

QM-2 V1

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ISO/IEC 17025:2017 Quality Manual

Document History

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1. Log of updates

Version	Date	Page(s) changed	Description of update
1		-	New document

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3. Outline of University of Aberdeen (UoA)

The University of Aberdeen was founded in 1495 and is Scotland's third oldest, and the UK's fifth oldest, university. In 1497 it was the first university in the English speaking world to create a chair of medicine.

The University of Aberdeen, which currently has 15,000 students, has invested heavily in medical research in Aberdeen. Located on the Foresterhill Health Campus are the Institute of Medical Science, The Health Sciences Building, Suttie Centre for Teaching and Learning in Healthcare and The Rowett Institute of Nutrition and Health. The testing activity included on the ISO/IEC 17025:2017 scope of accreditation shall be conducted exclusively in the Institute of Medical Science (qPCR Laboratory 4.55).

This document sets out the Quality Management System for all activities associated with testing activity planned to be included on the scope of accreditation and shall apply during the period in which University of Aberdeen is working towards gaining accreditation to ISO/IEC 17025:2017 with the United Kingdom Accreditation service (UKAS). It is planned that this shall be in place during 2021 and shall include rapid detection of COVID-19 from saliva samples by Multiplex qRT-PCR kit.

4. Glossary of Terms

CAPA/CCAPA	Corrective Action and Preventive Action/Correction and CAPA
GDPR	General Data Protection Regulation
GLP	Good Laboratory Practice
HSE	Health and Safety Executive
IEC	International Electrotechnical Commission
IMS	Institute of Medical Science
ISO	International Organization for Standardization
MHRA	Medicines and Healthcare products Regulatory Agency
MU	Measurement Uncertainty
NHSG	NHS Grampian
PCR	Polymerase Chain Reaction
QA	Quality Assurance
QAM	Quality Assurance Manager
QC	Quality Control
QMS	Quality Management System
QP	Qualified Person
qRT-PCR	quantitative Real-time Polymerase Chain Reaction
SOP	Standard Operating Procedure
UKAS	United Kingdom Accreditation Service
UoA	University of Aberdeen

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5. Quality Management System

General

University of Aberdeen (UoA) have defined the quality framework for activities within UoA. A Quality Manual (QM), Quality Statement and Standard Operating Procedures (SOPs) are in place; together these form the Quality Management System (QMS). This covers planning, operation and effective controls within testing activities carried out in UoA Institute of Medical Science (IMS). Records shall be maintained by staff to show evidence of compliance with the QMS and ISO/IEC 17025:2017.

A separate QMS exists for the purposes of GCP compliant activity conducted jointly by the University of Aberdeen and NHS-Grampian (NHSG). Some template documents shall be shared between both Quality Management Systems, however the joint QMS is regulated by the Medicine and Healthcare products Regulatory Agency (MHRA) against the Principles of Good Clinical Practice (GCP). Both Quality Management Systems are managed by the joint UoA – NHSG Quality Assurance Manager (QAM).

5.1 Quality Manual

This Quality Manual is the statement by UoA of its documented Quality Management System which conforms with ISO/IEC 17025:2017.

Conformance with the requirements stated in the Quality Manual and in the UoA IMS Standard Operating Procedures is required for all UoA staff engaged in testing activity included in the scope of accreditation. Where improved methods or procedures are identified, the documentation so affected shall be officially and properly changed, when agreement has been reached between all Groups/Teams involved. See SOP-IMS-28 (Management of SOPs).

This Quality Manual is a controlled document and is updated as required by the Quality Assurance Manager (QAM) and reviewed at least every three years.

All staff shall be able to view the Quality Manual on the Clinical Research Governance & Quality Assurance website (www.abdn.ac.uk/clinicalresearchgovernance) and, where accessible, Q-Pulse*. Only the current version shall be displayed. Printed copies shall be regarded as uncontrolled when printed and care should be taken to ensure that an out of date version is not being referred to.

*NHS Grampian Research and Development Q-Pulse system.

5.2 The Scope of the Quality Management System

5.2.1 This Quality Manual applies to all UoA staff participating in testing activity, or in support of such testing activity, included in the scope of testing.

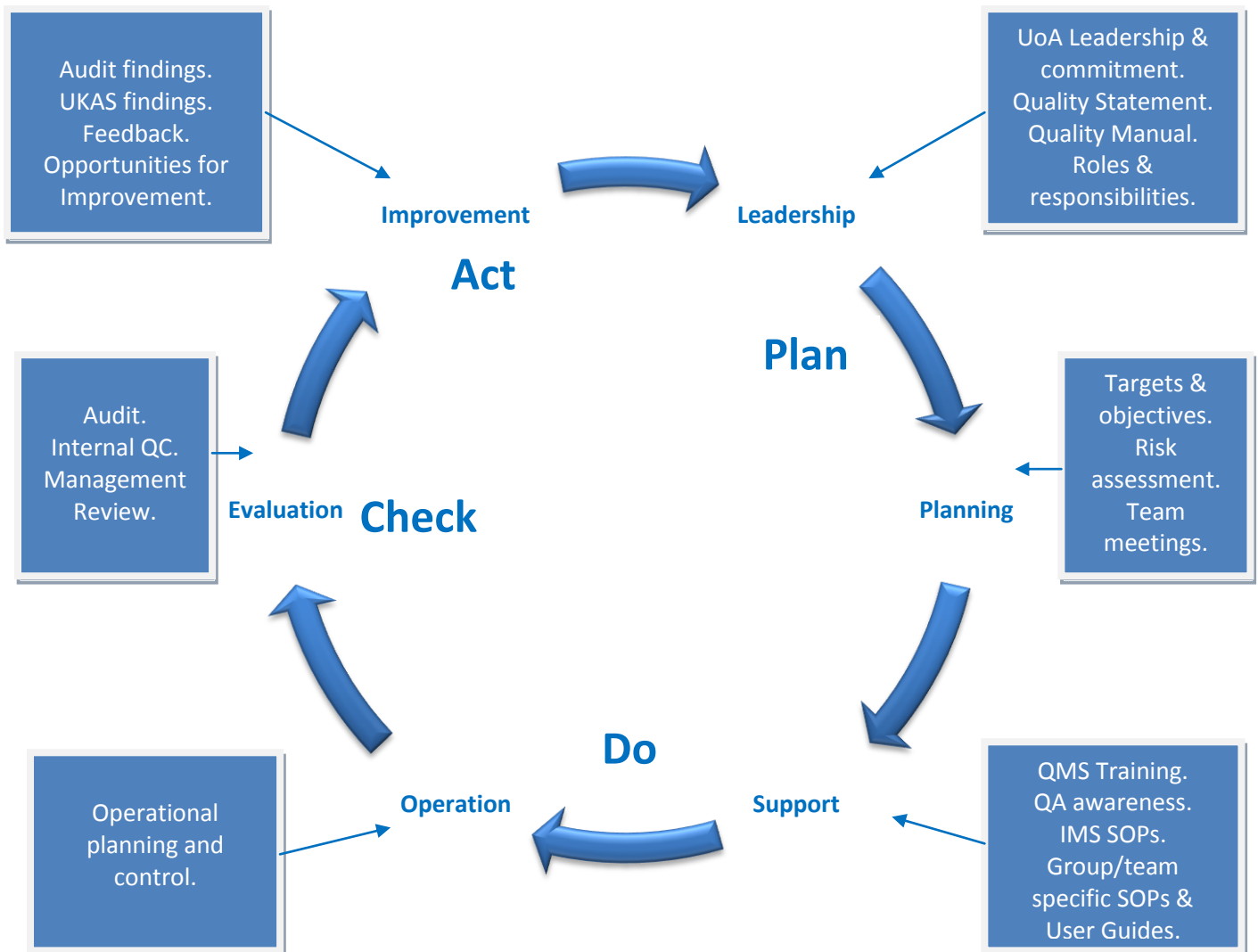
5.2.2 This Quality Manual demonstrates ‘**good practice**’ in all testing activity conducted in UoA. The principles contained within it may be applied to work not listed in 5.2.1 to demonstrate and encourage a quality culture which is compliant with various quality assurance standards and regulations.

5.2.3 This Quality Manual and UoA IMS SOPs may also be used by staff from other organisations with prior agreement.

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5.3 The interaction within the Quality Management System.



5.3.1 Like all Quality Management Systems the one operated by UoA uses the 'plan-do-check-act' principle of continual improvement. There is demonstrable management commitment with a **Quality Statement**, the **Quality Manual** (this document) and documented roles and responsibilities for key staff.

5.3.2 Specific plans are formulated with targets, objectives and risk assessments performed. Plans, targets and objectives are realised through training and awareness sessions, QA support, and the preparation of group and team specific SOPs and User Guides. SOPs and User Guides are implemented and become operational.

5.3.3 The processes and activities are checked for effectiveness through a programme of risk adapted audit to identify opportunities for improvement. Corrections and Corrective and/or Preventive Actions (CAPA) are identified and agreed, leading to continual improvement of the QMS.

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5.3.4 The Quality Management System is regularly reviewed (Management Review) for effectiveness and any improvements opportunities are identified. Stakeholder feedback is also sought to identify any improvement opportunities and is reviewed by senior management during the Management Review.

The cycle then starts again.

5.4 Quality Assurance

5.4.1 UoA is committed to delivering activities which consistently satisfies its stakeholders. As an organisation and as individuals, UoA shall continuously strive to improve the quality of its activities.

5.4.2 UoA is committed to providing the highest possible quality of analysis to its customers.

5.4.3 UoA is a diverse organisation and works closely with NHS Grampian (NHSG) on research activity. No single QMS covers all of the activities of both organisations. As a result some of the different component sections within both UoA and NHSG have achieved and maintained accreditation and certification to a range of standards which meet the needs and activities of the various parts of the organisations.

The following list provides some details of the regulations and guidelines that UoA and NHSG currently comply with:

- UK Policy Framework for Health & Social Care Research.
- Principles of Good Clinical Practice (as outlined in Directive 2005/28/EC).
- UK Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004 No. 1031) as amended.
- UK General Data Protection Regulations (UK GDPR).
- Data Protection Act (2018).
- NHSG diagnostic laboratories are accredited by UKAS to ISO 15189:2012.
- UoA Rowett Institute of Nutrition and Health hold certification to ISO 9001:2015.
- NHSG Biorepository holds accreditation from NHS Research Scotland.
- The University of Aberdeen-NHSG Data Safe Haven (DaSH) hold certification to ISO 27001:2013.

5.4.4 Like all Higher Education Institutions (HEIs) in the UK, UoA maintains the academic standards of qualifications and the quality of the student learning experience through a quality system that complies with the Code of Practice for the Assurance of Academic Quality and Standards in Higher Education, published by the Quality Assurance Agency for Higher Education (QAA), an independent body established to provide public confidence in the quality and standards of higher education.

6 Quality Management System Requirements

6.1 Organisation

6.1.1 Management System

The UoA Quality Management System (QMS) covers testing activity included in the ISO/IEC 17025:2017 scope of accreditation and is carried out in the IMS. All activities shall be undertaken impartially and UoA shall not permit commercial, financial or other pressures to compromise impartiality. Senior management shall identify risks to impartiality and review these regularly. See SOP-IMS-39 (Management review).

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6.1.2 Management – staff & specific duties

To demonstrate competence to work in accordance with the Quality Management System, records of qualifications, training and experience of all staff shall be maintained by each member of staff involved in testing activities. This shall include, as a minimum, an up to date CV, job description, evidence of appropriate education, qualifications, training (eg QA, trial specific training etc), relevant experience and an organisational chart.

Before commencement of testing, or any activity in support of testing which is included in the scope of accreditation, the Technical Manager (in liaison with the QAM) shall indicate which IMS SOPs each member of the team should read and understand, and record in their training file, or SOP sign-off sheet (TMP-QA-40). The Quality Management System Matrix (TMP-QA-44) indicates the component parts of the QMS which the various laboratory and support roles should be familiar with and may be used in place of the SOP sign-off sheet.

6.1.2.1 Specific responsibilities

6.1.2.2 Quality Assurance Manager (QAM)

The QAM ensures that effective quality management is in place for all testing activity, manages the Quality Management System (QMS) and oversee all auditing functions to demonstrate compliance. The QAM liaised directly with Senior Management regarding the performance of the QMS and identified improvements. The QAM is also the main contact with the accreditation body.

The QAM is also responsible for any third party assessments which may be necessary, and any archiving of documentation, in liaison with the Named Archivist.

All documentation which forms the QMS and all key trial documents must be controlled. The document control function is overseen by the QAM.

6.1.2.3 Technical Manager

The Technical Manager is responsible for the laboratory activities within the scope of testing, including the supervision of all staff involved in testing. This shall include selection, determining and monitoring of competence, training, supervision and authorisation.

Also included is the development, modification, verification and validation of methods. This includes the analysis of results, including QC and QA data (with the QAM) identification of any trends, and statements of conformity. The Technical Manager is also responsible for reviewing, authorisation and reporting of results.

6.1.3 Authorised Deputies

In the absence of any of the above, any managerial and technical responsibilities shall be delegated to appropriate personnel. Such delegation shall be documented appropriately.

6.1.4 Management – General

Each person within UoA is responsible for the quality of the work they do and at all times are required to be familiar with the QMS relevant to their role and activities. Each individual shall be responsible for ensuring they have a job description, which contains a brief summary of their key duties, and shall outline the extent and limitations of the job holder's responsibility.

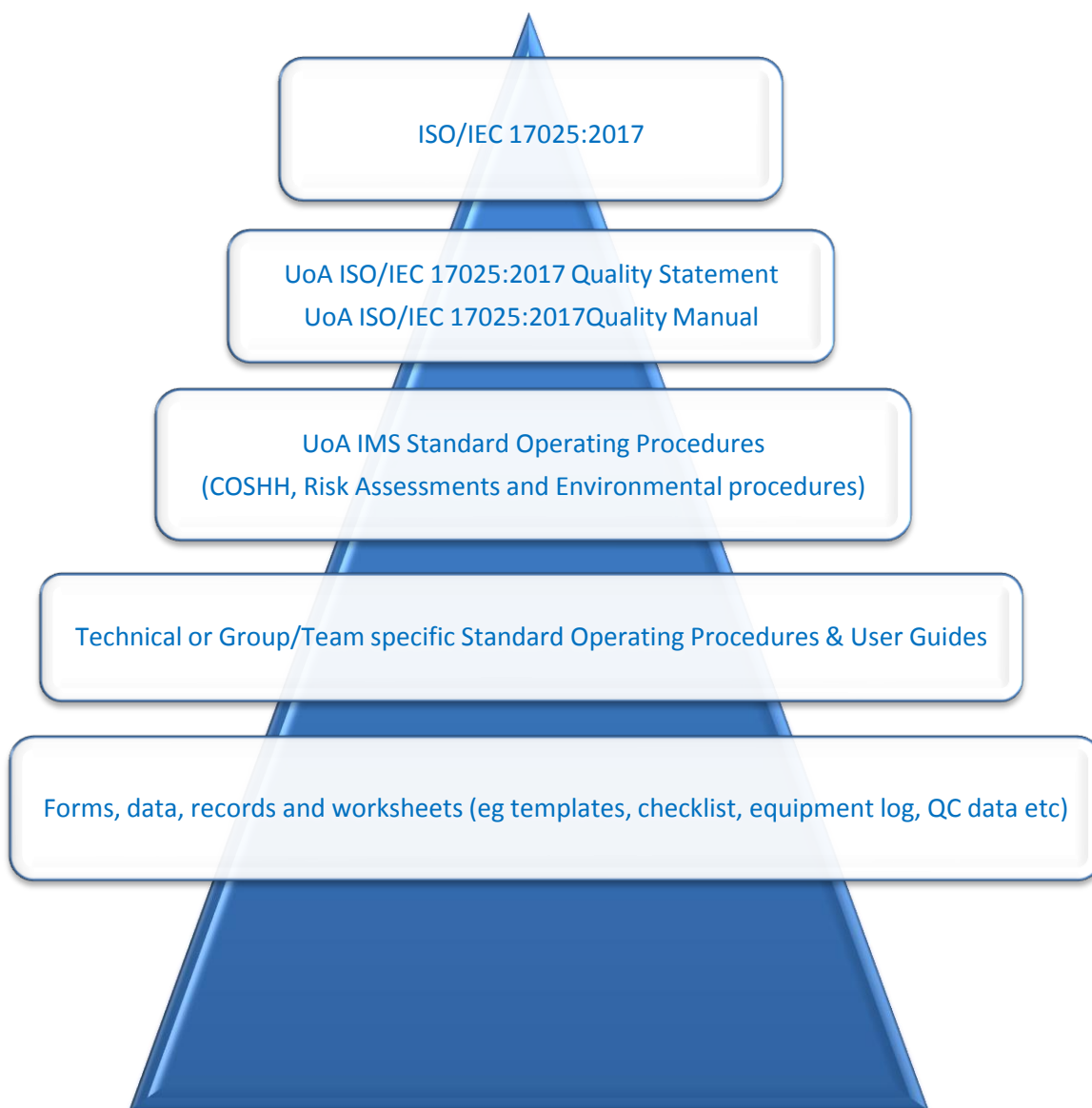
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6.1.5 Confidentiality

UoA shall ensure all information remains confidential and shall comply with the requirements of General Data Protection Regulations (GDPR) and the Data Protection Act (2018). All personnel shall keep confidential all information obtained or created during the performance of laboratory activities, unless required by law to release such information.

The Quality Management System documentation is structured in five levels as follows:



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Level 1 – Regulations and Guidelines

ISO/IEC 17025:2017 (General requirements for the competence of testing and calibration laboratories) is the international standard to which UoA adhere for all testing included on the scope of accreditation.

Level 2- Quality Statement and Quality Manual

The Quality Manual (this document) details the outline structure of the QMS and serves as a reference for its implementation and maintenance. It is a policy document, incorporating UoA quality policies and objectives, an outline structure of the organisation and the roles and responsibilities of key technical and management personnel.

The Quality Statement, signed by senior UoA management, demonstrates the organisations' intent to comply with and maintain quality assurance procedures. It shall list brief objectives and be reviewed regularly.

Level 3 – UoA IMS Standard Operating Procedures (also COSHH, Risk Assessments and any Environmental Management procedures).

The UoA IMS SOPs define the purpose and scope of activities necessary to meet the requirements of ISO/IEC 17025:2017. These procedures address the management requirements and technical requirements of the standard and outline how such activities are conducted, controlled and recorded. These SOPs shall be applicable to all UoA activities in support of testing which is included on the scope of accreditation.

SOPs shall be allocated a review date of three years, although they shall be reviewed when there is any reason to suspect they may no longer be valid (eg following a Deviation, Non-conformance, UKAS finding or a health and safety incident or near-miss), as significant new information becomes available, or when there have been significant changes to working procedures. Such reviews are unplanned reviews and are triggered by significant events or changes. Relevant new information may become available from various sources (eg new staff with different expertise and experience, new manufacturers and suppliers of raw materials and equipment, or as a result of technological or scientific developments).

COSHH (Control of Substances Hazardous to Health) and Risk Assessments shall be written and in place across UoA where appropriate. These are the responsibility of the UoA Health and Safety teams.

Environmental procedures may be in place to comply with environmental legislation, policies or Environmental Standard, such as ISO 14001:2015. This is the responsibility of the respective UoA Environmental teams.

Level 4 – Technical SOPs (Group or Team Specific SOPs) and User Guides.

This level of documentation outlines methods of implementation for specific activities associated with the individual groups and teams, and includes Technical SOP and User Guides.

Generally Technical SOPs and Group Specific SOPs shall only be applicable in the area pertaining to the work, although other groups or teams may use a document from another group or team if it is appropriate. If minor changes are required to such a document (or location specific requirements) to make it applicable to another team or group, these can only be made with the prior approval of the document owner.

Technical SOPs or Group Specific SOPs shall be controlled and reviewed in the same way as the UoA IMS SOPs but shall be managed by local management rather than the Quality Assurance Manager.

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User Guides are local controlled documents providing specific instructions, or further information, on a particular task (eg how to operate a specific autoclave or analyser, sample handling, how to arrange archiving of documentation etc). User Guides may be displayed on a wall (eg adjacent to the particular autoclave or analyser, where samples will be processed etc) and may not need to be reviewed on a regular basis (eg valid for the lifetime of an item of equipment or until a local process changes).

Level 5 – Forms, data and records.

Documentation used for QA purposes in support of a project or activity (eg templates, checklist, logs, laboratory workbooks etc).

Forms, data and records shall be controlled in the same way as SOPs and User Guides.

Relevant email communications concerning testing activity shall be printed out and retained by the Technical Manager as appropriate.

6.1.6 Responsibility

The responsibility for the compilation, distribution, amendment and maintenance of the Quality Manual and SOPs lies with the QAM. The Master Copy of this Quality Manual and QMS SOPs, and all subsequent amendments, are held on file (Q-Pulse) by the QAM.

Authors of Technical or Group Specific SOPs are responsible for their maintenance, although the QAM may perform this task on their behalf (eg using Q-Pulse).

6.2 Document Control

The Document Control procedure is included in SOP-IMS-28 (Management of SOPs). All change requests and controlled changes shall be made using the approved Change Control procedure (eg Q-Pulse) and involve the Technical Manager and QAM.

6.3 Complaints and non-conformances (Deviations and Breaches)

6.3.1 Process

It is UoA practice to ensure that all complaints and non-conformances identified within UoA remain confidential, are investigated and resolved in a timely and effective manner, and that necessary Correction and Corrective and/or Preventive Action (CAPA) are identified to prevent recurrence. See SOP-IMS-34 (Internal Audit), SOP-IMS-35 (External Audit) and SOP-IMS-36 (Deviations).

6.3.2 Non-conformances The QAM shall grade non-conformances as ‘serious’ or ‘non-serious’ and assess whether non-conformances shall be reported immediately to the customer. Serious non-conformances identified through internal audit, shall be reported to the IMS Director and if necessary escalated to the Head of School.

6.4 Improvement

6.4.1 Practice

It is UoA practice to ensure continual improvement of the effectiveness of the Quality Management System through the use of objectives, audit results, analysis of data, Corrections and Corrective Actions and Preventive Actions (CAPA).

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6.4.2 Audit

UoA groups and facilities may be subject to audit and inspection by external parties, which may include regulatory authorities (eg MHRA), accreditation bodies (eg UKAS) or certification bodies (eg LRQA or KPMG). All UoA staff are required to **fully co-operate** in such activities, under the direction of the QAM.

Audit and inspection findings shall be dealt with by the appropriate staff and groups to provide a resolution within previously agreed timescales. It is the responsibility of the Technical Manager to ensure Corrections and any Corrective Action and/or Preventive Actions (CAPA) are implemented; failure to do so shall be referred to senior management for appropriate action. See SOP-IMS-34 (Internal Audit) and SOP-IMS-35 (External Audit).

6.4.2.1 Auditing – a QA activity, conducted independent of the laboratory team, examining testing related activities in accordance with the QMS and regulatory requirements.

Audits shall only be conducted by competent and trained auditors. All audits shall be reported to the Technical Manager and IMS Director, and CAPA shall be progressed, using Q-Pulse.

6.4.2.2 Audit schedules shall be prepared by the QAM and Technical Manager and be based on risk; with increased audit activity for those areas judged by the QAM and/or Technical Manager to be at increased risk. Additional audits may also occur in response to Deviations and may be unannounced.

6.4.3 Correction, Corrective Action and Preventive Action (CAPA or CCAPA)

Correction is any action to eliminate a non-conformance. Corrections shall also be implemented if deviations from the policies and procedures in the Quality Management System or technical operations are identified. Corrective Actions are steps which are taken to remove the causes of an existing non-conformance. All CAPA shall be processed using Q-Pulse.

6.4.4 Corrective Action

Corrective action is any action which is taken to eliminate the cause of a non-conformance and therefore prevent a recurrence of the non-conformance.

6.4.5 Preventive Action

Preventive actions is any action which is taken to eliminate the cause of a potential non-conformance, in order to prevent their occurrence. Preventive actions may be noted as 'Observations' or 'Opportunities for Improvement' during audit.

6.4.6 Continuous Improvement

It is UoA policy to ensure that opportunities for improvement and potential sources of non-conformances, either technical or concerning the Quality Management System, are identified where required. 'Stakeholder' feedback shall be regularly sought to identify any opportunities for improvement. This shall be managed by the QAM and reviewed at Management Review Meetings (see 6.7).

6.5 Technical Records

The Technical Manager shall ensure that records of testing are retained which identify all factors which could affect results and enable recreation of the test if necessary. Such factors include: identification of

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operator(s); equipment, kit and reagent identifiers; dates and times; QC data; original observations; calculations and environmental factors.

Procedures for control of records is included in SOP-IMS-31 (Control of Records). The QAM has ultimate responsibility for all documents which form the Quality Management System.

Records held electronically shall be suitably controlled, secure and backed-up, with appropriately documented procedures. Software systems purchased 'off the shelf' may be considered suitably validated but any modified or bespoke software systems shall require validation before use. Any formulae or calculations used in data handling require regular checks to ensure they are still fit for purpose; such checks shall be recorded.

The Quality Manual, SOPs and User Guides shall be held, and controlled, using Q-Pulse.

6.6 Contracts

Any contracts or Service Level Agreements (SLAs) prepared for testing activities included in the scope of accreditation shall refer to ISO/IEC 17025:2017. Agreements with third party laboratories receiving samples for analysis shall document all relevant facts concerning the procedure, including who must receive results and data. The Technical Manager shall maintain oversight and regular communication with any third parties. The UoA Research & Innovation team may assist the Technical Manager in contractual matters.

Any potential third party laboratory service providers or suppliers must be assessed by the QAM for suitability prior to contracts being put in place. Only third parties which can demonstrate competence (eg certification or accreditation to a suitable quality standard) shall be used. A list of pre-approved third parties is maintained as an 'approved supplier' list by the QAM.

6.7 Management Reviews

This is a periodic (at least annual) review of the Quality Management System by senior Management, for its effectiveness, any opportunities for improvement and its fitness for purpose. It includes a review of findings since the last Management Review and identifies any concerns. See SOP-IMS-39 (Management review).

6.7.1 Practice

It is UoA policy to ensure the continuing suitability and effectiveness of the Quality Management System and testing activities with regard to ISO/IEC 17025:2017, by performing a Management Review.

6.7.2 General

Management Reviews shall be held at least once per year. The objective of the review process is to continually develop and improve the performance of the Quality Management System and to identify and progress any relevant preventive action and opportunities for improvement.

The following agenda items may be discussed and reviewed:

- Any feedback from interested parties on the functioning of the QMS.
- Review of findings from any UKAS inspections.
- Review of non-conformances and observations raised during internal audits.
- Systematic findings and trends noted in audit.

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- Effectiveness of CAPA.
- Possible areas of improvement and future development of the QMS.
- Review of Quality Manual for effectiveness.
- Review of Quality Statement for effectiveness.
- Staff training.
- Resource issues concerning the QMS.
- Review of feedback and satisfaction surveys.
- Planned assessment and regulatory inspections.
- Impartiality of activities.

6.8 Human Resources

All staff involved in testing activities, or in support of such activities, must be trained to comply with the requirements of ISO/IEC 17025:2017. This training may be provided in-house by the QAM. All staff involved in a testing must have documented training for equipment and procedures which form part of their duties, see SOP-IMS-30 (Training and Competence).

6.9 Control of Customer Property (including samples)

Customer property may be material or data supplied for analysis or intellectual property. UoA shall ensure that any property supplied by the customer shall be stored and handled ethically and in such a manner as to protect its integrity, security and confidentiality.

Samples shall be uniquely identified and the identifier shall remain with the sample whilst under the control of the laboratory.

Upon receipt, an evaluation of sample suitability shall be undertaken and any deviation from specified conditions shall be noted and reported to the customer. Samples may be analysed when deviating from specified conditions if requested by the customer, but this shall be declared on the laboratory report.

6.10 Equipment

All critical equipment must be functioning correctly, be fit for purpose and be capable of achieving the accuracy required. Only trained personnel shall use laboratory equipment, and procedures must be in place to document the use, service and planned maintenance of all critical equipment. All critical equipment shall be maintained and serviced according to manufacturers' instructions. See SOP-IMS-33 (Critical Equipment).

Each item of critical equipment shall be uniquely identified and intermediate checks shall be recorded appropriately to demonstrate confidence in the continued use of the equipment.

The frequency of intermediate checks must be justified based on national guidelines and/or regulations.

Any equipment that is used for a specific purpose/trial must be identified as such.

Any equipment that is out of use must be identified as such to preclude its use.

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6.11 Facilities

All facilities must be fit for purpose with appropriate procedures in place to protect the integrity of samples, prevent cross-contamination between samples and prevent risk to staff or visitors. Procedures shall be in place to ensure security, safety, hygiene and biosecurity.

Appropriate measures shall be in place for Containment Level 2 and Containment level 3 laboratories and facilities (there are no Containment Level 4 facilities in the UoA site). See SOP-IMS-32 (Accommodation and Environment).

6.12 Methods

The Technical Manager is responsible for ensuring methods are appropriate, current and documented (SOPs available at point of use). All standard methods must be verified before being used and records of verification retained. Ongoing QC checks (participation in proficiency schemes, interlaboratory comparisons etc) shall be undertaken. Where standard, established methods, which specify limits to the values of measurement uncertainty (MU) and presentation of results, are used no further measurement uncertainty shall be required.

Non-standard methods must be validated before introduction and records of validation retained, including a statement of validity detailing the method fitness for intended use. Where non-standard methods are used measurement uncertainty (MU) must be evaluated.

6.13 Health and Safety

Laboratories can be one of the most hazardous places in which to work and appropriate health and safety policies and procedures are available from the UoA Health and Safety Department. Staff shall ensure appropriate risk assessments have been prepared and that COSHH data is available for any chemicals and reagents used.

6.14 Archiving

All documents pertaining to testing activity shall be archived securely and confidentially for an agreed period. This can be either on-site, in a suitable facility, or subcontracted to a suitable certified archiving contractor (see below):

UoA have appointed a Named Archivist who shall have oversight and control of all archiving functions (See SOP-QA-32 - Archiving).

Any samples to be archived for possible future use in research must have appropriate informed consent in place and shall be stored at – 80 C (± 10 C) either in the approved NHSG Biorepository, under the management of the Biorepository Manager, or in an appropriately controlled ULT freezer.

Electronic data shall be locked and stored securely for an agreed period in an approved location (e-archive) under the management of the appropriate IT department (see SOP-QA-20 – Data management for clinical trials). E-data shall not be stored on any intermediate storage medium.

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