Oversight and Escalation

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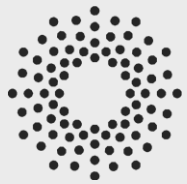

LONDON METROPOLITAN UNIVERSITY

Overview of Governance

The Royal College of Pathologists
Pathology: the science behind the cure

Patient safety and quality strategy 2019

Work with stakeholders to improve oversight, systems governance and funding of external quality assessment

The College will:

- support the development of a robust systems governance and assurance framework for external quality assessment (EQA), including a consistent approach to the identification and management of poor performance and a funding mechanism for the support services offered by the College
- develop and deliver a pilot project to determine the administrative support required for National Quality Assessment Advisory Panels.

Context

GIRFT
GETTING IT RIGHT FIRST TIME

Pathology

GIRFT Programme National Specialty Report

by Dr Tom Lewis *MA, PhD, MBChB, FRCPath*
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GIRFT Joint Clinical Leads for Pathology

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GIRFT Senior Clinical Advisor for Pathology

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NHS

Detailed recommendations: Foundation 1: Quality

Recommendation	Actions	Owners	Timescale
13. Make better use of EQA information at national level.	**a** The NPB and NEQAS to work together to establish national co-ordination and to ensure fuller use of the available information, also engaging with manufacturers to achieve greater consistency.	NPB, NEQAS	Within 2 years of publication
	b The RCPath EQA Oversight Board to: • use EQA data to ensure methodologies are of an acceptable quality, with harmonisation where possible; • set performance standards that manufacturers must meet for tests supplied to the NHS, ensuring that a manufacturer's method is fit for purpose.	RCPath EQA Oversight Board	Within 2 years of publication

Context

The Association for Clinical Biochemistry & Laboratory Medicine

Better Science, Better Testing, Better Care

UK NEQAS

International Quality Expertise

Weqas

Medicines & Healthcare products Regulatory Agency

IBMS

UKAS

LGC

QCMD

Quality Control for Molecular Diagnostics

Care Quality Commission

GenQA Genomics Quality Assessment

Member of UK NEQAS consortium

Purpose:

- To develop a robust framework for the system-wide governance and oversight of EQA

- To ensure high standards in quality management, embed patient safety into pathology, ensure excellence in pathology output and support safe, high-quality patient care across the health service.

EQA review programme

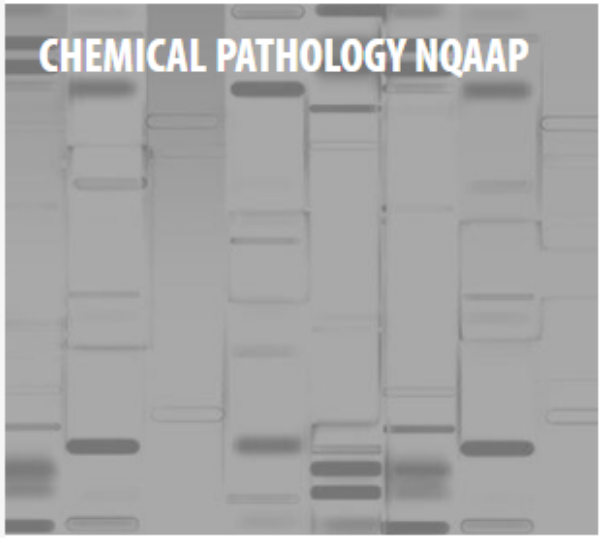
Two-year programme – achieving robust oversight and governance…

TECHNICAL EQA

A two year programme has been produced with the aim to develop a robust framework for the system wide governance and oversight of external quality assurance (EQA) to ensure high standards in quality management, embed patient safety into pathology, ensure excellence in pathology output and support safe, high quality patient care across the health service. In addition, the programme aims to produce a sustainable funding mechanism from financial contributions from the relevant EQA scheme providers, based on openness, transparency and fairness.

We will achieve this by concentrating on 4 objectives which comprise the delivery plan.

- Developing and implementing a robust multi-stakeholder governance and assurance framework incorporating new developments in systems governance, pathology service provision and External Quality Assurance.
- Agreeing and implementing a consistent approach to identifying and responding to poor performance.
- Developing systems, practices and policies to share learning relating to quality management, continuous quality improvement and assurance of pathology results with service providers, manufacturers, professional societies and oversight bodies.
- Strengthening collaboration with our external/regulatory partners across health services in the UK



Vision statement:

- A leading example of multi-stakeholder governance and assurance worldwide.
- We provide timely, relevant support that meets the needs of providers of pathology services through early interventions to prevent avoidable harm.
- We use our insights to support safe, high-quality patient care across the health service through continuous quality improvement, system-wide sharing of safety lessons and innovation.

EQA review programme

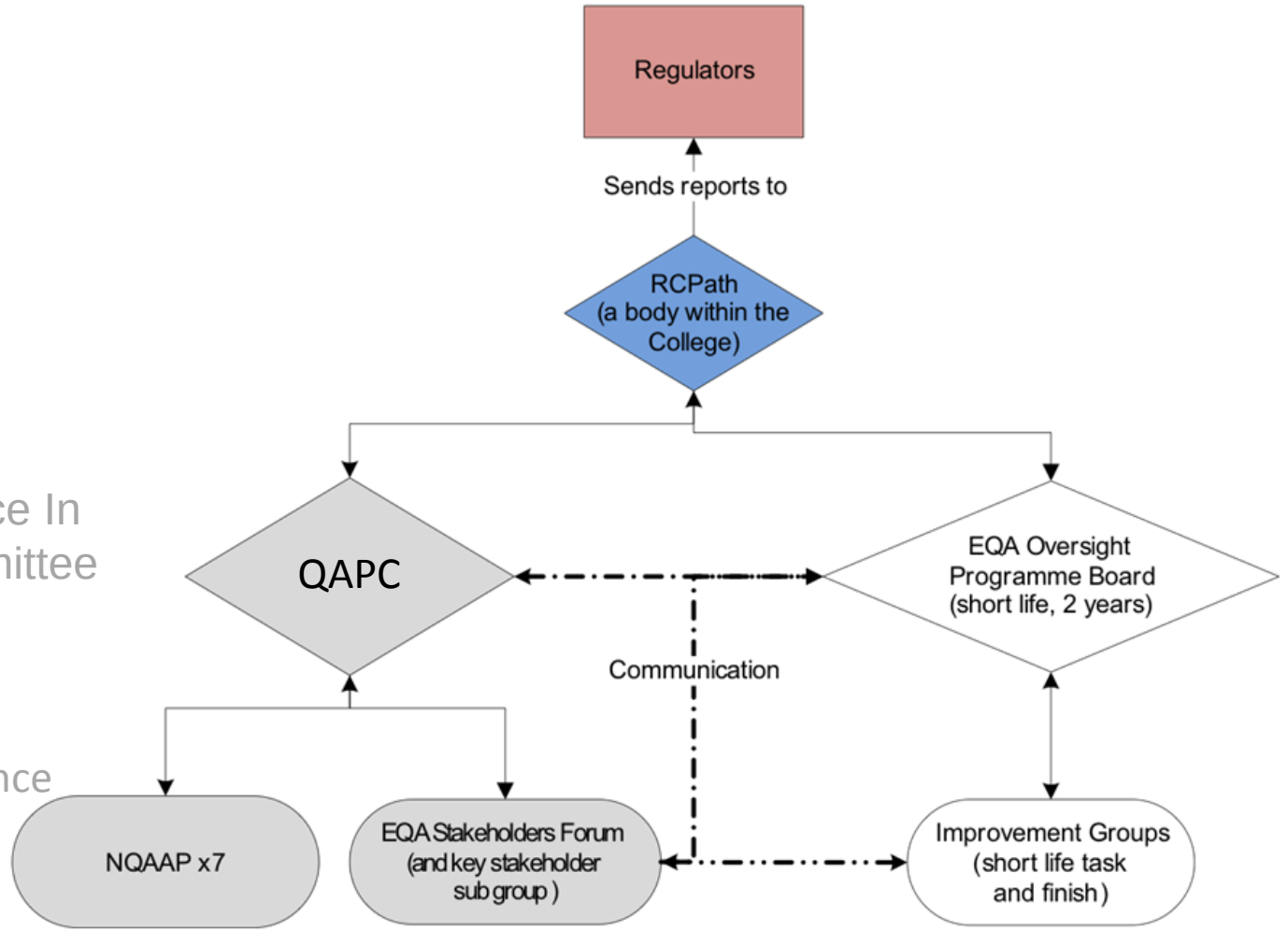
Two-year programme – achieving robust oversight and governance…

Strategic change plan

- Reporting structure
  - Oversight
  - Scrutiny
  - Improvement

Quality Assurance In Pathology Committee (QAPC)

National Quality Assurance Advisory Panel (NQAAP)

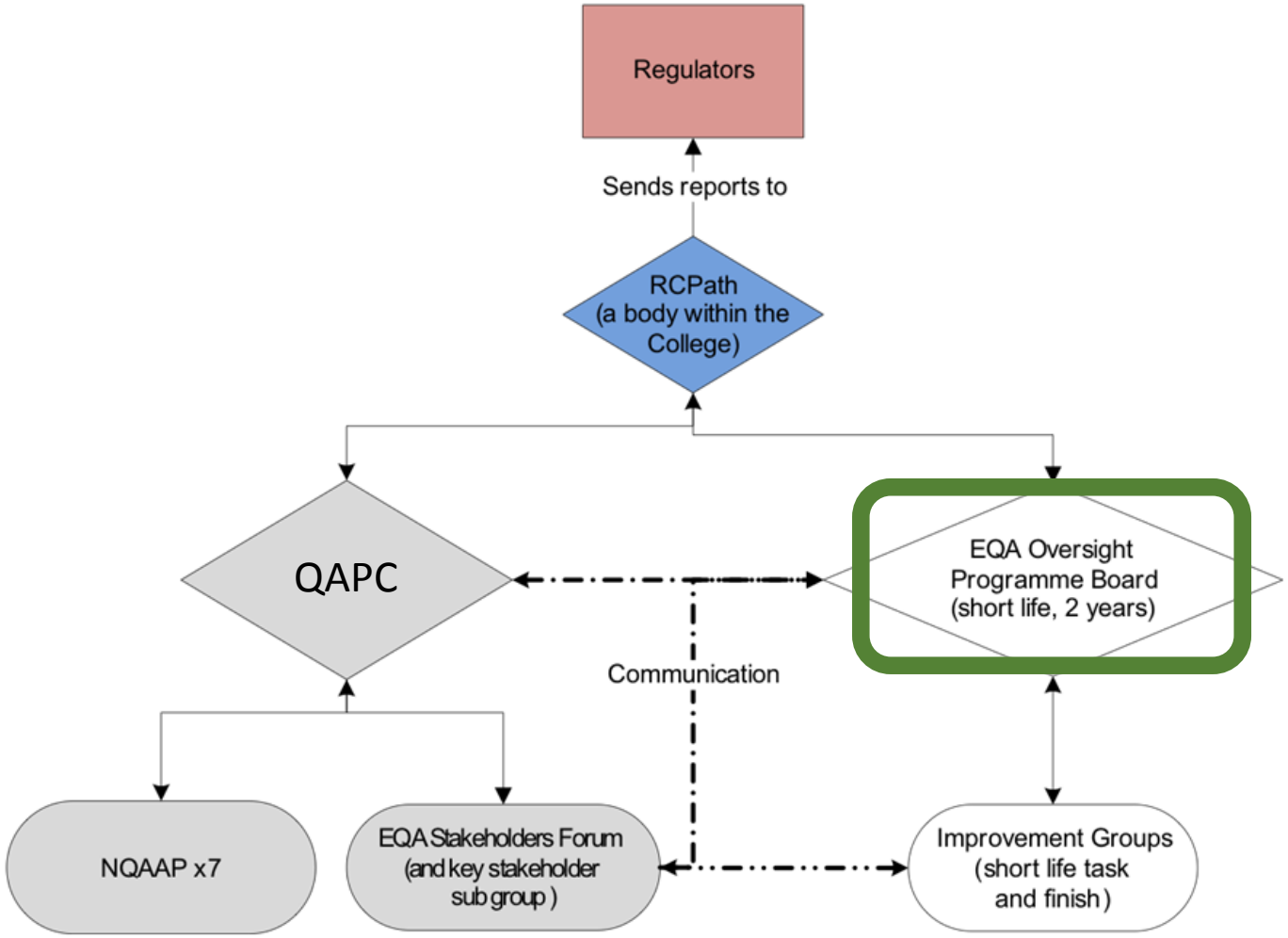


EQA review programme

Two-year programme – achieving robust oversight and governance…

Oversight

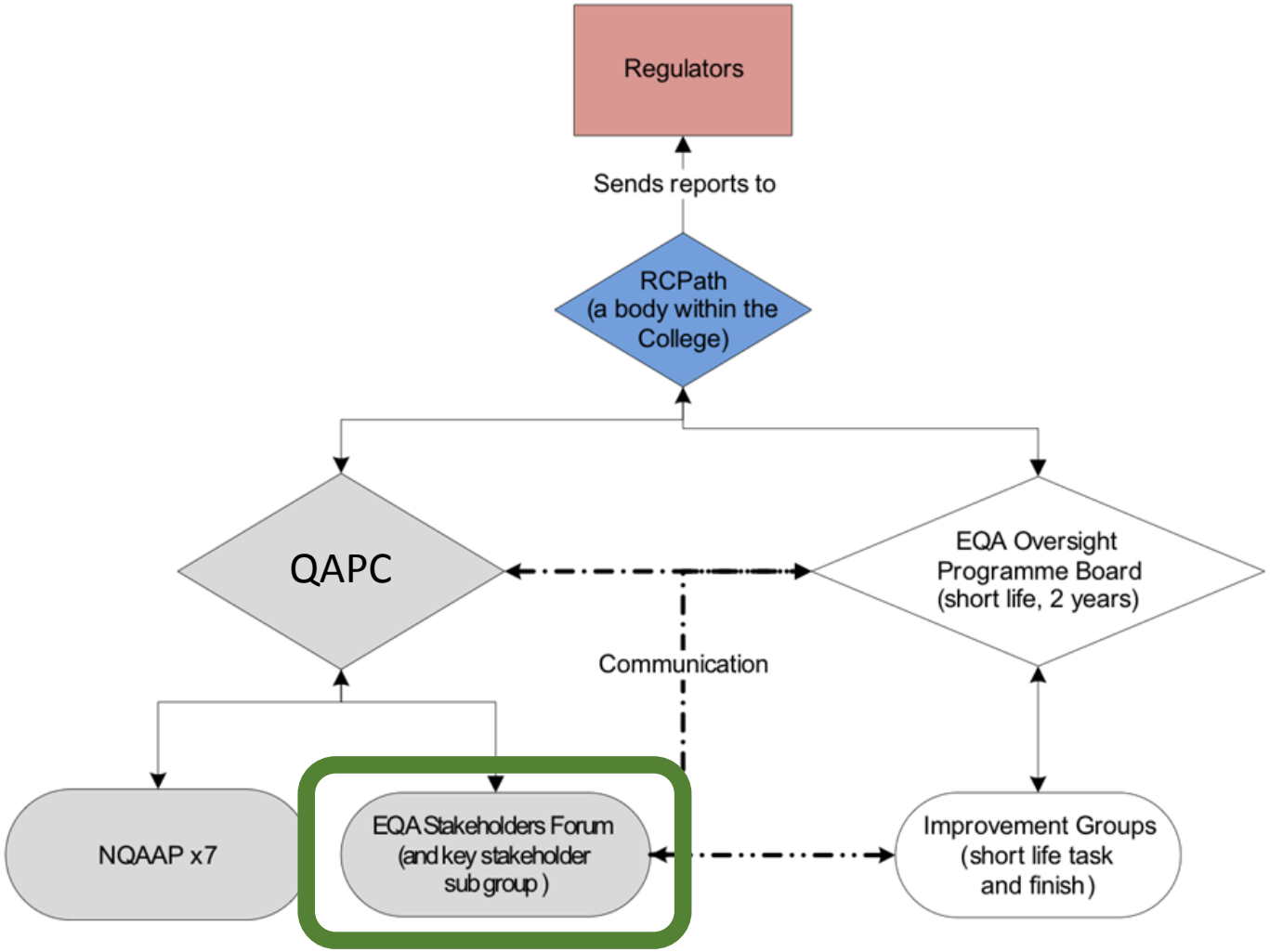
Collective oversight and assurance of progress



- Support and challenge continued QI and provide the system with a collective oversight and assurance of progress.
- Ensure sustained progression in the system governance of technical EQA
- Aware of current and emerging risks to the delivery of the quality improvement plan

Scrutiny

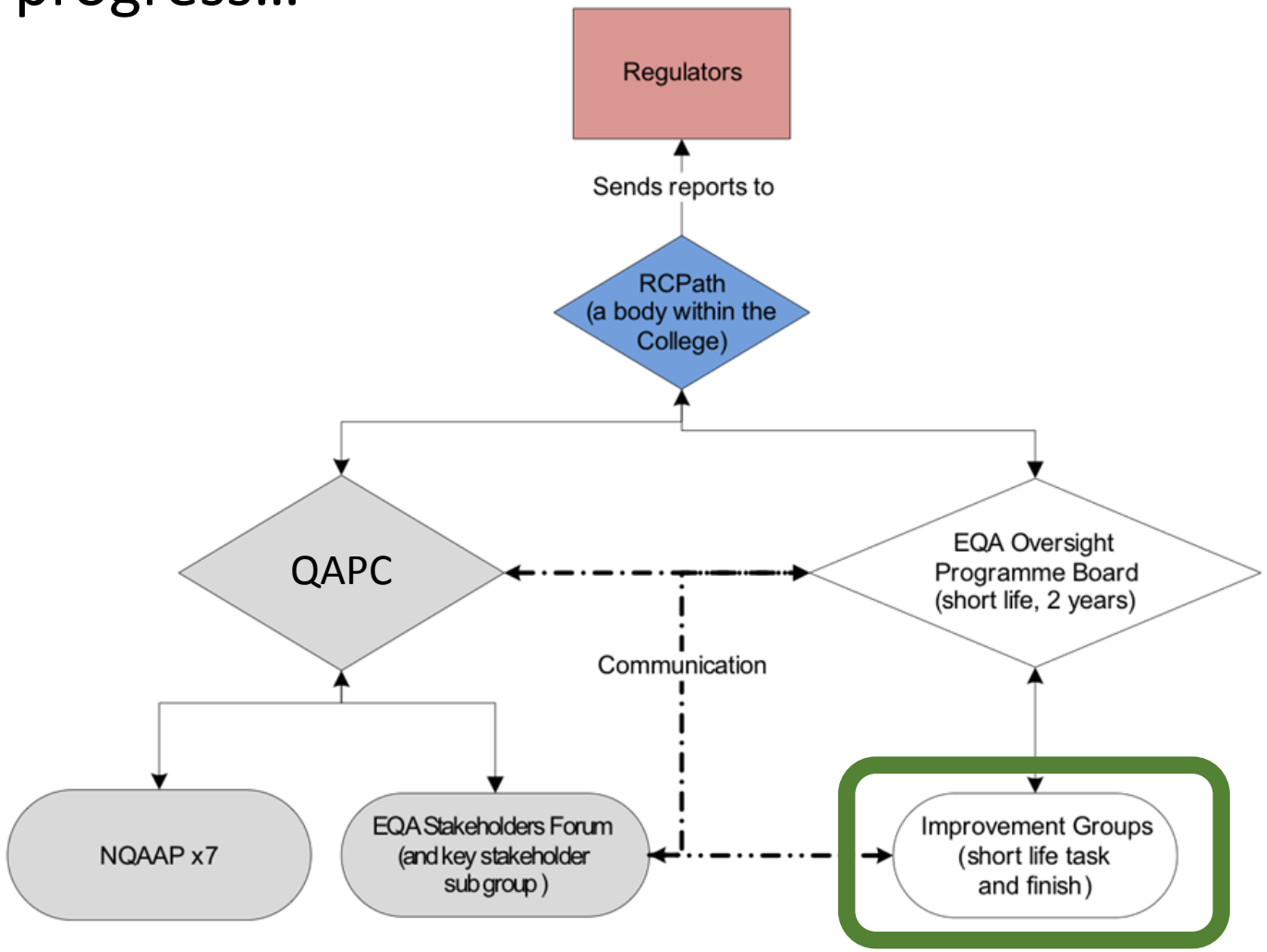
Stakeholder forum…



- To ensure that the work and priorities have **users' interests and perspectives** at the centre.

Improvement

Collective oversight and assurance of progress…



- To deliver the required work in an agreed quality improvement plan.
- The quality improvement plan defines the projects and tasks that will operationalise the agreed strategic objectives in order to allow the system to achieve its vision statement.
- Two Task & Finish group (Workstreams; WS1 & WS2) initially, based on priority, each led by a Chair.

The Royal College of Pathologists
Pathology: the science behind the cure

Strategic Objectives

Workstream 1	**Developing and implementing a governance and assurance framework**
Lead Chair	Liam Whitby (UKNEQAS)
Deputy Chair	Annette Thomas (WEQAS)
Workstream 2	**Agreeing and implementing a consistent approach to identifying and responding to poor performance**
Lead Chair	Barbara de la Salle (UKNEQAS)
Deputy Chair	Ros Hastings (GenQA)

EQA review programme

Two-year programme – achieving robust oversight and governance…

Escalation


What escalation is not


More Like Partnership

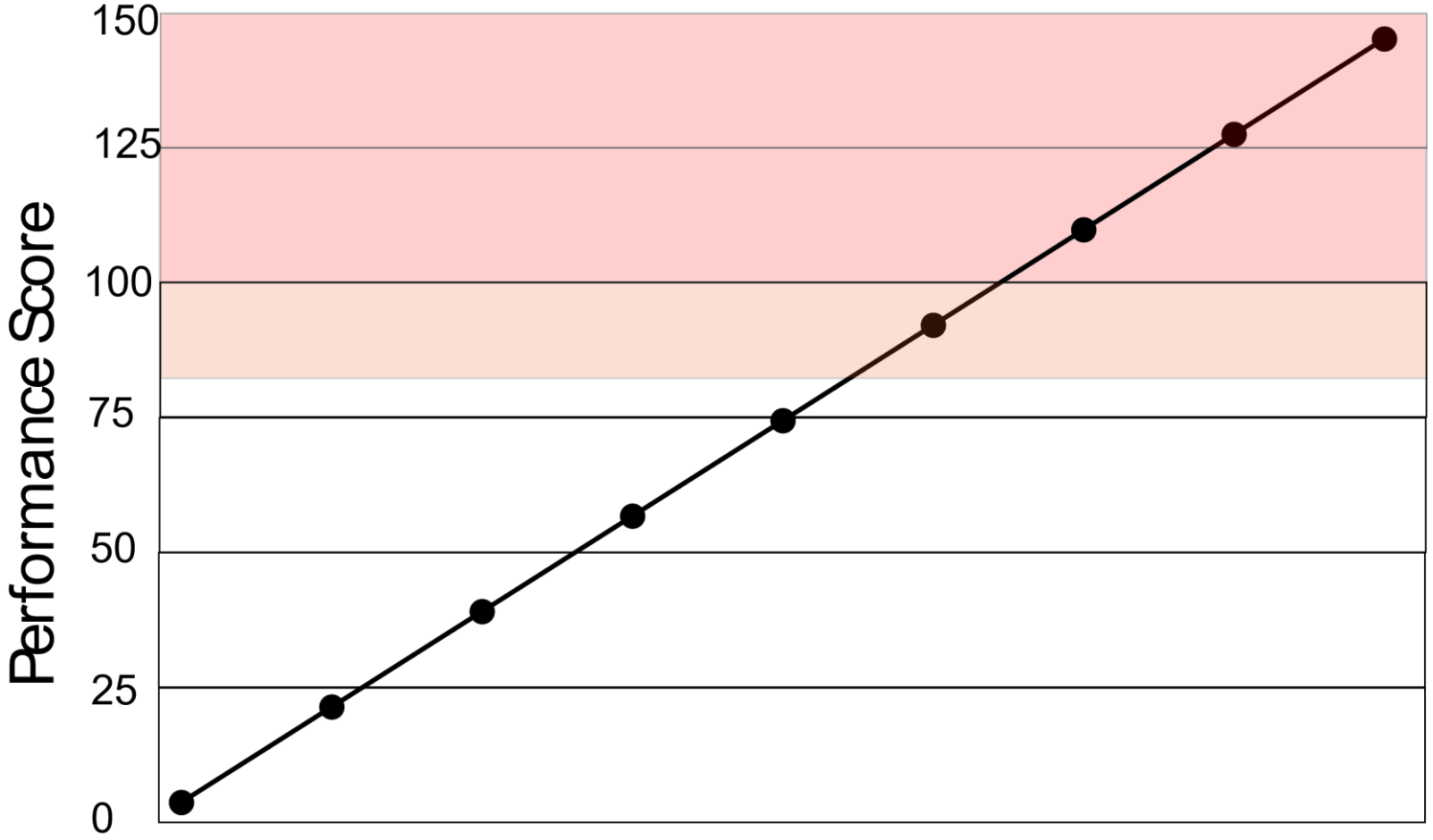
It Starts with Concerns about EQA Performance

- Poor or Unsatisfactory Performance
- Results that are consistently out of consensus with the majority of participants

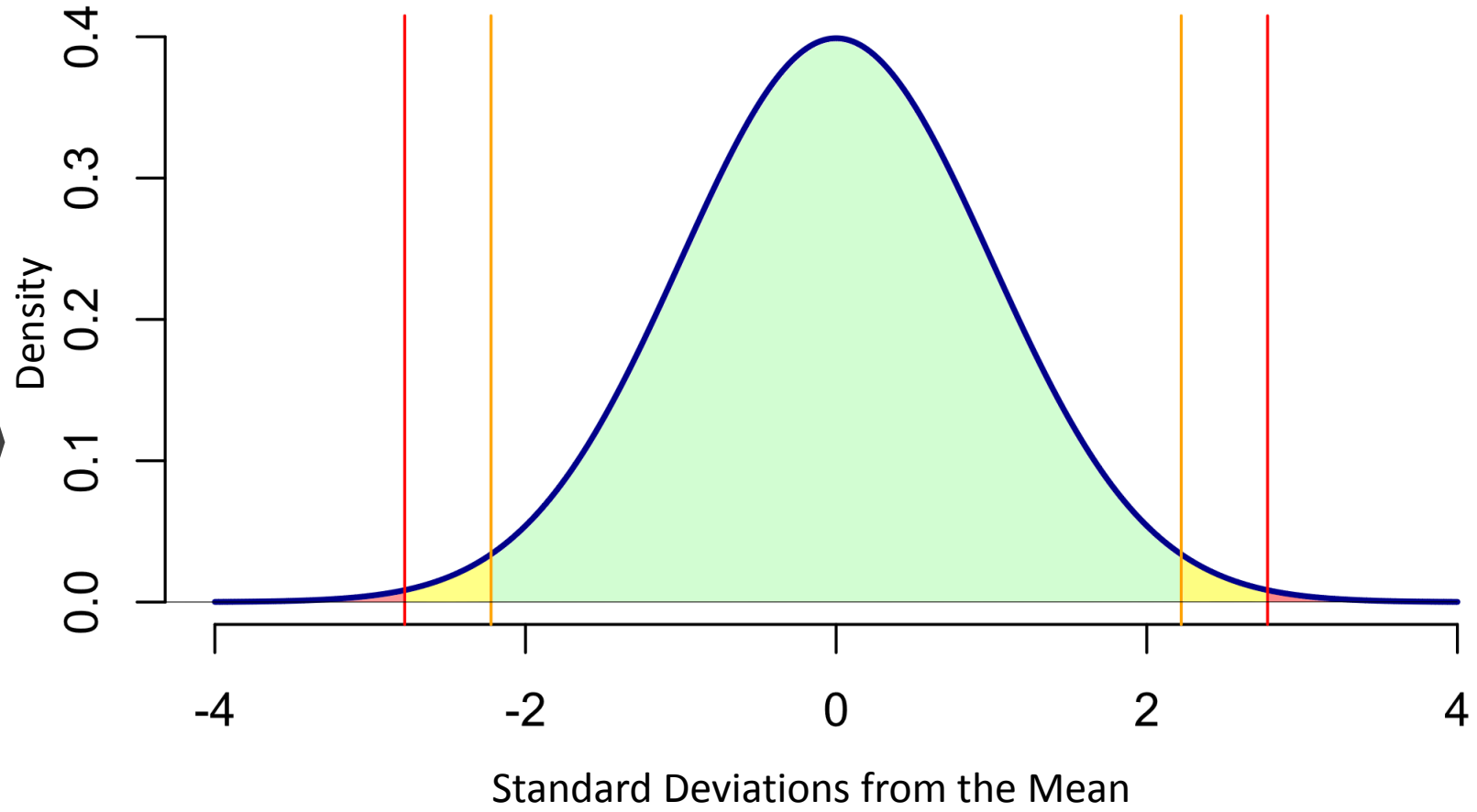
Poor Performance Score

- Performance Score of above 100 is poor.
- Assuming the common definitions of deviation index (DI) and factors. This is an average 2.78 standard deviations from the mean.
- Assuming a normal distribution of results. There is only **0.27%** probability that this will once happen by chance.
- Similarly, the probability of two in a row by chance is **0.07%**

On the Report



Poor Performance Assuming Normal Distribution of Data



Satisfactory performance in the green zone

Warning performance in yellow zone

Poor performance is in the red zone.

Poor Performance Escalation

- The scheme continually monitors all the participants for poor performance.
- Normally, if there are two consecutive poor performances.
  - The scheme director will write to the participant to alert the lab to the poor performance and discuss causes and possible patient safety concerns.
- Upon receiving the letter
  - The lab manager responsible contacts the scheme director to discuss the failure
  - The root causes investigated
  - Any possible patient safety issues are investigated fully

Outcomes of Discussion with EQA Scheme Director

- Resolved
  - If the scheme director is satisfied that there is a good reason for the poor performance and patients are not at risk.
  - If the participant's score returns to satisfactory in the subsequent distributions.
  - Then, the poor performance is reported anonymously in the end-of-year report to the NQAAP, and no further action is required.
- Unresolved – Persistent Unsatisfactory Performance (PUP)
  - If the poor performance is unresolved by the scheme director or the performance does not return to satisfactory
  - Then, the participant is escalated to the relevant National Quality Assurance Advisory Panel (NQAAP) Chair within two weeks.
  - For this escalation is the participant is identified.

Outcomes of Discussion with NQAAP Chair

- The NQAAP Chair then writes to the participant Laboratory manager.
- The NQAAP Chairs' primary concern is the safety of the patients in the care of the Laboratory.
- The first and most important question is:
  - What evidence can the laboratory provide that the poor performance identified has not affected the patients?
- If the NQAAP chair is satisfied with the laboratory evidence
  - The outcome is reviewed with the EQA provider with the aim of closing the incident.

NQAAP Chairs' Unresolved Incidents

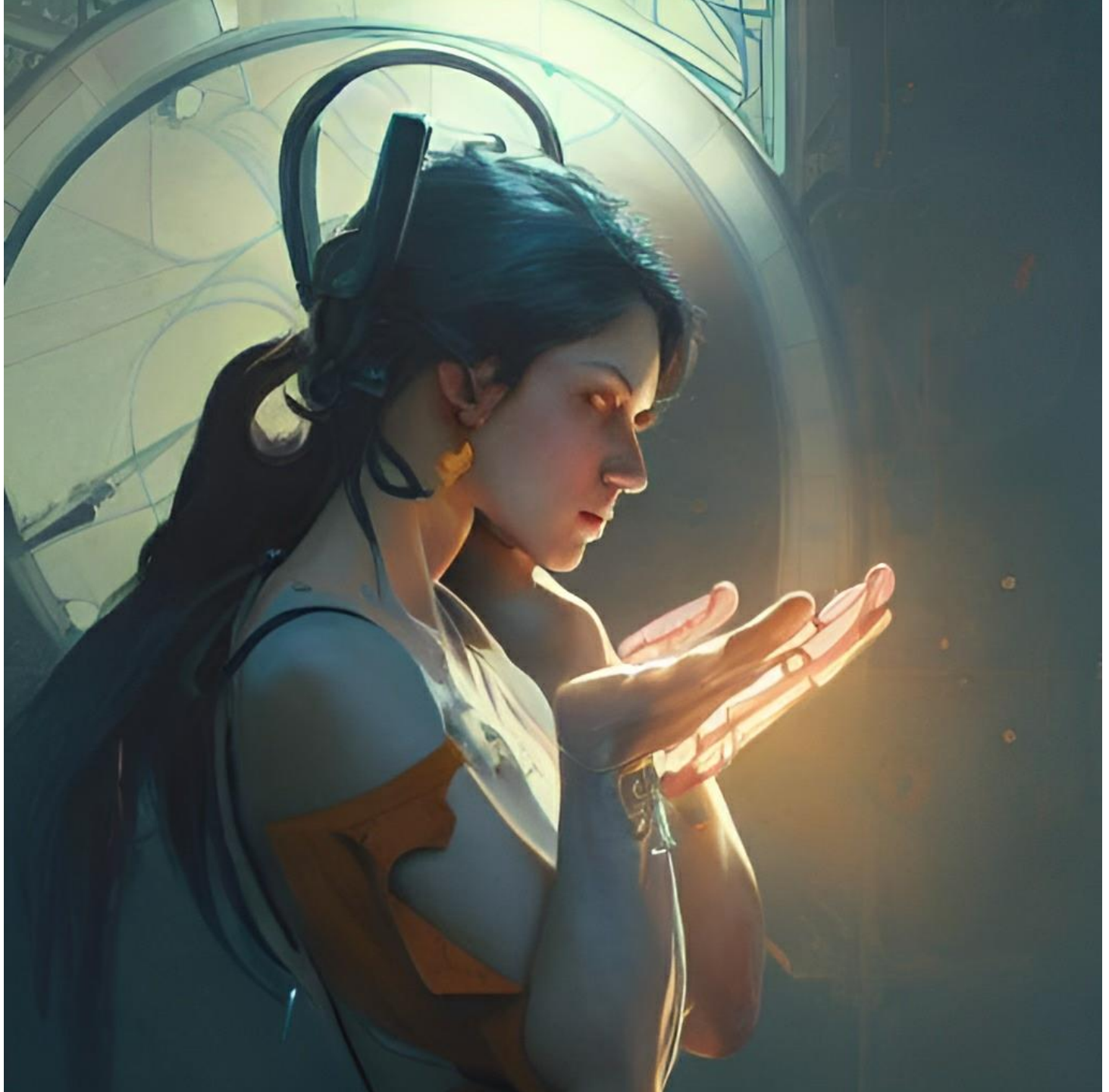
- If the NQAAP Chair is **not** satisfied with the laboratory's response.
- He or she can seek the UKAS number.
- After discussing the matter with the Quality Assurance in Pathology Committee (QAPC)
- He or she is able to refer the matter to the CQC, UKAS and MHRA.
- Learning outcomes would be shared widely.
- The process is to identify and remove the risk to patient safety.

PUP Case Study 1

- A Welsh Assessment of Serological Proficiency Scheme (WASPS) participant had a poor performance by submitting results that were out of consensus with other participants.
  - The participant recorded the results incorrectly.
- The same participant then rushed the test and did not complete the task.
- A Lab was classified as unsatisfactory performance (UP)
  - The UP letter was sent to the laboratory manager.
- The same participant was interrupted during pipetting and lost their place, so got the wrong result for the third time in a row.
  - Thus they became a PUP, and the NQAAP Chair was alerted.

PUP Case Study 1 – Consider

- What evidence can the Laboratory provide that these rushing, interruptions and typographical errors are not impacting patient safety?



PUP Case Study 1

- The Laboratory returned:
  - The participant's reflection on the incidents
  - Confirmed the participant had been given a verbal warning
  - Confirmed they would have formal disciplinary proceedings on any further incidents

Discussion

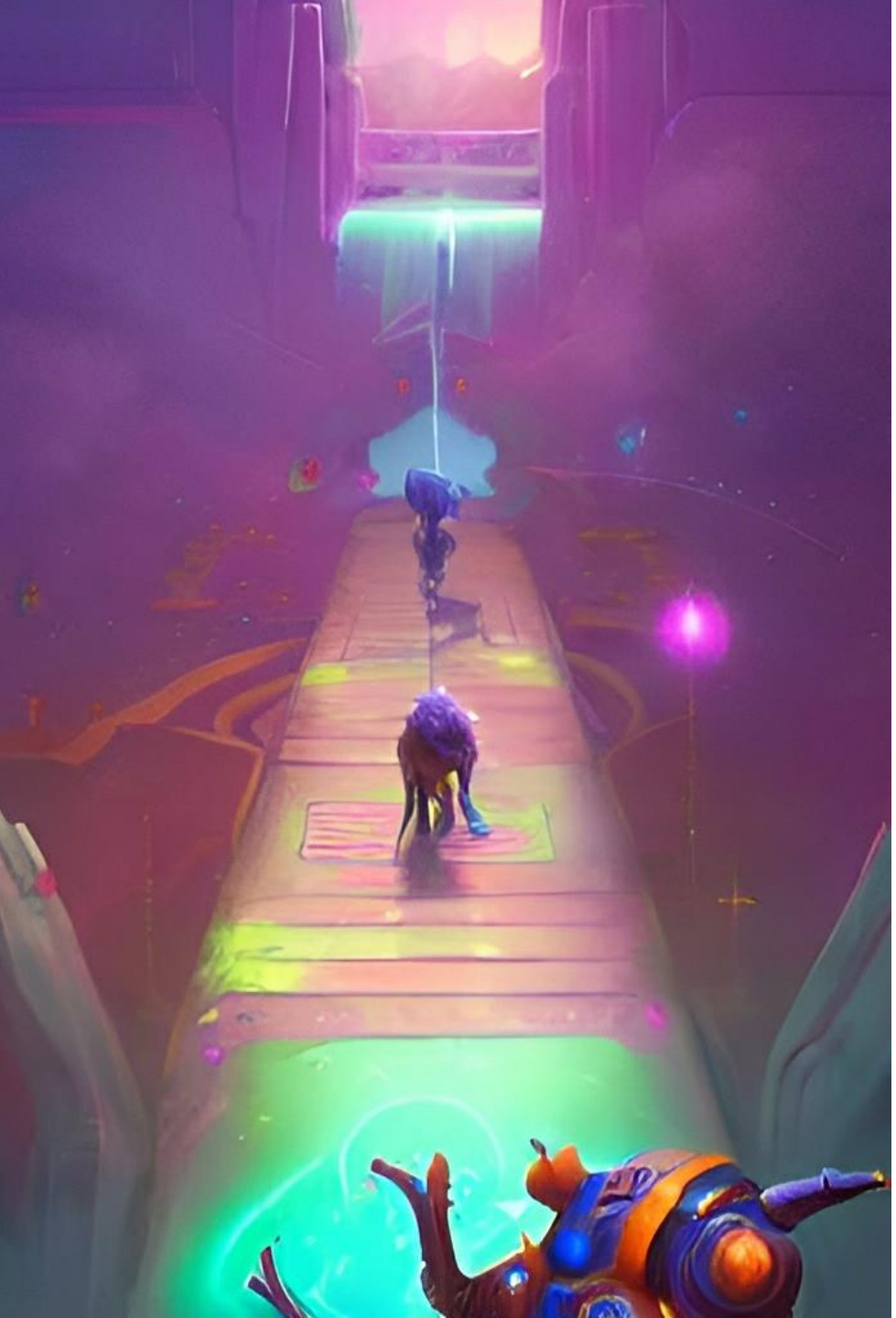
- Is it reasonable to place the whole burden of these interruptions, rushing and typographical errors on the BMS on the crossmatching bench?
- Has the laboratory **structure** been examined?
- Why are the interruptions happening?

PUP Case Study 2

- A laboratory returned two out-of-consensus results
- Then failed to return on the third distribution.
- The scheme director wrote to the lab.
- The lab investigated and discovered that SOP had not been updated after the methodological change (Hb unit harmonisation).

Lab Swift Effective Response

- The methodological error was discovered.
  - Changing the reporting unit in the automated section (Hb from g/dL to g/L) impacted the manual section (the results were ten times too small) without correction.
- The period of the error identified.
- The patients affected were identified.
- The clinicians were contacted.
- Corrected reports issued.



Discussion

- Although the lab’s response was excellent, what was the real learning outcome?
- How should that have been evidenced?

PUP Case Study 3

- CD3 was out of consensus for three samples in ten.
- The scheme director wrote to the lab.
- Conversation was held with the lab, and they stated that
  - Key staff have now returned from long-term sick
  - They are in consultation with BD regarding their systems and machine setup
  - They are reviewing and updating all SOPs in the department, as one critical was caused by selecting the incorrect data for submission (manual technique submitted rather than routine automated technique), and in this, the departmental SOP was not followed.
  - Have identified and retrained a member of staff that was not analysing samples correctly.

PUP Case 3

- Following this, the laboratory supplied dot plots for review. Issues highlighted to the lab were:
  - Incorrect volume of antibody used on 2 duplicate tests.
  - Incorrect gating of CD3.
  - Two duplicate result sets differed by 8% (maximum variation in the product sheet is 5%)
- Subsequent to this:
  - Laboratory introduced training and competency on pipette use.
  - Arranged a training day with the flow cytometer manufacturer for all staff.

Discussion

What is NQAAP primary concern?

Has this primary concern been addressed in the actions identified so far?

What actions should be taken next.

Thank you for Listening

Any Questions?