sharing and communication of ideas

Internal and External Projects – What are they, how do they impact

CPD – It's an obligation of the Employee and Employer – investors in people, what is the Trusts/ professional body Policy? What do the clinician and nursing staff do (setting precedence) – STUDY DAYS

Double Hatted – How many balls can you juggle

Breaking down barriers – Them and us, knowing both sides

Telephone communicates – Are they necessary, can they be filtered

Interruptions – Outside Staff, Alarms, Induction, Mandatory Training

Locums – Cost them out BOTH in employment costs but also with training and competency requirements

Summary

Not a battle between management and staff – BOTH SIDES MUST BE UNDERSTOOD

Evidence based approach – Make it realistic, don't be afraid to challenge

Report ALL breaches – Review and Audit

Start Assessing the Impact on Business Continuity – Risk Assess and suggest mitigation – Log it and keep what you have done and said.

Offer Solutions NOT just problems – Communication is key

Don't be afraid to approach the MHRA – Michael.dawe@mhra.gov.uk