UKAS, ISO 15189 and Bioinformatics

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Objectives of session

- UKAS – Who we are/what we do
- Bioinformatics and requirements of ISO 15189

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UKAS – what we do

- Accreditation – the recognition of competence of organisations to perform specific tasks
- UKAS assesses for compliance against criteria of competence (international standards)
- UKAS must comply with ISO 17011

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UKAS – who we are

- Established in 1995 by Ministers as a private company limited by guarantee
- UKAS appointed as sole national accreditation body by The Accreditation Regulations 2009
- EU Regulation 765/2008 provides legal framework for accreditation

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Impact on laboratories

- Pathology laboratories complying with ISO 15189, Point of care testing complying with ISO 22870
- Withdrawal of CPA Lab/POCT Standards March 2018
- EQA Schemes complying with ISO 17043 (CPA EQA Standards withdrawn March 2016)

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Where are we in the Transition?

- Laboratories undergoing transition to ISO 15189
  - Over 500 visits completed
  - Almost 50 accredited (first grants of accreditation September 2014)
  - 10% are Genetics laboratories
  - Approximately 20 visits per month for the rest of 2017 to complete the Transition

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So how does that affect you?!

- **Bioinformatics processes need to comply with ISO 15189**
- **There will be a Bioinformatics assessor on your assessment team!**

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5.5 Examination process

- **5.5.3: Documentation of examination procedures**

a) purpose of the examination;

b) principle and method of the procedure used for examinations;

c) performance characteristics (see 5.5.1.2 and 5.5.1.3);

g) required equipment (including software)

j) procedural steps;

k) quality control procedures;

m) principle of procedure for calculating results

s) potential sources of variation

4.3 Document control

- Approved by authorized personnel before issue
- Date of the current edition and/or edition number
- Current authorized edition need to be identified, and obsolete versions unavailable
- Changes must be identified
- Periodically review/update to ensure fitness for purpose

4.3 Document control

- **5.5.3: Documentation of examination procedures**
- **Documents that should be considered for document control are those that may vary based on changes in versions or time. Examples include policy statements, instructions for use, flow charts, procedures, specifications, forms, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software documentation, drawings, plans, agreements, and documents of external origin such as regulations, standards and text books from which examination procedures are taken.**

4.3 Document control

- ‘Bioinformaticians love documenting things in the code itself, in log files or in a code repository in a README file. This is fine but there MUST be a managed document that points to where this info can be found and how to read it, so that somebody who has never seen the code before can find out what it is doing (and what programs the pipeline is running)’

5.5.1 Verification and validation

- **Off the shelf software:**

- **Validated by method developer as relevant to intended use** - *confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled*
- **Verified by the laboratory to confirm performance claims met** - *confirmation, through provision of objective evidence, that specified requirements have been fulfilled*

5.5.1 Verification and validation

- **Software developed in-house or off the shelf software used outside of its intended scope:**

- **Validated by the laboratory as relevant to intended use**
- *The validation shall be as extensive as is necessary and confirm, through the provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use of the examination have been fulfilled*

5.3.1.4 Metrological traceability

- ***The laboratory shall have a documented procedure for the calibration of equipment that directly or indirectly affects examination results***

- **Metrological traceability shall be to a reference material or reference procedure of the higher metrological order available**

- **E.g. Genome in a bottle reference materials**

5.5.1.4 Measurement uncertainty of measured quantity values

- ***The laboratory shall determine measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples***
- ***Where examinations include a measurement step but do not report a measured quantity value, the laboratory should calculate the uncertainty of the measurement step where it has utility in assessing the reliability of the examination procedure or has influence on the reported result.***

5.5.1.4 Measurement uncertainty of measured quantity values

- **‘the lab had determined the capability of the system to detect mosaicism and have determined the measurement of uncertainty associated with normal, duplicated and deleted exons’**

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5.6 Ensuring quality of results

- **5.6.2 Quality control**
- ***The laboratory shall design quality control procedures that verify the attainment of the intended quality of results***
- **E.g. assessing the quality of the raw sequence (fastq) files and quality of the output from the bioinformatics pipeline**
- **Need to document/apply critical decision values for deciding if a run/sample/variant has passed quality control and can hence be reported**

5.6 Ensuring quality of results

- **5.6.3 Interlaboratory comparisons/EQA**

- **Pilot NEQAS NGS scheme for germline analyses**
- **Equivalent pilot scheme being set up for somatic work in Sheffield**
- **Where a suitable scheme doesn't exist, 5.6.3.2 Alternative approaches**

5.3.1 Equipment

- ***NOTE 1 For the purposes of this International Standard, laboratory equipment includes hardware and software, and laboratory information systems***

- **5.3.1.1 The laboratory shall have a documented procedure for the selection, purchasing and management of equipment**
- 5.3.1.2 Equipment acceptance testing
- 5.3.1.3 Equipment instructions for use
- 5.3.1.5 Equipment maintenance and repair

5.10 Laboratory information management

- Defined authorities and responsibilities of all personnel who use the systems
- Systems should be validated & verified before use and following any changes
- Protected from unauthorized access and in compliance with national or international requirements regarding data protection

5.10 Laboratory information management

- Safeguarded against tampering or loss
- Operated in an environment that complies with supplier specifications
- Maintained in a manner that ensures the integrity of the data and information
- Recording of system failures and the appropriate immediate and corrective actions

5.10 Laboratory information management

- **Documented contingency plans to maintain services in the event of failure or downtime in information systems that affects the laboratory's ability to provide service**

- **When the information system(s) are managed and maintained off-site or subcontracted to an alternative provider, laboratory management shall be responsible for ensuring that the provider or operator of the system complies with all applicable requirements of this International Standard**

5.1.5 Training

- **5.1.5 Training; the laboratory shall provide training for all personnel which includes the following areas:**

b) assigned work processes and procedures
c) laboratory information systems
f) confidentiality of patient information

5.1.6 Competence assessment

- **Following appropriate training, the laboratory shall assess the competence of each person to perform assigned managerial or technical tasks according to *established criteria*.**
- **ISO 15189 5.1.6 gives list of approaches for competency assessment e.g.**

b) direct observation

c) monitoring the recording and reporting of examination results

d) review of work records

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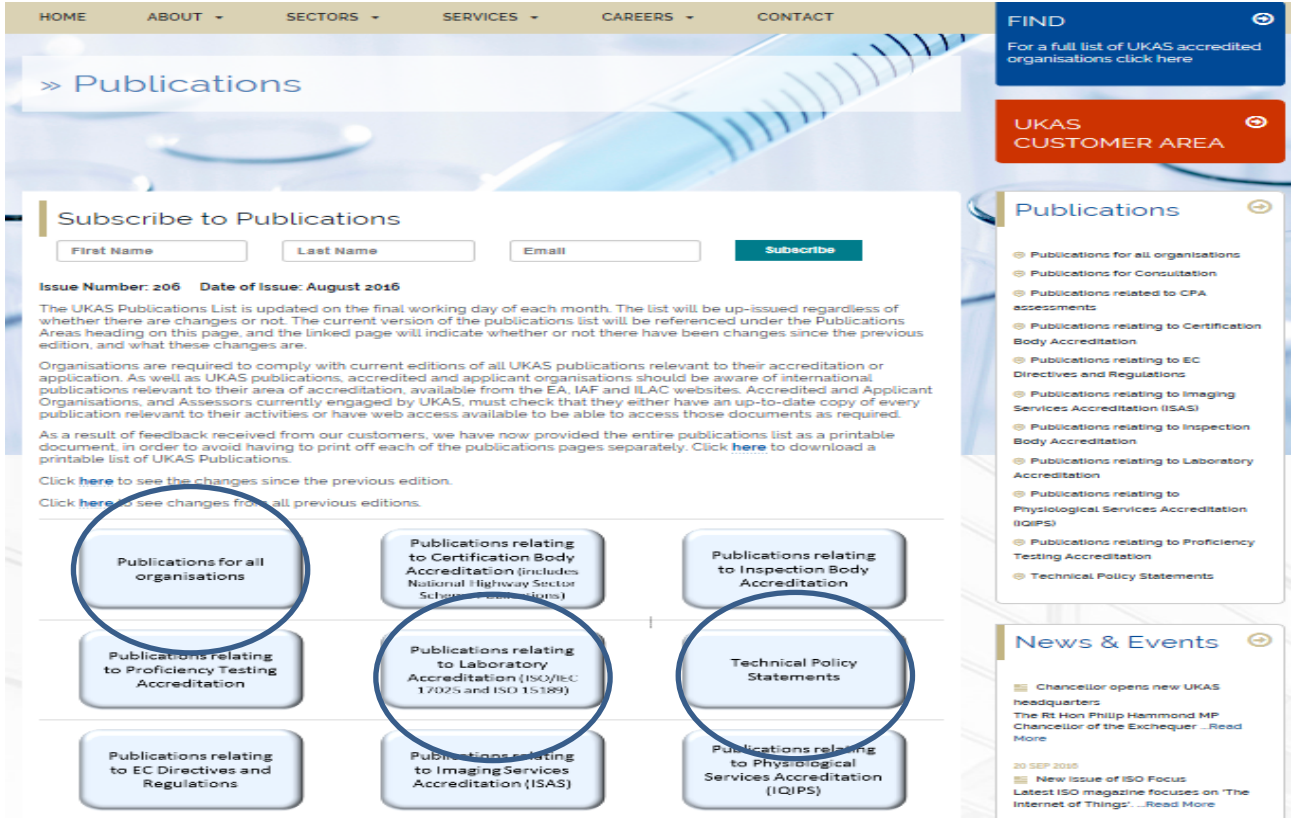
Other considerations

- **4.14.5 Internal audit**
- **4.13 Control of records**
- **4.1.2.6 Communication**

UKAS guidance documents



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Conclusions

- You need to address the challenge - consider how Bioinformatics processes fit into ISO15189, and how you comply with requirements
- Treat bioinformatics as an examination process in its own right i.e. needs the same level of documentation, validation, competencies etc. as the rest of the lab

Questions…?

UKAS and Accreditation for POCT

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