EPBS European Association of Biomedical Scientists

European Biomedical Scientists: Standards of Proficiency

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European Association for Professions in Biomedical Science
Association internationale sans but lucratif
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I – Introduction

The European Association of Biomedical Scientists (EPBS) was formed in May 1999 at The Hague, Netherlands. This International Non-Profit Association (AISBL) is committed to promoting best practice and ethics for biomedical laboratory scientists, herein after referred as biomedical scientists throughout Europe. It is officially registered under the Belgian law in Brussels.
EPBS is established to promote best practice and ethics among biomedical scientists working in clinical diagnostics and research in Europe.
The non-profit purpose of international interest is achieved through the following activities:

1. **Education and training**
   - Setting minimum criteria for the education and training of biomedical scientists in Europe to ensure that all scientists have the knowledge, skills and competence to provide a safe and effective clinical diagnostic laboratory service
   - Promoting the development and access to post graduate programmes leading to specialisation of biomedical scientists in all areas of clinical laboratories to enssure that Europe can respond to the changing healthcare environment
   - Co-operating with teaching establishments offering biomedical science education to achieve EPBS aims
   - Recognising the essential role of continuous professional development (CPD) to quality healthcare, promoting access to CPD programs for all biomedical scientists

2. **Public health and patient safety**
   - Promoting the essential role of biomedical science in health care systems to the general public
   - Promoting to healthcare stakeholders the essential role of biomedical scientists in delivering quality clinical laboratory diagnostics for the prevention, diagnosis and disease monitoring and in screening programs
   - Providing advice on best practice in the provision of clinical diagnostic services within healthcare organisations and community services

3. **Ethics**
   - Promoting adherence to the highest ethical standards by European biomedical scientists as outlined in the international code of ethics for biomedical laboratory scientists

4. **Political**
   - Ensuring the mutual and official recognition in equivalence of standards concerning biomedical science and its harmonisation, in matters of information, procedures, education, training, testing, measurement resources, laboratory standards, quality management and competence, regulation and code of ethics across Europe
   - providing advice, consultation and recommendations on aspects of biomedical science to the European Commission and other relevant European bodies and organisations
   - Working with competent authorities to facilitate the ‘free movement of the profession’ in Europe
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- Establishing relationships with active European and international organisations in the field of laboratory medicine
- Promoting the European vision of biomedical science among its members

In order to achieve its objectives, EPBS develops contacts with the European governing bodies, publish brochures, facilitate exchange programmes for students and professionals, draw up regulations intended to harmonise professional practices within the member countries and carry out any other activity consistent with the objectives above described
The Association may participate in any other activities and undertake any other actions that are directly or indirectly related to the objectives, or that are necessary or useful for the realization of such objectives.

II - Standards of Proficiency

The European standards of proficiency for Biomedical Scientists detail the basic knowledge skills and competencies that a biomedical scientist graduate must have in order to enter the profession. They are the threshold standards necessary to enter the profession.
These standards provide the assurance that the Biomedical Scientist has the basic knowledge, skils and competence to practise lawfully, safely and effectively, protecting the public.
The standards include generic elements, which apply to all professionals in healthcare, and profession-specific elements, which are relevant to biomedical science profession .
The standards are not hierarchical and are all equally important for practice.
This document sets out the European Standards of Proficiency for Biomedical Scientists under five domains:

1. Professional Autonomy and Accountability
2. Communication, Collaborative Practice and Teamworking
3. Safety and Quality
4. Professional Development
5. Professional Knowledge, Skills and Competencies

1. Professional Autonomy and Accountability

Biomedical Scientists will:

1.1 Understand Limits of their Practice

a) Be able to practise safely and effectively within the legal, ethical and practice boundaries of the profession within the country of practice;

b) Be able to identify the limits of their practice and know when to seek advice and additional expertise or refer to another professional;

c) Be able to make independent professional judgments which are evidence based.

1.2 Responsibility to the Patient

a) Be able to act in the best interest of patients at all times;

b) Be aware of current national guidelines and legislation relating to candour and open disclosur;

c) Respect and uphold the rights, dignity and autonomy of every patient;

d) Be able to exercise a professional duty of care;

e) Recognise the importance of practising in a non-discriminatory neutral, culturally sensitive way;

f) Understand and respect the confidentiality of patient and use information only for the purpose for which it was given/consented;

g) Understand and be able to apply the limits of the concept of confidentiality particularly in relation to child protection, vulnerable adults and elder abuse.

1.3 Responsibility for the Result

a) Ensure that there is traceability from patient sample to analytical result communication to the patient;

b) Analyse specimens using appropriate/relevant method/techniques;

c) Assess the validity of data/test results against a possible range of outcomes;

d) Interpret validated test results in light of clinical details provided;

e) Make decisions about reporting test results, repeating procedures, consulting senior staff and carrying out further testing within established guidelines;

f) Ensure the correct reference ranges and interpretative comments are provided to aid the clinicians treating the patient;

g) Ensure critical test results are given the correct attention and communicated promptly.

1.3 Responsibility to the Patient

h) Be able to act in the best interest of patients at all times;

i) Be aware of current national guidelines and legislation relating to candour and open disclosur;

j) Respect and uphold the rights, dignity and autonomy of every patient;

k) Be able to exercise a professional duty of care;

l) Recognise the importance of practising in a non-discriminatory, culturally sensitive way;

m) Understand and respect the confidentiality of patient and use information only for the purpose for which it was given/consented;

n) Understand and be able to apply the limits of the concept of confidentiality particularly in relation to child protection, vulnerable adults and elder abuse.

1.4 Responsibility to the Colleagues

a) Understand the role of policies and systems to protect the health, safety, welfare, equality and dignity of service users, staff and volunteers;

b) Understand confidentiality in the context of the team setting.

1.5 Responsibility to Healthcare System

a) Be able to recognise and manage the potential conflict that can arise between confidentiality and whistle-blowing;

b) Adapt and respond to extraordinary crisis situations in the laboratory such as pandemic, cyberattacks or war;

c) Ensure that contingency plans are in place to provide, and report on, analysis in emergency situations where equipment or Information technology systems fail.

1.6 Responsibility to Protect and Manage Data

a) Be aware of current data protection, freedom of information and other legislation relevant to the profession and be able to access new and emerging legislation;

b) Understand the importance of and, if relevant, be able to gain informed consent to carry out assessments, research or audit; be able to document evidence that consent has been obtained and be able to verify documented evidence that consent has been obtained;

c) Be aware of current legislation and guidelines related to informed consent for individuals with lack of capacity.

1.7 Responsibility to Self

a) Comply with the profession's Code of Ethics;

b) Demonstrate knowledge of contemporary ethical issues affecting biomedical laboratory science;

c) Recognise personal responsibility and professional accountability for one's actions and be able to justify professional decisions made;

d) Be able to take responsibility for managing one's own workload as appropriate;

e) Understand the principles of professional decision-making and be able to make informed decisions within the context of competing demands including those relating to ethical conflicts and available resources;

f) Be aware of and be able to take responsibility for managing one's own health and wellbeing.

2. Communication, Collaborative Practice and Teamworking

Biomedical Scientists will:

2.1 Communicate actively with service users

a) Be able to communicate results understandably to service users (e.g. patients, relatives, medical, health and social care professionals) – this may include diagnosis, prognosis, monitoring and treatment options in line with national legal requirements/regulations – and be aware when a professional translator should be involved;

b) Be able to provide both a summary of complex scientific ideas and findings of research and to critically evaluate evidence presented to you;

c) Be able to adapt communication style and methods to meet the different service user's understanding and background bearing in mind different cultures, languages, beliefs, health care needs along with variations in health literacy.

2.2 Collaborate with other health care professionals and patients.

a) Collaborate actively with other health care professionals by expressing professional, informed, and considered opinions;

b) Be able to discuss patients' health needs with them so they can be empowered to communicate their needs, choices, and concerns. Facilitate them to manage their well-being where possible and provide advice on self-treatment where appropriate;

c) Be able to produce clear, concise, accurate and objective documentation complying with local/national documentation standards (e.g. terminology, signature requirements).

2.3 Support and perform teamwork

a) Understand and be able to recognise the impact of effective leadership, management, and conflict management on practice;

b) Understand the need for collaboration and partnership with other health care professionals where appropriate by contributing effectively to decision making within a team setting to achieve the best treatment options for the patient and act in patient's best interests;

c) Understand the need of good relationship with professional and interprofessional colleagues based on mutual respect and trust and to be able to act as a team leader as well as a team player.

3. Safety and Quality

Biomedical Scientists will:

3.1 Have general knowledge of the requirement for safety and quality in laboratory investigations practices by:

3.1.1 ISO control setting:

a) Understand the significance of safety and quality throughout the research and measurement process, including pre-analysis, analysis, and post-analysis stages, is crucial for patient safety and accurate results;

b) Understand that the laboratory facilities and environmental conditions must be suitable for laboratory activities, including pre-examination facilities and sites other than the main laboratory premises, to ensure patient, visitor, laboratory user, and personnel safety, and to maintain the validity of results;

c) Additionally, it is important to promote sustainability in laboratory practices to minimize any negative impact on the environment and create an eco-friendlier laboratory;

d) Understand the need to monitor, evaluate and/or audit the quality of practice and be able to critically evaluate one's own practice against evidence-based standards and implement improvements based on the findings of these audits and reviews;

e) Understanding the impact of all inputs and environmental on the quality of analysis;

f) Understand the principles of quality improvement and quality management systems, with specific reference to quality assurance;

g) Understand how to manage the safe and ethical collection, handling, retention, biobanking, and disposal of cells, tissues, genetic and microbial material, as well as comprehend the various hazard groups and their associated risk containment measures and be able to apply appropriate standards and procedures;

h) Understand if a sample that is compromised and is clinically important or irreplaceable is accepted, the final report must disclose the issue and, if relevant, caution against interpreting results that may be influenced, considering the risk to patient safety;

i) Be able to justify the selection of, and implement, appropriate assessment techniques and be able to undertake and record a thorough, sensitive, and detailed assessment;

j) Be able to analyse and critically evaluate the information collected in the assessment process and to calculate and understand the impact of uncertainty of measurement;

k) Be able to demonstrate sound logical reasoning and problem-solving skills to identify root cause of process/analytical failures and determine appropriate corrective and preventative actions and to develop action plans to resolve;

l) Be able to demonstrate an evidence informed approach to professional decision-making, adapting practice to the needs of the service user and draw on appropriate knowledge and skills to make professional judgments;

m) Be able to prioritise and maintain the safety of patient samples and laboratory staff;

n) Be able to carry out and document a risk analysis and implement effective risk management controls and strategies; be able to clearly communicate any identified risk, adverse events or near misses in line with current legislation/guidelines and revise the plans as necessary and where appropriate, in conjunction with the service user;

o) Be able to establish safe environments for practice which minimises risks to service users, those treating them and others, including the use of infection prevention and control strategies;

p) Be able to comply with relevant and current health and safety legislation and guidelines.

3.1.2 Not an ISO control setting:

a) Be able to advise on safe environments for practice which minimises risks to service users, those treating them and others, including the use of infection prevention and control strategies;

b) Be able to advise of the choice of point of care testing for use in the community by professionals or for self-testing and quality control procedures which should be implemented;

c) Be able to advise on the education and training of non-laboratory staff undertaking clinical diagnostic testing in the community and their proficiency assurance and record keeping.

4. Professional Development

a) Take responsibility for your own professional development and understand the need of continuous professional development to integrate the most up to date knowledge, skills, and competencies in professional practice to enhance your professional growth and add benefit to patients;

b) Understand the need to have evidence of ongoing continuous professional development and education, and be aware of the National and European professional regulation requirements;

c) Be able to reflect critically on your own professional practice and then establish personal goals for professional development;

d) Be able to communicate how your professional goals are aligned with your institution goals where possible;

e) Having established your professional development needs prepare a plan and be able to select appropriate activities to achieve your aims, and be able to integrate new knowledge and skills into professional practice;

f) Participate in post-graduate qualifications, or research opportunities, as available and appropriate to aid your professional development;

g) Understand the importance of supervision, feedback, and peer review opportunities in your professional development;

h) Be able and willing to mentor Biomedical Laboratory Science students and new graduates, participating actively in professional group and scientific development;

i) Understand and recognize the relevance of active participation in performance review for personal and professional development and for effective service delivery;

j) Understand and recognize the impact of personal values and life experience on professional practice and be able to manage this impact appropriately without compromising patient care.

5. Knowledge, Skills, and Competencies

5.1 Knowledge

A graduate in Biomedical Sciences must be able to demonstrate knowledge and understanding of health and disease states relevant to their practice by:

a) Providing evidence of mastery of the key concepts of biological, physical, social and physiological sciences supporting the practice of laboratory medicine;

b) Understanding the structure and function of the human body in normal and disease states along with the pathophysiology of disease;

c) Understanding the structure, function and metabolism of organs, cells, tissues and molecules involved in the physiological mechanisms in health and disease in order to identify and recognise cell, tissue and metabolic changes, relating them to the diagnosis, prognosis and therapeutic intervention;

d) Understanding of the genetic determinants of health and disease along with the methods to analyse genetic material in both clinical laboratory and research settings;

e) Understanding of diseases, immunological disorders, and immune response principles;

f) Understanding the classification, structure and biochemistry of microorganisms, their classification as pathogens and their adaptive response to environment and therapeutic interventions;

g) Understanding the principles of genetic and genomic medicine and the mechanisms of heredity;

h) Understanding the effects of toxins or drugs on the body;

i) Understanding of the unique contribution to, and critical importance of, each specialty, and subspecialty of biomedical science in the diagnosis and treatment of disease;

j) Understanding the contribution of laboratory medicine in establishing the cause of death.

k) Evaluating and verifying laboratory tests and methods to support diagnosis, screening and monitoring of disease;

l) Understand how laboratory results can help distinguish between normal and disease state;

m) Evaluating data, from both routine analysis and research findings, using appropriate statistical analysis.

5.2 Skills

A graduate from a programme educating Biomedical Scientists for practice will be able to:

a) Undertake essential practices in the areas of measurement, production and analysis of clinical and laboratory data;

b) Use diagnostic techniques and appropriate equipment correctly and safely;

c) Be aware of the need to validate and evaluate new methods of diagnosis before the routine use;

d) Be aware of appropriate ISO or other standards and the need for, and methods, to evaluate and verify new analytical methods before the routine use;

e) Demonstrate skills in the use of information technologies and adequate communication methods;

f) Safely and appropriately use information technology and communication methods and compliance with General Data Protection Regulation legislation;

g) Translate professional principles into practice ensuring the most appropriate analysis and approach to meet the needs of the individual and the presenting situation;

h) Critically interpret scientific research data contributing to epidemiological research and evidence-based practice;

i) Maintain Continuous Professional Development, ensuring that professional knowledge, skills and competencies remain current through a combination of self-directed lifelong learning and academic updates;

j) Ensure that quality assurance processes in use are robust and appropriate, meet the needs of the service and protection of the public;

k) Lead and participate in practice and quality audit;

l) Demonstrate leadership, initiative and creativity exercising their professional skills autonomously and supporting the professional development of colleagues;

m) Offer professional opinion relating to their area of expertise contributing to clinical and scientific decision making;

n) Develop and lead the quality management system in the laboratory and ensure adherence to biosafety;

5.3 Competence

A graduate from a programme educating Biomedical Scientists for practice will have a basic competence in; and be able to practice in all areas of diagnostic pathology and laboratory medicine.

a) Selecting, and where necessary collecting the appropriate biological samples for clinical and laboratory analytical need;

b) Selecting, evaluating, and implementing specific techniques in histopathology, cytopathology, immunohistochemistry and molecular diagnostics for use in anatomical pathology and postmortem practice;

c) Preparation, staining and screening of cervical smears and other cytological specimens;

d) Performing biochemical analysis of specimens to assist in the diagnosis, detection and monitoring of health and disease understanding the limitations of such analysis and uncertainty of measurement;

e) The use of routine and specialized instrumentation including for advanced molecular techniques;

f) The principles of analysis and its appropriate use in the measurement of immune response and assessment of the host response to organ transplantation;

g) The assessment of blood cells in peripheral and bone marrow circulation in diagnosis of anaemia; hemoglobinopathies, thalassemia, coagulation disorders and hematologic malignancies;

h) Identification of alloimmune antibodies in blood to ensure correct matching of donor blood for recipients and to diagnose and monitor Haemolytic Disease especially in the fetus and newborn;

i) The safe preparation, storage and use of blood components; selection of blood components for transfusion and possible adverse effects; destruction of the blood cells by the immune system and on histocompatibility transplantation;

j) Selection, evaluation and implementation of appropriate techniques for the analysis of genetic material and the implications of the use of algorithms for data analysis;

k) Assessing the adequacy of staining for safe diagnosis of disease in tissue and the appropriate use of stains, immunohistochemical and molecular techniques to contribute to diagnosis;

l) Selecting evaluation and implementation of appropriate techniques for the identification pathogenic and environmental microorganisms from clinical or environmental samples, understanding epidemiology of diseases, assessing susceptibility to antimicrobial therapies;

m) Use of laboratory analysis to monitor response to therapeutic interventions;

n) Evaluate the results of laboratory analysis and their contribution to patient care in light of the uncertainty of measurement;

o) Adhere to standard operating procedures and ensure compliance with *In Vitro* Diagnostic Regulation legislation;

p) Assess patient data in light of quality control data, ensuring error is minimised, undertaking risk assessments and where appropriate initiating recall of issued results;

q) Design and execute research, evaluate and interpret data, collating findings in a scientific report for presentation and publication.

Appendice

Appendix 1: Constitution of the EPBS Working Group

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