GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Caerdydd a'r Fro | Cardiff and Vale University Health Board	**Reference Number: UHB 120** **Version Number: 2** **Date of Next Review: 21/04/2018** **Previous Trust/LHB Reference Number: T/74**

QUALITY POLICY OF THE DIRECTORATE OF LABORATORY MEDICINE, CARDIFF AND VALE UNIVERSITY HEALTH BOARD

Policy Statement

The Directorate of Laboratory Medicine is committed to providing a service of the highest quality and will be aware of, and take into consideration, the needs and requirements of its users. A "user" is defined as a healthcare professional (e.g. hospital doctor, general practitioner, nurse practitioner, laboratory director, third party payment organisations, etc.) or Coroner who requires a laboratory investigation, blood component or product for transfusion, storage of cells, tissues or nucleic acid, stem cell processing or a post mortem examination. Whilst due consideration is given to patients and their families they are not routinely direct users of the Laboratory Medicine services, with the exception of Point of Care, Phlebotomy and Mortuaries. In these areas the views of the patients and families are paramount in informing and shaping the service delivery model.

Policy Commitment

The aim of this policy is to affirm that the Directorate of Laboratory Medicine is committed to providing a service of the highest quality, and will be aware of, and take into consideration, the needs and requirements of its users.

Supporting Procedures and Written Control Documents

The policies below and the supporting procedures held within the Laboratory Medicine document control system (Q-Pulse) and guidance held on the Intranet sites describe the UHB's aims, objectives and operational organisation in regard to discharging its obligations in respect of patient safety, quality and governance.

- Labelling of Specimens Submitted to Medical Laboratories Policy Reference Number 17
- Patient Identification Policy Reference Number 101
- Blood and Component Transfusion Policy Reference Number 068
- Point of Care Testing (POCT) Policy Reference Number 062
- Professional Registration Policy Reference Number 169

Other supporting documents are:

- Clinical Pathology Accreditation *Standards for the Medical Laboratory* 2010.
- ISO15189:2012 *Medical laboratories - Particular requirements for quality and competence.*
- ISO 9001:2008 *Quality Management Systems - requirements*
- *The Blood Safety and Quality Regulations (amended)* 2005
- *The Human Tissue Act* 2004
- *The Human Tissue (Quality and Safety for Human Application) Regulations* 2007

Scope

This policy provides a framework for establishing and reviewing quality objectives, encompassing the diagnostic analytical, interpretive and advisory services of the Medical Biochemistry & Immunology, Toxicology, Haematology & Transfusion, Laboratory Genetics, Cellular Pathology (excluding gynaecology screening cytology) and Laboratories, including Pathology Specimen Reception; the therapeutic laboratory service of the Stem

Cell Processing Unit; the Mortuaries and the Phlebotomy Service. This policy applies to all of our staff in all locations including those with honorary, locum and bank contracts.	
Equality Impact Assessment	An Equality Impact Assessment (EqIA) has been completed and this found there to be no impact.
Health Impact Assessment	A Health Impact Assessment is not required for this policy.
Policy Approved by	Committee
Group with authority to approve procedures written to explain how this policy will be implemented	Quality Safety and Experience Committee.
Accountable Executive or Clinical Board Director	Director of Therapies and Health Science
Disclaimer **If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.**	

Summary of reviews/amendments

Version Number	Date Review Approved	Date Published	Summary of Amendments
1	14/06/2012 By Quality, Safety and Experience Committee	04/07/2012	New Policy
2	21/04/2015 By Quality, Safety and Experience Committee	11/05/2015	Revised to include move from CPA standards to ISO 15189:2012.

CONTENTS

1. INTRODUCTION

The Cardiff and Vale University Health Board (UHB) Laboratory Medicine Quality Policy links to the organisational action plan 'Organising for Excellence'. The builds on the work Cardiff and Vale highlighted they did well and the areas they could improve upon. The Laboratory Medicine Quality Policy continues this theme by committing to:

- providing a quality service to meet the needs and requirements of its users,
- meeting the appropriate standards set by accrediting and licensing bodies and legislation,
- providing a programme of continuing improvement.

2. OBJECTIVES

The objectives of this policy are to ensure that the laboratory and allied services meet the requirements set out in appropriate standards and legislation and maintain accreditation, certification or licence, thereby assuring users and stakeholders of the quality of the services provided.

3. RESPONSIBILITIES

3.1 Chief Executive

The Chief Executive has overall responsibility for the performance of the UHB and the quality of the services it provides.

3.2 UHB Quality and Safety Committee

The Clinical Diagnostics and Therapeutics Clinical Board Quality and Safety Group reports to the UHB Quality & Safety Committee.

3.3 Clinical Diagnostics and Therapeutics Clinical Board Quality and Safety Group

The Directorate Quality Manager reports to the Clinical Diagnostics and Therapeutics Clinical Board Quality and Safety Group

3.4 Directorate of Laboratory Medicine

In order to ensure that the needs and requirements of users are met, the Directorate of Laboratory Medicine will:

- operate a Quality Management System (QMS) to integrate its organisation, procedures, processes and resources to meet the needs of users and ensure user satisfaction;
- set and periodically review objectives and plans to implement this policy and achieve continual improvement;

- monitor the quality objectives and plans, prioritising actions based on highest risk, with defined outcomes;
- ensure that all personnel are familiar with this policy, the quality manual and all policies and procedures relevant to their work;
- commit to the health, safety and welfare of all its staff, and all those who visit its premises or use its services;
- uphold professional values and be committed to good professional practice and conduct;
- comply with all relevant environmental legislation.

The Directorate of Laboratory Medicine currently complies with

- Clinical Pathology Accreditation (UK) Standards for the Medical Laboratory, ISO9001:2008 preparing for the transition to ISO15189:2012 by United Kingdom Accreditation Services (UKAS), (POCT services does not currently have CPA accreditation status but is working toward achieving ISO 15189:2012).
- Blood Safety and Quality Regulations (amended) 2005
- Human Tissue Act 2004
- Human Tissue (Quality and Safety for Human Application) Regulations 2007
- Other appropriate standards and codes of practice.

The Directorate of Laboratory Medicine is committed to:

- the recruitment, training, development and retention of staff at all levels to provide a full and effective service to users;
- the proper procurement and maintenance of equipment and other resources which are needed for the provision of the service;
- the collection, transport, handling and storage of all specimens in such a way as to ensure the correct performance of laboratory examinations;
- the collection, transport, handling and storage of all blood components and products and cellular therapy products in such a way as to ensure that safety and quality are not compromised;
- the use of examination procedures that will ensure the highest achievable quality of all tests performed that are fit for the intended purpose, suitable for clinical application through periodic review whilst ensuring a cost-effective service delivery;
- reporting results in ways which are timely, confidential, accurate and clinically useful;
- the assessment of user satisfaction, internal audit and external quality assessment, in order to produce continual quality improvement.

3.5 Departmental Teams

Each service has a regular meeting at which quality issues are reviewed (including audits, incidents & untoward events, corrective and preventive actions, risks, concerns, quality initiatives, quality assurance and assessments) and operational managers are updated on progress and any actions required are agreed. Each service will have an annual management review to review performance and set quality plans.

3.6 Laboratory Quality Manager

The Directorate Quality Manager is responsible for the overall management of the QMS and co-ordinates the activities of the individual service Quality Officers. She/he reports on the status and functioning of the QMS to the Directorate Management Team, and reports to the Clinical Board Quality and Safety Group on quality matters. She/he will keep up to date with developments in standards and legislation and advise the service of the implications of any changes.

3.7 Quality Officers

The individual Quality Officers for Biochemistry & Immunology, Haematology, Transfusion, Cellular Pathology, Laboratory Genetics, Phlebotomy and POCT are responsible for the day to day running of the QMS in their own services and escalating concerns to the Quality Manager when appropriate. Quality Officers may be supported by Quality Leads that will have quality duties assigned as part of their role, such roles will exist within the Specimen Reception and the Mortuary.

3.8 Designated Individual (DI)

Designated Individuals have a key role to play in implementing the requirements of the Human Tissue Act. They are the person under whose supervision the licensed activity is authorised to be carried out. They have the primary (legal) responsibility under Section 18 of the HTA to secure:

- that suitable practices are used in undertaking the licensed activity;
- that other persons working under the licence are suitable and;
- that the conditions of the licence are complied with.

The DI may designate particular individuals in a Notice to the Human Tissue Authority; therefore they are not licence holders but are can provide direction in relation the HTA.

4. RESOURCES

This policy reflects existing practice. The impact of implementing ISO 15189:2012 is under review and additional resources will be supported by business plans and will be a transition from the CPA standards.

5. TRAINING

Training in quality and the Laboratory Medicine QMS is provided to all Directorate staff as part of their induction and their ongoing development. It is envisaged that formal training will be required as a result of implementing ISO 15189:2012 but not as a direct result of updating this policy. The training to support quality initiatives or system will be to appreciate the new standards/new audit requirements. These will be identified as they arise.

6. IMPLEMENTATION

This policy reflects existing practice and therefore can be implemented immediately.

7. EQUALITY IMPACT ASSESSMENT

Cardiff and Vale UHB is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff, patients and others reflects their individual needs and does not discriminate, harass or victimise individuals or groups. These principles run throughout our work and are reflected in our core values, our staff employment policies, our service standards and our Strategic Equality Plan & Equality Objectives. The responsibility for implementing the scheme falls to all employees and UHB Board members, volunteers, agents or contractors delivering services or undertaking work on behalf of the UHB.

We have undertaken an Equality Impact Assessment and received feedback on this policy and the way it operates. We wanted to know of any possible or actual impact that this policy may have on any groups in respect of gender, maternity and pregnancy, carer status, marriage or civil partnership issues, race, disability, sexual orientation, Welsh language, religion or belief, transgender, age or other protected characteristics. The assessment found that there was no impact to the equality groups mentioned.

8. AUDIT

Internal quality audits are performed as part of the QMS. User surveys are also carried out. These are reported to individual service quality and /or service groups, and issues are discussed at the Clinical Board Quality and Safety Group.

9. DISTRIBUTION

This policy will be made available on the UHB Intranet and Internet sites.
An extract from the policy detailing the Policy Statement and responsibilities of the Laboratory Medicine Directorate will be displayed in laboratories, included in the Directorate Quality Manual and will be available to view by Laboratory Medicine staff on the controlled documents database (Q-Pulse).

10. REVIEW

The Directorate will review this policy annually or more often if appropriate to ensure its continuing suitability and to ensure it is aligned with the needs of service users and the regulatory and/or accreditation requirements.