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Sponsoring Executive Director: Dr Quentin Sandifer, Executive Director Public Health Services/Medical Director
Who will present: Dr Quentin Sandifer
Date of Board / Committee meeting: 5 July 2016
Committee/Groups that have received or considered this paper:
Public Health Services Leadership & Delivery Team
Public Health Services Executive Team

The Board / Committee are asked to: (please select one only)
Approve the recommendation(s) proposed in the paper
Discuss and scrutinise the paper and provide feedback and comments X
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Link to Public Health Wales commitment and priorities for action:
(please tick which commitment(s) is/are relevant)

Priorities for action include relevant priority for action(s)
1 Introduction

This report outlines the current position of the Screening and Microbiology Division’s Laboratories against the accreditation requirements of ISO 15189. It provides the Quality & Safety Committee with assurance that planning and action to retain the accreditation is being carried out appropriately in both Divisions.

2 Background

Public Health Wales has two laboratory services requiring ISO 15189 accreditation:

- The Microbiology laboratory network, and
- Screening Division’s Magden Park laboratory,

Both services currently have CPA accreditation and CPA accreditation is based on the requirements of ISO 15189. The ISO standards are more demanding in some areas and have required a great deal of work to review and formulate plans to ensure that the laboratories are working towards compliance in readiness for the assessment, which will take place in August 2016 (microbiology) and October 2017 (screening).

3 Description

- Planning for accreditation remains on track in both Microbiology and Screening Divisions.

- Additional staff resource has been sought to deliver success in microbiology.

- Microbiology accreditation assessment will occur between 10 August and 11 October 2016. The key areas for consideration in the microbiology network are Uncertainty of Measurement, Validation and Verification, Information Technology and Contracts and Service level Agreements and third party IT software.

- The Screening Division laboratory accreditation assessment will take place in 2017. The main areas for consideration will be on training and competency assessments, evaluation and management of equipment and consumables, and working with other areas of the screening programmes such as the Cervical Screening Admin Department/ Central Admin Department of Bowel Screening Wales to ensure post-examination processes performed in these areas also meet the requirements of ISO 15189.
4 Recommendation(s)

Quality & Safety Committee are asked to note the work undertaken throughout Public Health Services in preparedness for ISO 15189 Accreditation. The Executive Director has given assurances to the laboratory staff that work towards ISO accreditation will be recognised as a priority for the Directorate in the coming months.
1. Microbiology Laboratories: Due Summer 2016

Background

In recent years the laboratories have been assessed by Clinical Pathology Accreditation (UK) Ltd as a network. Accreditation was awarded in 2008 and maintained through subsequent assessments. CPA (UK) Ltd has joined with the United Kingdom Accreditation Service (UKAS) and now assesses to ISO 15189:2012 standards.

These standards are more stringent in some areas and have required a great deal of work to review and formulate a plan to ensure that the laboratories are working towards compliance in readiness for the assessment.

A Gap Analysis was undertaken at the start of the process and is used to review progress made in each laboratory and by the network quality manager. Progress is slow, but the regular network meetings undertaken ensure that ISO 15189 is considered at all local laboratory meetings where relevant.

Microbiology Quality Network

The microbiology network quality group has always been very strong with attendance and input from quality leads in all areas of the division. This includes operational, health and safety and quality. The group is also there for guidance, and learning from peers has been essential in supporting staff in readiness for the assessment. Meetings of the network quality group are held monthly and a fortnightly teleconference specifically for issues regarding ISO 15189 is also held and open to all members of staff wish to attend.

The network has also been able to work to a “do once and share” ethos which has helped reduce the workload when reviewing SOPs and undertaking retrospective verification work as required by the new standards.

Current Status

- Standard operating procedures are being reviewed and updated to ensure compliance with ISO 15189 standards
- All equipment, kits and standard operating procedures are being verified to provide assurance that they are fit for purpose. More evidence is needed to prove this, including uncertainty of measurement and traceability of calibration.
• Standardisation of competency assessments and training across all bands needs to be undertaken.
• Audit procedures have recently been rewritten to comply with the new standards and a new timetable has been issued. Laboratory staff are finding difficulty in ensuring that the audits are performed and reviewed and also that remedial, corrective and preventative actions are actions undertaken and signed off in a timely manner.
• Fortnightly teleconferences for ISO 15189 issues continue as well as monthly quality meetings. The quality manager is about to start weekly visits to UHW and Swansea and fortnightly visits to Aberystwyth and Carmarthen as well as a few days a month in North Wales to provide support to the local quality leads, managers and other staff involved in readiness for the assessments.

**Concerns**

ISO 15189 is more stringent in some new areas and standards which must be complied with. These include Uncertainty of Measurement, Validation and Verification, Information Technology and Contracts and Service level Agreements and third party IT software. There are also changes to the emphasis on previous standards which has meant that all of our protocols and procedures are currently being reviewed. For example, all equipment and procedures undertaken have to be verified retrospectively if not done at the time of installation.

Compliance with the requirement for uncertainty of measurement and traceability of calibration and control organisms has meant an increase in the cost of servicing for items like pipettes, and soon, centrifuges. There is also a cost implication in ensuring that the organisms that we use for control organisms can be traced back to an accredited source (e.g. NCTC). External Quality Assurance Schemes have been sourced to ensure that, wherever possible, all procedures are assessed by an EQA scheme.

There is a huge time cost for staff to review documentation and follow the SOP for performing retrospective verification. This is on top of current staffing concerns and other issues e.g. implementation of new equipment for the managed service contract, tender for plated media, bottled media and antibiotic discs etc. Wherever possible all work has been shared with the local quality leads.

A request has been made for a part time temporary auditor for the network. This will ensure that the laboratories which are currently under pressure with verifying new methods, kits, equipment and reagents can have support by ensuring that audits in that department are undertaken and reviewed. This has been an issue in most of the laboratories.

The training lead post is about to go out to advert, but in the meantime there is an issue with ensuring that the competencies are reviewed for
compliance with the new standards and rolled out to all laboratories for staff to be assessed. The staff who are currently trying to help with this are all operational leads who have very little time to spare.

In bacteriology, work is needed to take place to verify the media as part of the media tender process. The tender has been delayed for a few months but the information will be very useful as evidence for verifying the media once the tender has been awarded. Staff in serology in Swansea and UHW are working together to verify the new DS2 machines.

**Dates of the Assessment**

Although one of the assessors has asked to undertake assessment of a particular machine in Singleton Hospital, Swansea on August 10\textsuperscript{th} 2016, the opening meeting and start of the main assessment will take place on 15\textsuperscript{th} August 2016. The assessment closing meeting will take place on October 11\textsuperscript{th} 2016 in UHW, Cardiff.

We are expecting to pick up a number of non compliances across the network, but all are likely to be actioned and signed off within the allowed 12 weeks.

**2. Screening laboratory: Due 2017**

**Background**

- The Laboratory currently has CPA accreditation and the CPA standards are based upon those of ISO 15189. However, there are significant differences, which will require the Laboratory to implement appropriate actions before the accreditation visit due in 2017. The main areas of impact will be upon training and competency assessments, evaluation and management of equipment and consumables, and working with other areas of the screening programmes such as CSAD/CAD to ensure post-examination processes performed in these areas also meet the requirements of ISO 15189. Listed below are some of the major areas of the ISO standard, and the Laboratory’s current position against these.

**Management requirements**

**Organisation and management responsibility**

- These requirements are mostly covered by current Laboratory structures. The main non conformities are found in 4.1.2.4 Quality objectives and planning, where these requirements have been satisfied, but are not well-defined or documented. Also, the Quality Policy (4.1.2.3 Quality policy) is due for review.
Quality management system

- The Laboratory is undergoing a major redesign of its Quality Management System in order to satisfy the requirements of ISO. The new QMS is based upon the Qpulse system, with local adaptations to ensure it meets the needs of the service. This project is around 75% complete. The Quality Manual is due for review and will be updated following completion of the new QMS (4.2.2.2 Quality manual).

Document control

- In line with the redevelopment of the QMS, document control has also been improved and now meets the requirements of this standard. All previous versions of documents are being updated to a new ISO compliant format as they meet their review date, and all new documents are ISO compliant.

Service agreements

- Service agreements are in place where appropriate, but the Laboratory must ensure these show evidence of review and compliance.

Examination by referral laboratories

- The question has been raised whether screening laboratories that are not part of Public Health Wales must also be ISO 15189 accredited if they are to be part of a hub and spoke arrangement. This has yet to be resolved.

External services and supplies

- Current mechanisms for procurement, acceptance and verification are fit for purpose but are likely to require review and improvement to satisfy the more stringent requirements of ISO.

Identification and control of non-conformities

- The Laboratory is developing a comprehensive system for the identification and control of non-conformities, based upon configured modules within the Qpulse system. This enables recording and analysis based on laboratory areas, processes, personnel or accreditation standard.

Corrective action

- Corrective actions are recorded and assigned to specific members of staff. These are evidence based actions and reviewed on a regular basis.
Preventive action

- Preventive actions are also recorded and assigned to specific members of staff. These are evidence based actions and reviewed on a regular basis.

Continual improvement

- Continual improvement is achieved through regular scheduled audits that are used to pick up non conformities, clinical and process audits, training audits and reviews, as well as actions recorded against stakeholder inputs.

Technical requirements

Personnel

- The Laboratory operates to personnel management policies and guidelines of Public Health Wales. These are documented within the Laboratory. The Laboratory will need to update its training structures (5.1.5 Training) and competency assessments (5.1.6 Competence assessment) to meet the more demanding requirements of ISO. Reviews (5.1.7 Reviews of staff performance) are overdue but planned for the near future ('My Contribution').

Accommodation and environmental conditions

- The Laboratory benefits from modern and spacious accommodation that should meet the requirements of ISO. Environmental control measures are in place, and are documented and reviewed.

Laboratory equipment, reagents and consumables

- The control and documentation of equipment is one of the areas of greatest change between CPA and ISO. The Laboratory needs to update its equipment records and procedures to comply with ISO. Work on this has begun, but is at an early stage. Some calibration and traceability work has begun (5.3.1.4 Equipment calibration and metrological traceability); this is dependent on the ability of suppliers and manufacturers to work with the Laboratory towards ISO standards of equipment maintenance and repair. Equipment incident reporting is being redeveloped in line with the audit and control of non conformities sections of the Laboratory QMS (based on modules within the Qpulse system that have been developed specifically to enable the Laboratory to meet these needs). All parts of 5.3.2 Reagents and consumables are currently requiring updating of the Laboratory’s processes to meet this standard. This work has begun, particularly with regards to acceptance testing, inventory control and storage, where new systems are beginning to be rolled out.
Pre-examination processes
- Parts 5.4.1 to 5.4.4.3 of this standard are covered by the activities of the Bowel and Cervical Screening Programmes. The Laboratory has limited input, so it may be of benefit for the Laboratory to become more involved in these parts of the Programmes’ activities in order to demonstrate compliance with these standards. From the information available, the Laboratory is satisfied we currently meet these requirements. Sample transportation (5.4.5 Sample transportation) is documented and audited (although not on a regular basis) and meets the requirements of ISO. The Laboratory also meets the standards set out for 5.4.6 Sample reception and 5.4.7 Pre-examination handling, preparation and storage of specimens.

Examination processes
- Many parts of this requirement are currently met by the Laboratory, but the main areas of non-conformity are 5.5.1.2 Verification of examination procedures, where these processes are under development and have been trialed on some new equipment. The need to meet 5.5.1.4 Measurement uncertainty of measured quantity values is one the main challenges of ISO accreditation and the Laboratory is working on including this within all relevant clinical processes. The documentation of examination processes is currently transitioning to the requirements of ISO, and the Laboratory is satisfied this will be completed before accreditation is due.

Ensuring quality of examination results
- The Laboratory meets the requirement of this standard through a combination of documented quality control steps, quality assurance records and participation in accredited External Quality Assurance Schemes. Quality control material is used throughout all examination processes. The Laboratory does not participate in any interlaboratory comparisons.

Post-examination processes
- The requirements of this standard will mean the Laboratory needs to work closely with associated programme administration departments. They are part of the process of issuing a report, and are likely to need to conform to the ISO standards. The impact of this has not yet been assessed.