LOTHIAN UNIVERSITY HOSPITALS DIVISION

1. JOB IDENTIFICATION

Job Title: Principal Clinical Scientist

Responsible to Director, UK NEQAS [Edinburgh] (Peptide Hormones)

Department(s): UK NEQAS [Edinburgh]

Directorate: DATCC

Operating Division: Lothian University Hospitals Division (LUHD)

Job Reference: 037591

No of Job Holders: One

Last Update (insert date):

2. JOB PURPOSE

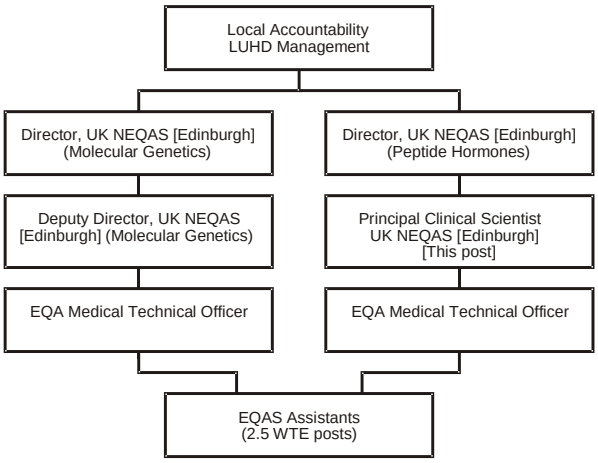
To provide specialised national and international external quality assessment (EQA) services to standards required by Clinical Pathology Accreditation (UK) Ltd / United Kingdom Accreditation Service (UKAS).

To ensure the efficient and effective logistical management of all services provided by UK NEQAS [Edinburgh].

3. DIMENSIONS

UK NEQAS [Edinburgh] monitors laboratory performance nationally and internationally and accordingly contributes to Clinical Governance on a national and international level. The service aims to reduce harm to patients caused by erroneous test results, and to improve test quality by education and demonstration of best practice. The post-holder assists with supervision of a medical technical officer and three EQAS assistants.

4. ORGANISATIONAL POSITION



Note: National Accountability is to the UK National External Quality Assessment Service [UK NEQAS].

Note: The Principal Clinical Scientist acts as UK NEQAS Quality Co-ordinator. In this role, the post-holder reports to the NHS Lothian Compliance Manager and through her to the Director of Laboratory Medicine. The role involves maintaining a total quality management system to meet the requirements of UK NEQAS [Edinburgh] [Appendix 2]. Duties include the development, management and maintenance of the quality system, providing leadership, highly specialist advice, direction and training to UK NEQAS [Edinburgh] staff including issues relating to accreditation, governance and quality assurance in pathology.

5. ROLE OF DEPARTMENT

UK NEQAS [Edinburgh] is a National Quality Assurance system linked to Clinical Governance, principally with a national role as provider of this service for more than 600 UK laboratories and 100 laboratories in 42 other countries. It has routine, educational and research components.

6. KEY RESULT AREAS

Managerial

- To assist the Director in ensuring effective delivery of the UK NEQAS services to its participants, which will include planning and implementation of scheme logistics, day-to-day supervision of UK NEQAS staff, maintenance of quality documentation (e.g. relevant Standard Operating Procedures) and input to its financial management, and to assist in appointment and management of junior staff as required, according to the Organisation's policy and procedures.
- To support the Centre's adherence to the Quality Standards required to maintain accreditation by the United Kingdom Accreditation Service (UKAS) including preparation for the annual inspections required,
- To provide expert scientific advice and interpretation on quality assessment to Scheme participants, Specialist Advisory Groups, Steering Committees, the UK NEQAS Board, Consortium, and Office, Scheme Organisers and other staff.
- To contribute actively to the setting of national and international standards and policy, to support standard-setting as appropriate and to initiate and to carry out audit of these standards nationally.

Scientific and Technical

- To oversee the preparation of EQA specimens in accordance with specifications and policies and to undertake analytical procedures of an advanced or highly complex nature as appropriate, requiring special knowledge for their execution and involving handling of biological material (e.g. blood, serum, urine, DNA and/or unfixed/ fresh tissue samples) and noxious chemicals as required by the post.
- To undertake complex calculations, manipulations and interpretation of data requiring long periods at the computer and a high degree of accuracy, so as to ensure the accuracy and appropriateness of all reports - annual and monthly (including expert commentaries and surveys of recent literature sent to all participants and written and verbal communications with individual participants) - prepared by the post holder and to keep records of these as required by UKAS, often working under considerable time pressure in order to meet essential deadlines.
- To be responsible for and carry out proactive surveillance of participants' performance as is required of EQA schemes by the Department of Health and other professional bodies and to assist the Director in providing regular reports to the National Quality Assurance Advisory Panels (NQAAPs), reports which may result in UK clinical laboratories with unacceptable performance being required to stop performing tests.
- To assist the Director in identifying the need for and preparing reports on adverse method performance and other relevant clinical incidents relating to all analytes monitored by UK NEQAS [Edinburgh] for the Medicines and Healthcare products Regulatory Agency (MHRA) as appropriate.

Laboratory Informatics

- To be responsible for the specialist UK NEQAS [Edinburgh] websites and EQA software, which underpins provision of the UK NEQAS [Edinburgh] service and to select appropriate replacement computer software and hardware when required, in consultation with relevant staff of the LUHD IT Unit and the University of Edinburgh Computer Services Unit.

- To comply with local and national policies for the safe, secure and confidential processing and storage of technical and other information provided by UK NEQAS participants or related to patients treated at LUHD or elsewhere, in accord with local, national and other policy and to use UK NEQAS Databases according to authorised protocols.
- To be competent in spreadsheets and processing of data for audit, research and other scientific information gathering, including preparation of complex graphs for UK NEQAS *Annual Reviews* and other reports.

Clinical

- To provide expert advice to multidisciplinary professional groups developing regional, national and international services relevant to diagnostic tests within the remit of UK NEQAS [Edinburgh], e.g. maternal serum screening tests for Down's syndrome and parathyroid hormone.
- To maintain clinical competence, e.g. through participation in relevant duty biochemist rotas if appropriate.
- To develop and maintain knowledge of the use of test results in patient care, e.g. by participating in educational and other appropriate activities of the Department of Laboratory Medicine.

Research and development

- To undertake research (which may include the evaluation of new and improved procedures, instruments and reagents) within the remit of EQA activities, to publish research work in peer reviewed journals, to present the work locally and nationally (usually to audiences of 20 to 200 specialists and non-specialists) and to referee papers for scientific journals.

Educational

- To give undergraduate and postgraduate teaching in the LUHD hospitals, community, the University of Edinburgh and other Universities - including supervision of research projects, training of medical scientific and technical staff, and education of users of the UK NEQAS service nationally and internationally – while maintaining current awareness of scientific developments relevant to the work of UK NEQAS through participation in relevant CPD activities at all levels.

General

- To comply with the policies and procedures of the LUHD NHS Organisation, by observing and adhering to local and national health and safety policies, maintaining good work relations with all members of staff, promoting effective teamwork, and treating everyone associated with LUHD and all UK NEQAS participants with courtesy and respect, at all times maintaining and promoting the professional image of UK NEQAS and LUHD NHS Organisation.

7a. EQUIPMENT AND MACHINERY

The post holder has

- Responsibility for the planned replacement, selection, evaluation and commissioning of highly specialised laboratory equipment and instrumentation for UK NEQAS [Edinburgh], within the overall direction of the UK NEQAS [Edinburgh] Director.
- Responsibility for the planned replacement, selection, evaluation and commissioning of computer hardware and related equipment for UK NEQAS [Edinburgh], within the overall direction of the UK NEQAS [Edinburgh] Director.
- Broad ranging knowledge of equipment, technologies and methods used by UK NEQAS [Edinburgh] participants, including immunoassay and mass spectrometric techniques.
- Responsibility for the daily operation, staff training, maintenance and performance quality of highly specialised laboratory investigations and highly complex laboratory instrumentation, used by UK NEQAS [Edinburgh].

7b. SYSTEMS

The post holder is required to become proficient in the use of:

- The UK NEQAS [Edinburgh] computer systems and websites for data input and analysis, production of reports for participants, manufacturers, and national UK NEQAS and other advisory groups.
- The University of Edinburgh and UK NEQAS [Edinburgh] computer systems for e-mail communications, Internet access, word processing and statistical and graphical applications (e.g. Excel, Fig P).
- The Laboratory Medicine Quality Management System for document and error control.
- Relevant local, national and international standards [e.g. UK NEQAS performance targets, Clinical Pathology Accreditation standards, NHS National Screening Committees (e.g. Down's Syndrome),] and guidelines (e.g. produced by the National Institute for Health and Care Excellence, Royal College of Relevant Pathologists, Healthcare Improvement Scotland).

8. ASSIGNMENT AND REVIEW OF WORK

The post holder

- Works autonomously, with a high level of individual responsibility, with or without scientific and technical support, within the overall direction of the Scheme Director.
- Participates in monthly meetings of all UK NEQAS [Edinburgh] staff to discuss strategic objectives, evaluate progress, audit UK NEQAS errors (agreeing remedial action to be taken), and agree on assignment of work.

- Is subject to annual appraisal by the Scheme Director.

9. DECISIONS AND JUDGEMENTS

The post holder

- Works autonomously to implement managerial and clinical policies, procedures and guidelines relating to the work of UK NEQAS [Edinburgh].
- Assists the Director in managing the UK NEQAS [Edinburgh] workload, staff deployment and allocation of resources.
- Organises their own time and prioritises work accordingly.
- Contributes to the supervision of trainee and other scientific and technical staff as appropriate.

10. MOST CHALLENGING/DIFFICULT PARTS OF THE JOB

- As a senior member of UK NEQAS [Edinburgh] staff (representing UK NEQAS directly and LUHD indirectly) communicating with other LUHD staff, individual participants and colleagues or larger groups of scientists and clinicians (from hospitals, universities or diagnostic manufacturers nationally and internationally), whether in writing, by telephone or in person, is a challenge that requires both advanced specialist knowledge and communication skills.
- Assessing and interpreting UK NEQAS data is a demanding role requiring advanced specialist knowledge, analytical and mathematical skills, and the ability to concentrate on and manipulate large amounts of numerical laboratory data for long periods of time.
- The nature of the work is often unpredictable, requiring multitasking and frequent changes to work prioritisation, as well as being subject to frequent interruptions e.g. from telephone calls and other members of staff seeking advice. An ability to work under pressure, to handle complaints effectively and to communicate clearly with all grades of staff in many different organisations is essential.

11. COMMUNICATIONS AND RELATIONSHIPS

The post holder is required to

- Explain the analytical and clinical significance of highly complex results to a range of staff including Heads of Department of participant laboratories and senior executives in diagnostics manufacturers.
- Communicate effectively with staff of the UK NEQAS Executive, Consortium and Office,

National and International organisations [e.g. Department of Health, National Quality Assurance Advisory Panels (NQAAP), NHS National Screening Committees, Steering Committees and Specialist Advisory Groups], and NHS Lothian Department of Laboratory Medicine, LUHD, and University of Edinburgh.

- Interact with clinical scientists and other health care professionals as required at local, national and international level, including participating in professional networks of staff.
- Interact with biomedical and other scientific staff about work prioritisation, work quality etc.
- Present research and development results, audit findings, and new policies and guidelines at local, national and international meetings.
- Teach laboratory staff in formal lectures and seminars in both small and large groups, and provide instructional training and on-going education as required.
- Investigate, identify, troubleshoot and communicate about analytical or clinical problems in order to ensure their effective and rapid resolution.
- Motivate and train junior staff.
- Maintain participant confidentiality in line with UK NEQAS and NQAAP policy.
- Occasionally challenge vigorously managerial or medical opinions, maintaining conviction in the post holder's own knowledge and opinions.

12. PHYSICAL, MENTAL, EMOTIONAL AND ENVIRONMENTAL DEMANDS OF THE JOB

Physical
Combination of sitting, standing and walking required. Occasional requirement for lifting (e.g. equipment). Required accurate hand-eye coordination for fine pipetting.

Mental
There is frequent requirement for prolonged intense concentration, e.g. evaluating UK NEQAS data requires the ability to concentrate for long periods of time, with frequent interruptions for enquiries, handling complaints etc. These interruptions are unpredictable and may require multi-tasking and re-prioritisation of work pattern. Occasionally need to challenge vigorously medical or managerial opinions, maintaining conviction in own knowledge and opinions.

Emotional
Occasionally required to direct staff to implement changes with which they may not agree to some aspect of work procedures or priorities. Occasionally need to vigorously challenge medical or managerial opinions.

Environmental

Occasional exposure to unpleasant working conditions (e.g. uncontained blood, urine, serum. plasma), toxic/carcinogenic chemical hazards and potentially infectious agents.

13. KNOWLEDGE, TRAINING AND EXPERIENCE REQUIRED TO DO THE JOB

Essential qualifications

- First or second-class honours degree or equivalent in chemistry, biochemistry or allied subject.
- Masters degree (or assessed equivalent level of knowledge) in the Specialty of Clinical Biochemistry and/or PhD in a relevant field.
- Demonstrable knowledge and experience in research – as evidenced by formal qualifications (e.g. PhD) and/or appropriate publications in peer-reviewed journals.
- Demonstration of Continuing Professional Development (e.g. Royal College of Pathologists Scheme or progress towards the FRCPath).

Registration

- Clinical Scientist State Registration with the Health Professions Council.

Experience and knowledge

- Previous time in post as a Registered Clinical Scientist.
- Experience and knowledge of the specialist theory and practice of EQA required for the provision of a comprehensive EQA service.
- Ability to analyse problems and evaluate solutions.
- Ability to work to tight deadlines.
- Sound knowledge and expert skills in computing, including computer programming (e.g. of complex databases).
- Good practical skills and experience in immunoassay.

14. JOB DESCRIPTION AGREEMENT

A separate job description will need to be signed off by each jobholder to whom the job description applies.	
Job Holder's Signature:	Date:
Head of Department Signature:	Date:

Appendix 1. Remit and organisation of UK NEQAS [Edinburgh].

- **Operational policies and staffing.** The UK NEQAS [Edinburgh] service has developed over a period of more than 20 years and has a formal service agreement with LUHD. It currently employs five members of staff and has its own dedicated laboratory, situated within the Royal Infirmary. Under the overall direction of the UK NEQAS [Edinburgh] Director, the day-to day scientific activities of the UK NEQAS Service are delivered independently from the Department of Laboratory Medicine, while in other matters (e.g. safety, staff conditions of employment) the UK NEQAS service works closely with Departmental staff in implementing Lothian University Hospitals Division (LUHD) policy.
- **Range of tests monitored** The UK NEQAS [Edinburgh] service provides quality monitoring for specialised biochemical blood tests used in reproductive medicine, including pregnancy testing, paediatric and adult endocrinology, prenatal screening for Down's Syndrome and spina bifida, oncology (colorectal, testicular, choriocarcinoma and liver cancers), and metabolic bone disease.
- **Volume of service and workload** UK NEQAS [Edinburgh] provides this service to approximately 600 hospital laboratories in the UK and 400 laboratories in 42 countries outwith the UK. Annually more than 84,000 blood serum specimens containing one or more of 14 analytes are distributed by post on a weekly schedule. Participating clinical laboratories analyze the specimens "blind" and return their results to the EQA centre, where they are collated and processed. The UK NEQAS centre then issues a report to each laboratory, which indicates its closeness to the 'target value' and comparability with other laboratories. Data from a number of distributions are combined and scored against nationally agreed performance criteria, providing a long and short-term picture of the quality of each laboratories service. There are accordingly strict deadlines to be met.
- **Quality assurance of UK NEQAS activity.** All hospital laboratories must show satisfactory performance in the UK NEQAS (or other equivalent accredited EQA scheme) in order to gain UKAS Accreditation. There is, therefore, an absolute responsibility of the Director of the UK NEQAS service to ensure that the quality monitoring service is reliable, and valid. In order to achieve this, the UK NEQAS service regularly reviews the quality of its own work, and is subject to external independent review by representatives of the Royal Colleges and other professions.
- **Communication with participating laboratories** In cases where a laboratory is shown to have unsatisfactory performance, UK NEQAS [Edinburgh] staff make contact with the individual laboratory to attempt to elucidate the cause of the problem. Where the participating laboratory is a commercial manufacturer of diagnostic test kits or equipment, UK NEQAS staff communicate with the manufacturer's senior scientific staff. This requires expert knowledge, tact and confidentiality from UK NEQAS staff.
- **Collaboration with Royal Colleges and Professional Associations.** Where the participating laboratory is unwilling or unable to correct its poor performance and this is considered potentially dangerous to patient care, the UK NEQAS centre liaises with a Panel representing the Royal Colleges and other professions, to assist in correcting the problem. In addition, because of their unique knowledge of the quality issues surrounding test performance, the UK NEQAS Director and other senior UK NEQAS staff are also from time to time invited to contribute their expert knowledge to expert professional committees, both national and international, and to advise on acceptable quality levels of performance.
- **Liaison with other UK NEQAS Centres** UK NEQAS [Edinburgh] is one of 23 UK NEQAS Centres located in hospital and University laboratories throughout the UK, which

together provide a comprehensive quality monitoring service for all commonly performed tests done in hospital laboratories and which share common procedures and policies.

- **Presentation of data at national and international meetings, and through publications.** Education of laboratory staff is recognised as a key strategy to improve quality of performance and forms a major part of the work of the UK NEQAS Centre.
- **Financial management.** UK NEQAS [Edinburgh] is entirely self-funding through fees paid by participating laboratories. It operates in a competitive market with other providers of EQA schemes, and must therefore ensure “value for money” to participants. The UK NEQAS Director has ultimate responsibility for deciding the level of service and participation fees on an annual basis, requiring skills in budget setting, and some commercial acumen. The current income is in excess of £350,000, and over the last 10 years, UK NEQAS has contributed to LUHDincome through service charges and modest surpluses of income over expenditure.
- **UK NEQAS [Edinburgh] and LUHD.** Although the activities of UK NEQAS [Edinburgh] are largely independent of the Trust’s core activities, there is a mutually supportive relationship between UKNEQAS and LUHD. The recognition of UK NEQAS [Edinburgh] as a quality centre raises the profile of LUHD nationally and internationally.

Appendix 2. Remit of post-holder as Quality Coordinator for UK NEQAS [Edinburgh]

As Quality Co-ordinator for UK NEQAS [Edinburgh] the post-holder is responsible for maintaining a total quality management system to meet the requirements of UK NEQAS [Edinburgh]. In this role the post-holder is responsible to the Compliance Manager for NHS Lothian, who provides a link to higher management (i.e. the Department of Laboratory Medicine Service Manager and the Associate Medical Director) as well as access to support (if required) from the Quality Compliance Team for the NHS Lothian Department of Laboratory Medicine.

Specific duties within the remit of the Quality Co-ordinator include the following:

- Maintaining UKAS accreditation to ISO standards for all relevant services and departmental activities.
- Developing, managing and maintaining an appropriate quality system that covers both sections within UK NEQAS [Edinburgh].
- Providing leadership, highly specialist advice, direction and training to all UK NEQAS [Edinburgh] staff on quality issues including accreditation, governance and quality assurance in pathology.
- Taking responsibility for developing, reviewing, implementing and managing policies and procedures for the UK NEQAS [Edinburgh] centre.
- Setting quality objectives for UK NEQAS [Edinburgh] and agreed measurable milestones and timetables.
- Contributing to regular meetings to monitor performance and ensure that staff members are discharging their responsibilities and meeting agreed objectives and deadlines. In case of difficulty in ensuring the latter, support (and if necessary intervention) is readily available from the Compliance Manager and through that staff member also from the NHS Lothian senior management team.
- Providing advice and guidance on the quality management implications of all new service developments within UK NEQAS [Edinburgh].
- Maintaining and developing all aspects of the quality management system.
- Planning and conducting internal audit activities relevant to the requirements of accreditation.
- Investigating or coordinator investigation of user complaints and serious incidents to ensure effective root cause analysis and remedial action.
- Maintaining good working relations with all levels of staff, which is key to the delivery of the effective quality management of services. This may require skills of persuasion to alter the opinions of staff who may be resistant to change.