



GOOD PROFESSIONAL PRACTICE FOR BIOMEDICAL SCIENTISTS

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About this document

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Comments: The IBMS has updated this version to account for changes and reform that have influenced and impacted on the profession in the last couple of years. However, many of these changes are still ongoing while there are a number of reports to be published in the near-future that will also affect concepts and standards outlined in GPP. The IBMS will therefore be further considering and consulting on GPP and will be releasing a final updated version in early 2011.

The interim version was developed by all the IBMS standing committees and advisory panels. It was also put out to consultation with IBMS member between 10 June 2008 and Friday 15 August 2008 and comments received contributed to the development of this version.

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1 INTRODUCTION

1.1 Why we need *Good Professional Practice*

Professions hold a body of specialist knowledge and skills that provide an important need and function for society. There is a further responsibility on all professions in medicine and healthcare to have a duty of care for the health and well-being of patients who require their services.

Biomedical scientists, like other professionals, follow a model of education, registration and professional qualification. They are regarded as autonomous accountable professionals who can make informed, reasoned and justifiable decisions about their practice and ensure it is effective and competent. They also provide and participate in complex services that can involve many different professional groups.

One of the most important roles of the IBMS as a professional body is the development and monitoring of professional standards of practice to protect patients and to support the progress of biomedical science.

To help with decision-making, leadership and safe effective practice biomedical scientists, like other professionals, require and expect expert guidance from their professional body. *Good professional practice* outlines how, as a profession, biomedical science can aim to provide the highest quality of service. It defines the level of practice expected from biomedical scientists and their duty of care to patients as well as their responsibilities to fellow scientists, other healthcare professionals and the profession itself.

Good Professional Practice for Biomedical Scientists summarises current regulations and guidance relating to laboratory medicine, provides information on generic requirements set by regulation and clarifies how these relate to biomedical science.

Biomedical scientists must be aware of British, European and international standards that govern and affect pathology laboratory practice, yet also understand that no set of standards or guidance can be fully prescriptive. *Good professional practice* will always require a degree of personal judgement; therefore biomedical scientists are always encouraged to seek and give advice and support from employers, professional bodies, fellow professionals and colleagues.

Good Professional Practice also provides information on additional professional and specific guidance provided by the IBMS and other organisations such as The Royal College of Pathologists.

First and foremost practising biomedical scientists must abide by the legal and statutory requirements regulating the profession. Failure to do so could result in a biomedical scientist being suspended or removed from the Health Profession Council's register. Institute members should note that failure to adhere to legal requirements of practice and recommended principles of professional good practice could affect an individual's cover under the Institute's professional indemnity insurance scheme, and may result in expulsion from the Institute's membership.

While much of *Good Professional Practice* relates to biomedical scientists working in the National Health Service, its principles can equally apply to and guide all professionals working in the field of biomedical science.

1.2 Help and support for good professional practice

The Institute can provide professional support for its members in a number of ways.

- Members can directly contact the IBMS, either by telephone on + 44 (0)20 7713 0214 or by email on mail@ibms.org.
- Members can contact their local national or regional Council member for advice and support. Contact details are available in the IBMS diary or by contacting the IBMS office.
- Specialised support and professional representation is also available in the devolved home countries of the United Kingdom.

- Although the IBMS is a multidiscipline organisation with members working in a diverse range of specialties, its advisory panels provide pools of scientific and professional expertise, knowledge and advice to guide the IBMS. The members of these panels are recognised for their experience and expertise, which is used to develop biomedical science and the work of the Institute. The panels also provide expert advice for members on request. More details on contacting the panels and their work can be found at www.ibms.org or by contacting the Institute.
- Web discussions forums are available in the members area of the Institute's website that enables biomedical scientists to provide support, exchange information and post questions and comments.

1.3 Your help

Good Professional Practice reflects and outlines standards and practice that in the modern professional and scientific environment are constantly evolving. One set of guidance or standards cannot fully embrace the diversity and complexity of biomedical science. Biomedical scientists are therefore encouraged to communicate with the Institute with suggestions and feedback on *Good Professional Practice* to further develop and enhance professional guidance for the benefit of colleagues and the profession.

2 IBMS AND EXTERNAL STANDARDS

Biomedical scientists benefit from and practise to professional standards set by a wide range of external bodies and systems. These standards cover many specific areas of practice such as quality assurance, health and safety, infection prevention and control and transport of infectious substances.

See *Useful contacts* for reference of website links.

The Institute through its Council and its network of representatives are fully involved in the development of external standards and guidance to practice through consultation, representation and professional body input.

2.1 Health Professions Council (HPC)

The HPC is an independent, UK-wide regulatory body responsible for setting and maintaining standards of professional training, performance and conduct of the healthcare professionals that it regulates, including biomedical scientists.

The *Health Professions Order (2001)*¹ provides statutory regulation for all professionals practising under the protected title of 'Biomedical Scientist' and gives authority to the HPC to register biomedical scientists and to regulate their activities.

Thus members of the public who need the services of biomedical scientists can be assured that they are receiving attention from professionals who have met, and are continuing to meet, minimum standards of practice and training.

The Institute of Biomedical Science verifies that professional competence assessed against the *HPC Standards of Proficiency*² has been achieved and awards certificates of competence to biomedical scientists that are eligible to become registered with the HPC.

2.2 The IBMS and the HPC

The Institute, although entirely independent of the HPC, works in close cooperation with it to ensure that regulatory framework and professional standards are in harmony. The IBMS endorses all HPC standards and expects its members to integrate and maintain them as part of their practice. Where biomedical scientists work outside of the statutory remit of the HPC the IBMS expects them to work to equivalent professional standards.

The IBMS may initiate disciplinary action that could lead to the expulsion from its membership of anyone who has had an allegation about their fitness to practice upheld by the HPC, or has been found guilty of gross professional misconduct.

2.3 Clinical Pathology Accreditation CPA (now part of UK Accreditation Service - UKAS)

The CPA was purchased by UKAS in 2009 although accreditation standards and documents are still referenced to CPA. UKAS externally audits and accredits laboratories against defined standards of practice, which are confirmed by peer review. The Institute, with other professional bodies, provides professional input essential for the development and maintenance of standards for the assessment of laboratories.

2.4 Other relevant bodies

Further relevant bodies that have authority and influence standards include:

- Royal College of Pathologists
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- Health and Safety Executive (HSE)
- Human Tissue Authority (HTA)
- National Health Service Cervical Screening Programme (NHSCSP)
- NHS Breast Screening Programme (NHSBSP)
- Other national screening programmes and counterparts in Northern Ireland, Wales and Scotland

- NHS Blood and Transplant and counterparts in Northern Ireland, Wales and Scotland)
- NHS Litigation Authority (NHSLA)
- National External Quality Assessment Schemes (NEQAS)
- National Pathology Benchmarking Service
- government departments and devolved authorities across the United Kingdom.

See *Useful contacts* for reference of website links

2.5 The IBMS and The Science Council

The Institute of Biomedical Science has been granted a licence by The Science Council to award the designation Chartered Scientist (CSci) to qualifying IBMS members.³

It is a requirement of The Science Council that all Chartered Scientists demonstrate their role in the wider scientific community by maintaining continuing professional development to reflect the benchmark of best practice and scientific status. The IBMS monitors the continuing professional development of biomedical scientists who have been awarded CSci through the IBMS as a licensed body.

2.6 IBMS, Agenda for Change and trade unions

The Institute, by its nature as a professional body, cannot be involved in negotiations over Agenda for Change, pay or terms and conditions of employment, which are set by the employer and represented by trade unions.

2.7 The IBMS and employers

The main employers of biomedical scientists in the United Kingdom (UK) are the health services across the UK which encompass individual trusts and affiliated employers, e.g. Health Protection Agency (HPA) and the National Blood Service (NBS).

Other employers are universities, veterinary institutions, and industrial and commercial sector employers. All these bodies have professional practice policies and procedures of their own with varying fields of applicability. Biomedical scientists, whether employed primarily in clinical practice, teaching research or management of their profession, must conform to their employer's policies and procedures.

2.8 Devolution

Devolved home country health departments are exercising differing influences through their evolving national policies on health and workforce. The IBMS works to ensure that interests of biomedical scientists are represented equally with the devolved authorities in each home country.

2.9 International standards

Increasing globalisation, the expansion of the European Union and greater workforce mobility has seen an increasingly influential international dimension to biomedical science in the UK with a greater consciousness of international standards. The coordination of international standards relating to the education of professionals is becoming increasingly important, especially within Europe, where regulation could be freely transported from one national regulatory body to another.

There are a number of international standards relevant to the profession:

- CPA standards incorporate all the requirements of the international standard ISO 15189; 2007 *Medical laboratories - Particular requirements for quality and competence*⁴
- ISO 15190 *Medical laboratories - Requirements for safety*⁵
- TC 212 WG1 *Clinical laboratory testing and in vitro diagnostic test systems*⁶
- ISO 22870:2006 *Point-of-care testing*⁷.

Institute representatives have been involved in multidisciplinary international forums, developing British and international standards at the BSI such as ISO 15189, ISO 15190, which has significant impact on the profession, and ISO TC 212 WG1.

3 CAREER-LONG LEARNING

Science, technology and best practice are constantly evolving and therefore biomedical scientists need to continuously maintain fitness to practice and update their skills and knowledge through career-long learning.

3.1 Continuing professional development (CPD)

CPD should be integrated within all steps of the career pathway of a biomedical scientist. The Institute's CPD scheme provides a framework of learning activities, which may be undertaken throughout the career of a biomedical scientist to maintain, improve and extend knowledge and skills for safe and professional practice. The Institute's scheme is mature and comprehensive and addresses the requirements of the HPC and The Science Council.

The HPC has set standards for CPD that all registered biomedical scientists must meet in order to retain their registration.⁸ Full details of the HPC requirements for demonstration of undertaking CPD can be found on the HPC website at www.hpc-uk.org.

The IBMS is licensed to award the designation, Chartered Scientist, to eligible biomedical scientists. One of the criteria for Chartered Scientist is being able to provide documented evidence of CPD, either through the Institute's scheme, that of another professional association, or a personal development plan for two years prior to application. Maintaining chartered scientist status requires a CPD report summary of activity at the point of revalidation currently every five years but from 2011 becoming annually due to changes in the Science Council revalidation rules.

3.2 Standards of practice

Following registration biomedical scientists can follow a diverse range of career pathways. Whatever roles and responsibilities are assumed during career progression, biomedical scientists must never abandon the core values of the profession. Basic standards of proficiency must still be met whatever a biomedical scientist's current scope of practice.

The *HPC Standards of conduct, performance and ethics* state that biomedical scientists must be "able to practice the basic skills of your profession safely, even if this no longer forms the basis of your day-to-day work".⁹ HPC registrants in management, education or research must still be able to meet the *HPC Standards of Proficiency*.

3.3 Professional qualifications

The Institute supports the professional and career development of biomedical scientists through a framework of training and qualifications. This enables biomedical scientists to demonstrate their expertise within their discipline or specialism with qualifications unique to biomedical science, developed by the profession in direct response to service needs.

The framework of qualification is a nationally recognised system of professional certification independently recognised by the College of Biomedical Scientists. It has been developed to align with the healthcare scientist career framework¹⁸ levels and also the banding criteria of Agenda for Change.

The aim is not just for skill and expertise to be recognised by the professional body, but also to help the biomedical scientist demonstrate required knowledge and skills to employers and the public.

3.3.1 Specialist Practice: Specialist Diploma

The IBMS has developed the Specialist Portfolio to enable the recognition of post-registration (newly qualified) training and assessment of biomedical scientists. The portfolio enables biomedical scientists to provide evidence of training, practical skills, specialist knowledge and competency gained in the two years after registration and the award of the Licentiate class of membership by the IBMS. Completion of the portfolio and successful assessment will lead to the awarding of a Specialist Diploma.

Experienced biomedical scientists may also wish to complete additional portfolios to demonstrate broadening of their specialist knowledge into other areas outside their original specialism. This is particularly relevant when laboratories merge or when deciding to move to a new area of practice.

3.3.2 Certificates of expert practice

Certificates of expert practice operate below the level of the Higher Specialist Diploma (HSD). These enable biomedical scientists to demonstrate knowledge and skills in a highly specific area of practice within their normal specialty. These are available in some scientific specialist areas and also in quality management and training. The latter two are available via a distance learning programme.

3.3.3 Higher Specialist Diploma

The Higher Specialist Diploma (HSD) is the Institute qualification for biomedical scientists wishing to be recognised for the acquisition of professional knowledge, skills and competence beyond the level of an MSc. It is designed to demonstrate readiness for promotion to a more senior level within the overall healthcare scientist career pathway. It is a benchmark, not just of scientific knowledge and interpretative skill, but also of an understanding of laboratory management, pathology service planning and delivery and political and professional awareness.

3.3.4 Diplomas of expert practice

Diplomas of expert practice are the consolidation of high levels of skill and scientific expertise in more traditional areas of biomedical science practice. These are only open to members in the class of Fellow.

3.3.5 Advanced specialist diplomas

Advanced specialist diplomas are for roles and responsibilities in traditional areas of pathology and laboratory medicine at the highest level of clinical practice and/or consultation.

Detailed information on all the Institute's professional qualifications is available on the Institute's website.

4 CODE OF CONDUCT

All members of the Institute of Biomedical Science shall always:

1. Exercise their professional knowledge and skill with judgement and care for the benefit of the wider general public and in the best interests of the users of the service.
2. Demonstrate the highest standards of conduct, honesty and integrity in their personal and professional behaviour.
3. Understand, recognise and work within the limits of their professional knowledge, skills and experience.
4. Recognise the beliefs and values of the wider general public, the users of the service and professional colleagues, treating them on a fair and equitable basis.
5. Ensure their own beliefs and values do not prejudice or compromise their ability to carry out their professional roles and duties.
6. Maintain, improve and keep up to date their professional knowledge and skills.
7. Aid and support the development of biomedical science by education or training of their professional colleagues, the users of the service and the wider general public.
8. Promote the study and activity of biomedical science by promotion of the values, aims and objectives of the Institute of Biomedical Science.

Failure to comply with this Code of Conduct may result in action being taken under Article 16 of the Institute's Articles of Association which state: "A member shall cease so to be if the Council considers him to have been guilty of improper conduct rendering him unfit to be a member of the Institute".

5 GUIDE TO GOOD PROFESSIONAL PRACTICE

5.1 Professional standards and guidelines

There are several standards and guidelines to which biomedical scientists in healthcare, collectively and individually, should conform. These include:

- Health Professions Council standards
 - Standards of Conduct, Performance and Ethics⁹
 - Standards of Proficiency²
 - Standards of Education and Training¹⁰
 - Standards for Continuing Professional Development⁸
- this guide to *Good Professional Practice* issued by the IBMS
- *Standards for the Medical Laboratory* issued by Clinical Pathology Accreditation (UK) Ltd (now part of UKAS)^{11,12,13,14}
- Good Laboratory Practice¹⁵
- External Quality Assessment¹⁶
- continuing professional development
- Chartered Scientist standards
- Care Quality Commission regulation and guidance for all healthcare staff and independent staff.

The ethos behind all standards is patient safety and the provision of a high-class professional service and safety for patients.

The IBMS publishes guidance on specific topics which is available in leaflets available from the IBMS office or on the IBMS website at www.ibms.org/publications. These guidelines are not exhaustive and opportunities to implement further good practice should always be acted upon.

5.1.1 Independent health care

The Care Quality Commission (CQC) is the health and social care regulator for England, whether they're provided by the NHS, local authorities, private companies or voluntary organisations. The CQC works to ensure that essential common quality standards are being met where care is provided and has a wide range of enforcement powers to take action if services are unacceptably poor.¹⁷

5.2 Professional ethics

Registration with the HPC permits the use of the protected title 'Biomedical Scientist'. The HPC document *Standards of Conduct, Performance and Ethics*⁹ establishes the framework within which biomedical scientists work in relation to patient expectation, professional limitations and confidentiality. However, ethics are more than just documented enforceable requirements. The ethical framework within which biomedical scientists should practise is concerned with:

- professional competence
- personal conduct
- professional relationships with other healthcare colleagues
- public duties - confidentiality, honesty, diligence, integrity.

The Institute's Code of Conduct sets the ethical standards of personal and professional conduct required of its members.

5.3 Professional practice

5.3.1 Scope of practice

Biomedical scientists have gained a generic basic level of knowledge and skills by the time they have completed a biomedical science degree accredited by the IBMS. Degree accreditation by the

Institute confers a quality 'kite mark' and ensures the content and delivery of the curriculum is appropriate to professional requirements.

Publications such as the QAA *Benchmarking Statement for Biomedical Science*¹⁹ and the HPC's guidance that accompanies the *HPC Standards of Education and Training*¹⁰ describe the educational core of pre-registration education, while the *HPC Standards of Proficiency*² describe the outcomes to be demonstrated at the point of registration.

Following registration the career of a biomedical scientist can move into areas of specialised practice and their scope of practice can evolve beyond a generic, basic foundation where they may be unable to meet all of the professional standards. The HPC recognises this and advises that this is not a problem if registrants practice within the limits of their scope of practice. Any registrant moving out of their scope of practice must do so lawfully and safely.² This means that biomedical scientists must exercise personal judgement in determining the necessary training and experience needed for safe and effective practice.

However, the basic standards of proficiency must continue to be maintained for one's current scope of practice. Biomedical scientists must always ensure that, when moving to practise in a new area, or returning to practise in an old area, they undertake suitable refresher training or education before engaging in autonomous practice.

5.3.2 Skills for Health and competencies

Competences are National Occupational Standards (NOS) and National Workforce Competences (NWC) describe performance as outcomes of a person's work. Competences set out the performance criteria (what the person must do) and underpinning knowledge and understanding required to undertake that particular function.

Skills for Health has lead responsibility for developing competences for the health sector, and work collaboratively with the relevant stakeholders, practitioners and experts to write the competences. They are not compulsory but using competences is recommended good practice by Skills for Health and the UK Commission for Employment and Skills.

5.3.3 Competence

All laboratory staff should be appraised annually as a minimum, so that further education and/or training needs can be identified, discussed and incorporated into a Personal Development Plan. The appraisal of competence itself should evolve and respond to professional and scientific changes and influences, as well as the requirements of the individual employer.

Continuing professional development is integrated within HPC registration as one method of ensuring that staff retain their capacity to practise safely, effectively and legally within their evolving scope of practice.

Biomedical scientists working outside organisations with a formal appraisal system are encouraged to seek out an appropriately experienced and qualified colleague as a professional mentor.

5.3.4 Returning to practice

The Health Professions Council have published a guidance document *Returning to Practice* for health professionals who have taken a break from practicing, and who wish to start practicing again.

Some of the main points emerging from the HPC document are:

- The individual has personal responsibility for deciding what their specific needs are and how they are addressed within their own scope of practice. They decide if they met the HPC standards of proficiency, i.e. fitness to practice. In this context it is worth noting that the supervisor (of any supervised training) must be on the relevant part of the register but does not need to confirm fitness to practice, but simply countersigns to confirm the period of supervision.

- The HPC guidance contains clear descriptions regarding updating activities: supervised practice, formal study or private study.
- The 30 or 60 day period for updating knowledge and skills can be through any combination of supervised practice, formal study or private study (the latter to a maximum of half the period).

Although the Institute is not involved in the assessment of the individual returning to practice, the Institute recommends the following guidance to assist with structuring the updating period. This should be used in conjunction with the HPC guidance document.

The Institute recommends that:

1. Individuals wishing to return to practice in a clinical laboratory should use the Institute portfolios as a framework for updating their knowledge and skills, for example, the Specialist Portfolio in discipline specific areas.
2. A self-assessment of knowledge and skills achieved prior to a break in practice should be conducted against the portfolio to identify training needs (Gap Analysis)
3. Training should be carried out in an Institute approved training laboratory and in accordance with IBMS Good Professional Practice guidelines.
4. The period of updating should be signed off by a registered biomedical scientist as a record of areas of the specialist portfolio completed and whether competence to practice was achieved.
5. The individual completing the period of updating should complete an IBMS reflective practice statement to confirm how they consider the period of updating to be successful.

5.4 Working in partnerships

Biomedical scientists operate in many diverse roles as members of a team providing multi-disciplinary and multi-professional healthcare across different care pathways.

Biomedical scientists must be able to work in partnership with other professionals, support staff and service users, both as individual biomedical scientists and as part of a multi-disciplinary team.

Biomedical scientists must be aware of and respect the integrity of other professional groups and work together in the interests of patients and users of their services. They should exhibit a professional, courteous and respectful attitude towards patients and healthcare colleagues and be sensitive to the objectives and values of other professional work groups.

Good communication skills are vital for relaying clear and concise information, advice, instruction and professional opinion to colleagues and service users. Biomedical scientists must be able to clearly inform colleagues of the outcomes of diagnostic procedures and supply colleagues with sufficient information to make informed decisions on the care of a patient.

When dealing with patients there should be a conscious awareness of their anxieties and those of their relatives. Concern and compassion are important elements of the proper handling and analysing of patients' samples.

5.4.1 Working for the organisation

The majority of biomedical scientists work for a NHS organisation or trust and they should be aware of their employer's mission statement and objectives. They should be clear about the personal contribution expected of them in support of these aims.

Biomedical scientists working outside of the NHS should also be cognoscent of their employer's corporate goals and standards.

The key role of diagnostics services in healthcare means that biomedical scientists need to be involved at all levels of the organisation as their professional input will help deliver service or influence change to improve patient care.

Within the NHS and other healthcare organisations, there may be working groups whose outcomes will impact on pathology services. Biomedical scientists are encouraged and have a professional responsibility to offer advice and expertise to such committees or working groups, for example those dealing with point of care testing, health and safety, or clinical governance. Biomedical scientists should also seek to ensure that the profession's voice is heard on other relevant groups, for example those with human resources, developing education and training strategies, workforce and trust site development remits. (See *Healthcare science and networking*)

Part of the professional role of biomedical scientists is to work with healthcare science colleagues or groups to enhance networking and clinical engagement.

Contributions must be made with integrity, respect for the views of others and without compromise to professional standards.

6 MANAGEMENT AND LEADERSHIP

Biomedical scientist managers have key roles in the management and leadership of laboratory services to ensure the good professional practice of individual, team and service. They will ensure that all staff are appropriately recruited, trained, qualified and competent. They will also seek to ensure that the performance and quality of laboratory services reaches the highest possible standards.

Regulatory and accrediting provide primary reference for laboratory and quality management and managers must make themselves familiar with the laws and regulations relevant to their workplace and working practices.

These laws and regulations will include:

- human resources (HR) issues, including
 - equal opportunities (diversity awareness)
 - recruitment and selection
- safety issues
 - Infection prevention and control
 - H&S at work
 - COSHH
- education issues, including
 - pre- and post-registration qualifications
 - training programmes
 - continuing professional development
 - appraisals
- flexible working regulations
 - maternity and paternity leave
 - adoption leave
 - carer leave
 - job share
 - part-time working
 - fixed term contracts
 - locum workers
- European law related to
 - staff and recruitment issues
 - purchasing standards
 - working time.

The above list is not inclusive and it is the responsibility of managers to keep abreast of new and revised laws, regulations and standards as they are introduced. Mis-understanding or lack of knowledge about laws and regulations can have a major effect on the provision of service. Managers will be expected to participate in in-house training and appropriate external courses that will help enable them to comply with policy, legislation and standards.

6.1 Awareness of organisational policies

It is necessary to be familiar with the policies of the organisation, including its strategic plans and visions, so that members or employees realise and enhance the value of their professional input. Professionals also have to balance their responsibilities to their employing organisation with their responsibilities as a registered professional.

6.2 Development of management awareness and ability

Management does not happen only at the top of a career ladder; rather it is a gradual evolution of experience, knowledge and needs, which begins early and continues throughout a career. Management and leadership is a skill that must be expressed at all levels within the profession.

By a process of continuing interest, education and development, there is an onus on the individual to progress his/her knowledge and abilities in the field of laboratory management. Those with responsibilities for other staff must exhibit appropriate management skills by fostering and developing management awareness and opportunities in their staff.

6.3 Head of department / laboratory director

The clinical head of department has ultimate responsibility for all clinical matters.

6.4 Laboratory manager

The laboratory manager provides leadership and deploys resources equitably in the best interests of department and to meet the service needs. The laboratory manager's role may also include responsibility for the scientific and technical work within the laboratory, for overall staff management and training and for the smooth administration of the department.

Laboratory managers will be involved with other managers in budget management and control and in the overall organisation of supplies and maintenance contracts for their own departments.

Staff recruitment is the responsibility of the manager and requires liaison with the personnel or HR department, to ensure that organisational policies are maintained¹².

Biomedical scientists in leadership and management positions have a responsibility for the teaching, training and education of all groups of staff in the laboratory. Statutory requirements are to be regarded as an absolute minimum, together with ensuring that best professional practice is achieved. Effective staff communication will be a crucial part of this role.

Business management is a wider role with responsibilities, which include liaison with users of the service and meeting their needs and demands.

6.5 Relationship between management and professional issues

With increased managerial responsibility there may be more potential for conflict between professional standards and organisational demands. Good management must be able to blend apparent differences and defend high professional standards whose primary aim is safeguard patient safety.

6.6 Staff management

Good working relationships are essential to a high quality laboratory service. Individual members of staff should be annually assessed so that their strengths can be used to benefit service while weaknesses can be addressed with specific development programmes which may include mentoring, additional training and CPD.

The needs of individual staff members must be addressed so that they may contribute fully to the effectiveness of the unit as the service develops. Job plans, personal professional development and appraisal will all form part of optimising the contributions each individual may make, including helping to realise ambitions and recognising limitations.

6.7 Training

Each laboratory will ensure that training managers and others have sufficient time within their job roles to perform the duties associated with the necessary initial and continuing training of laboratory staff. (See *Training*)

An essential part of delivering training is ensuring that individual members of staff receiving training are given appropriate time and financial resources to complete that training programme. It is the responsibility of the laboratory manager to ensure that appropriate resources are in place to achieve this.

6.8 Budgets

Management of the budget may be a responsibility devolved to the head biomedical scientist or to the business manager. These two functions may be combined.

The responsibility of the budget manager is to ensure that the budget is used appropriately for service provision and, by forecasting, help ensure it is sufficient to meet the demands on the service. All biomedical scientists have a responsibility to ensure that resources are used as efficiently as possible and to facilitate effective budget management in their area of practice.

6.9 Communications

Good understanding of aims and objectives are central to the operation of the laboratory. Misunderstandings are a common cause of grievance and may easily undermine the morale and enthusiasm of the workforce. Biomedical scientists should participate in relevant departmental meetings and ensure they are conversant with minutes and other appropriate documents. All biomedical scientists should be aware of formal (and informal) relationships within the department and with structures outside it.

7 MANAGING STAFFING AND WORKLOAD

For full information on managing staffing, skill mix and supervision please refer to the Institute's publication: *Managing Staffing and Workload*²¹.

8 LABORATORY RECORDS AND ARCHIVES

Confidentiality of information on individual patients must be preserved in accordance with CPA standards and the *Data Protection Act 1992*.²² Failure in this also contravenes one of the central tenets of the HPC Standards and can result in the ultimate sanction of removal from the Register.

The ethical use of tissue for non-diagnostic purposes has been an area of great public concern and biomedical scientists must be aware of and follow published guidance based on the requirements of the *Human Tissue Act 2004*.²³

The IBMS and The Royal College of Pathologists have produced guidance^{26, 24} on the retention and storage of pathological records and archives which includes recommendations to satisfy the requirements of the Act which must be observed. The Human Tissue Authority²⁵ has also issued codes of practice relating to the removal, storage, use and disposal of human tissue and organs.

Separate guidance has been published on the legitimate transfer of pathological specimens that may be requested for legal and forensic reasons.²⁸

9 TRAINING

Science, technology and best practice are constantly evolving and therefore biomedical scientists need to continuously maintain fitness to practice and update their skills and knowledge by implementing career-long learning and training.

All biomedical scientists have a professional obligation and a duty of care to ensure that they maintain their professional standards. This includes supporting the education and training of fellow biomedical scientists. This is essential to:

- maintain and develop the quality of service to ensure that it is compatible with the needs of service users and laboratory accreditation requirements,
- ensure a workforce that is competent and fit for purpose,
- meet the regulatory standards of the Health Professions Council,
- maintain and develop professional standards as set by the Institute of Biomedical Science,
- develop and promote biomedical science within the healthcare team,
- improve the quality of the professional pool of expertise,
- incorporate and develop new technologies,
- provide a system for staff development and progression,
- conform to Health and Safety legislation²⁷⁻³⁸ and external standards.

9.1 Trainers

The Institute recommends the appointment of a training manager as an individual with responsibility for planning the training needs of all non-medical staff in the department.

Individuals are required to have the appropriate knowledge and skill to deliver a training and education programme (CPA standard B 9.1) in accordance with guidelines from the relevant professional and registration bodies and commensurate with the needs of the service and professional development of staff.

The objective of the training manager is to plan programmes for all staff, which meet mandatory, departmental and individual objectives while still enabling the staff to deliver an effective laboratory service.

It is recommended that a training manager should be appropriately registered and a Fellow of the Institute, (FIBMS) and have a minimum of five years post-registration experience in an Institute approved training laboratory. It is desirable that the training manager holds a recognised training qualification such as an Institute Certificate of Extended Practice in Training or equivalent.

Further information on the role of training managers is available in the Institute's publication, *Guidance on the Management of Training*.

9.2 Training in the laboratory

There should be appropriate numbers of staff, with the required education and training, to support the training of student placements and trainee staff whilst meeting the demands of the service. (e.g. CPA Standard B2-1; HPC SETs 5.2, 5.8, 5.12 and 5.13).

Training must be supervised by registered biomedical scientists.

The IBMS recommends the following as evidence of commitment to professional training:

- an updated laboratory training policy and programme,
- a separate written programme that details the structured programme for training delivery,
- evidence of training and learning outcomes for peer assessment - all persons in training must complete the relevant professional portfolio with accompanying evidence of education and training and completion of learning,
- outcomes, including internal assessment, for peer assessment,

- a policy statement defining the differing roles of an appropriately qualified individual(s) managing and overseeing the training process (see CPA Standard B9, HPC SETs 5.1 and 5.2) and how that relates to the delivery of the training to all persons undergoing training,
- documentary evidence of the set learning outcomes as agreed with partner higher education institutions for placement students,
- a minimum of 5% of the biomedical scientist staff complement to be allocated to training,
- imaginative methods of training are encouraged and these may include, for example:
 - extra-numerary posts
 - co-operation between disciplines
 - co-operation between neighbouring hospitals and/or trusts,
- employers' requirement that all staff keep up to date and that staff participate in mandatory continuing professional development (CPD) as required by the HPC⁸,
- documentary evidence of staff development reviews conducted on an annual basis to identify further training needs with the appropriate evidence of actions taken (e.g. CPA Standard B7),
- a quantified training budget described in an appropriate currency per annum per biomedical scientist.

9.3 IBMS-approved training laboratories

Approval for laboratory training is granted by the Institute on the basis of initial self-assessment (conditional approval) and subsequent review (full approval) as laboratories are visited as part of the registration portfolio verification and specialist portfolio assessment processes.

The Institute's standards for pre-and post-registration training in clinical laboratories³⁹ uphold existing and established standards of good practice and are used to ensure that individuals completing either the Institute's Registration Portfolio, the Institute's Specialist Portfolio or higher qualifications, receive structured and supported training. A requirement for completion of the associated portfolios is that it takes place in Institute approved training laboratory or laboratories.

Laboratories approved for training by the Institute will be expected to either have CPA accreditation or be working towards it. Where CPA accreditation has not yet been achieved, the laboratory has conditional approval, or CPA accreditation is deemed inappropriate, then working towards compliance with CPA *Standard B9 – Staff Training and Education* will still be expected.

9.4 Induction training for higher grades

All new staff must receive induction training that must include an introduction to a new workplace and training for newly promoted roles and responsibilities, according to the specific needs of the individual. The individual organisation's mandatory training programmes will be included in this compliance.

9.5 Training of support grades

Appropriate and thorough training is an integral part of the responsibility for supervision of all staff employed in support grades. A named individual biomedical scientist should be responsible for support worker training, including induction training.

Training of support workers must ensure a thorough understanding of the function of the laboratory and its role within hospital and healthcare. In many cases, the relevant training will be in-house, will be specifically directed to the needs of the laboratory, and will be updated as necessary.

Training must include the core generic values of *HPC's Standards of Proficiency*², as well as compliance with the organisations mandatory training programme.

9.6 Service re-organisation

Where service reconfiguration or rationalisation involves the merger or amalgamation of laboratory disciplines it is important to ensure sufficient resource and planning is given to re-orientation and retraining for staff required to work in a different discipline or environment. It is essential to incorporate this training into any planned workload redistribution.

9.7 Point of Care Testing

Although Point of Care Testing (POCT) refers to analytical processes performed outside the clinical laboratory, it should be monitored and supervised by qualified staff of a local Clinical Pathology Accreditation (CPA) Ltd enrolled pathology laboratory. The training manager, in conjunction with the quality manager, must have the authority to develop and maintain appropriately trained individuals to enable the implementation of POCT, where relevant, and to ensure that all current professional guidelines are implemented within POCT systems to ensure that patient safety is maintained at all times.

10 PROFESSIONAL DEVELOPMENT

All professionals offering a public service, especially in healthcare, should be committed to ensuring that their knowledge is up to date and relevant. Consequently greater emphasis is now placed on continuing professional development.

10.1 Continuing professional development (CPD)

The Institute defines CPD as:

“A process of lifelong learning, which enables you to meet the prerequisite knowledge and skill levels that relate to your evolving scope of practice, thereby maintaining competence in your scope of practice as a biomedical scientist”.⁴⁰

Similarly the HPC defines CPD as “a range of learning activities through which health professionals maintain and develop throughout their career to ensure that they retain their capacity to practise safely, effectively and legally within their evolving scope of practice”.⁸

CPD has been a feature of normal professional life for many healthcare professionals and has become an integrated and mandatory requirement of their registration as a demonstration of competence. The HPC requires all health professionals to undertake CPD as a legal requirement and biomedical scientists may have to provide evidence of CPD activities and that their participation has contributed to the quality of practice and service delivery.

CPD is seen as a means of:

- demonstrating, maintaining and improving competence to practice,
- continuously updating and acquiring scientific theory and practice,
- encouraging reflective practice,
- ensuring that career-long learning is relevant to current or future practice,
- ensuring that CPD has contributed to the quality of practice, patient safety and service delivery,
- supporting HPC and Chartered Scientist registration,
- developing individuals both personally and professionally,
- contributing to the knowledge base of the profession,
- increasing job satisfaction.

CPD must be a mixture of different kinds of learning experiences or activities that are relevant to current or future practice and should benefit the laboratory and pathology service delivery. Biomedical scientists are encouraged to analyse and make their own considered decisions about the kind of activities for their CPD. Participants are also required to maintain a continuous, up-to-date and accurate record of their CPD activities for possible audit by the HPC.

Biomedical scientists can take part in schemes run by professional bodies, employers or structure their activities around a personal development plan.

The Institute's organises a mature, robust scheme that has been carefully designed to enable biomedical scientists to meet the HPC standards and empower participants in career-long learning through reflective practice.

It provides a framework of learning activities which may be undertaken throughout the career of a biomedical scientist to maintain, improve and extend knowledge and skills for safe and professional practice.

10.2 CPD time and funding

CPA (UK) Ltd laboratory accreditation makes it implicit that opportunities and facilities for CPD should be available to all grades of staff. The requirements of Agenda for Change⁴¹ also mean that employers must make provision for CPD.

However, staff must also take individual responsibility for their own CPD, as clearly guided in *A first class service – quality in the new NHS*²⁰. Individual responsibility for CPD is considered by professional bodies, government and all other partners to be one of the foundations of professional practice. The IBMS makes a big investment and emphasis in its own CPD scheme to support its members in their career development. A model of good practice and time management by both individual biomedical scientist and employer will identify and allocate time for continuing professional development.

Routine laboratory activity should be scheduled to include quality issues such as CPD, audit and training. They should be features of, and given equal priority within the scope of normal working practice. Continuing professional development should also be conceptually embedded within routine practice and not just viewed as a series of external courses and activities.

10.3 Monitoring and directing CPD

The IBMS as a professional body plays an important role in providing CPD, through courses and other activities, local support and monitoring.

Laboratory and training managers should assess and direct individuals towards identified CPD targets to meet the needs of the HPC standards, employer and personal staff development. Both the IBMS and HPC audit a random sample of biomedical scientists to ensure standards are being met and individuals are competent.

10.4 Responsibility for staff development

All staff have a duty to set an example and to encourage and facilitate participation by their colleagues in CPD activities. Goals and objectives for such development should be set and reviewed regularly. Achievement should be measured against targets set and discussed with all staff involved. An awareness of the importance of personal development should be encouraged and facilitated for all colleagues.

10.5 Need for individual professional appraisal

All biomedical scientists supervising or responsible for staff training should make themselves familiar with the progress, shortcomings and aspirations of the staff and seek to guide their progress. It is recommended that this is achieved by a process of individual staff appraisal, which includes mutual participation in reviewing progress, discussing real and perceived problems and developing targets and monitoring progression over regular periods.

10.6 Limitations of CPD

It is unreasonable to expect that CPD alone can provide the individual with all the skills and knowledge necessary within a given specialty. It is important that these skills are held collectively. Acknowledgement of this situation means that no biomedical scientist should be reluctant to seek help or advice from colleagues. CPD should form an exciting and challenging part of a career, from initial registration for practice to retirement. No practising biomedical scientist should ever stop learning to improve their practice.

11 PROMOTION OF THE PROFESSION AND ITS IDEALS

Good professional practice and standards represent the collective wealth, values and ethos of the profession. The individual therefore has a personal responsibility to meet and maintain standards set jointly by peers in the profession and promote the profession and its ideals.

11.1 Chartered Scientist (CSci)

'Chartered' is an internationally recognised benchmark of quality and excellence. It has done much to improve the profile of science and scientists and cement the professional ethos of biomedical scientists. Chartered status is the cornerstone of the Institute's professional qualification framework and is a prestigious achievement for ambitious professionals in biomedical science.

In terms of good professional practice CSci ensures high and improving standards across all scientific disciplines as:

- it is only available to those scientists who can demonstrate the advancement or application of science and who stay up-to-date in their scientific field,
- candidates must also be able to demonstrate the benefit of their work to the wider community,
- Chartered Scientist status is aimed at those practising science at the full professional level and at those for whom scientific knowledge or practice at that level forms an essential element for the fulfilment of their role,
- Applicants are required to demonstrate a systematic understanding of knowledge and critical awareness of current problems or new insights, much of which is informed by the forefront of their field of study or area of professional practice.

Biomedical scientists are eligible to apply for Chartered Scientist status through the Institute of Biomedical Science if they:

- have at least four years corporate Institute membership and in the appropriate class of membership for which they are eligible (either a Fellow or Member),
- have a Masters level qualification, or equivalent,
- have documented evidence of continuing professional development, either through the Institute's portfolio scheme, another professional association or a personal development plan for the two years prior to application,
- are currently in practice, application and teaching of biomedical science with at least four years post graduate professional experience.

11.2 Get involved

Biomedical scientists are encouraged to become involved in the promotion of their profession, expertise and roles in healthcare. This can include participating in scientific forums, employer organisation, careers promotion, school links, ambassador schemes, laboratory open days, national events such as Healthcare Science Week, media and local groups.

Information on getting involved can be found on the Institute's website.

11.2.1 IBMS professional roles

Members of the Institute are encouraged to become involved in the Institute's advisory groups, university-employer liaison committees, local groups, and CPD scheme and events organisers. This adds to the collective expertise and sharing of good practice for the profession.

11.2.2 Helping with Good Professional Practice

Good Professional Practice reflects and outlines standards and practice that in the modern professional and scientific environment are constantly evolving and fluid. Nor can one set of guidance or standards fully embrace the diversity and complexity of biomedical science. Biomedical scientists are therefore encouraged to communicate with the Institute with suggestions and feedback

on *Good Professional Practice* to further develop and enhance guidance for the benefit of the profession as a whole.

11.2.3 Healthcare science and networking

There are opportunities at a wider organisational level for biomedical scientists to engage with the broader perspective and network as part of healthcare science. The concept of the healthcare scientist is to provide a collective voice for science in the health service to the government, other health care professionals and to members of the public. Such collective professional networking will become increasingly important, especially as Strategic Health Authorities (SHA) will rely on professional and reference groups for advice in, for example, developing education and training strategies or dealing with hospital acquired infections. In turn the progress of healthcare scientists, and therefore biomedical scientists, will depend on adequate representation, promotion, communication and clinical networking to influence and lead strategic planning.

While Strategic Health Authorities (SHAs) may use reference groups, NHS Trusts and other organisations should also be encouraged to have healthcare scientist representation of an appropriate level within their strategic and operational development processes.

11.2.4 External assessors for appointments

The Institute recommends that the appointment process to a senior post should include an external assessor to ensure consistency and transparency, especially where there are internal candidates. The external assessor ideally should be at the equivalent or above level as well as relevant discipline and role. The assessor should play a full part in the appointment and decision-making process.

11.2.5 Biomedical scientists and other professions

Biomedical scientists may and are encouraged to engage with kindred scientific, leadership and management non-healthcare professions for mutual learning and to informally discuss common issues.

11.2.6 Publication of developments

Biomedical scientists are encouraged to share their experiences in the evaluation and assessment of new developments. As shared objectives and experiences make for a good team environment, so dissemination of information facilitates the advance of the profession for the good of those requiring its services.

Opportunities to share this collective experience can be through discussion groups, workshops, seminars, email groups and publications.

11.2.7 Publications: IBMS media

Biomedical scientists are encouraged to share their professional experiences by submitting material to be considered for publication in the Institute media, such as the website and its monthly publication, *The Biomedical Scientist*.

The Institute also encourages biomedical scientists to offer for publication articles and features that have a broad appeal on any subject pertaining to the profession, for example or science, personal experiences, safety matters, overseas issues or projects.

Further information on writing for the Institute's media can be found on the website at www.ibms.org.

12 QUALITY

Quality lies at the heart of the delivery of pathology services. The incorporation of quality control and quality assurance into all aspects of laboratory practice has become second nature within pathology, particularly since the creation of Clinical Pathology Accreditation (UK) Ltd (CPA) with its nationally recognised set of minimum quality standards for pathology laboratories. This has been further exemplified by Lord Darzi's report, *High Quality Care for all*.

12.1 Quality managers

A quality manager is an individual with responsibility as a service representative for ensuring all aspects of quality within a quality management system are applied and function correctly.

The quality manager is an integral part of the overall laboratory clinical and management team and, within these structures, will oversee the implementation, development and co-ordination of quality systems and processes. These will include adherence to relevant professional standards and guidelines, involvement with risk management and clinical governance issues, audit, as well as providing advice and being a focus for all issues relating to quality in the laboratory. The quality manager must be aware of any current and evolving legislation and will ensure that quality systems meet the requirements of this legislation.

The Institute's distance-learning course in quality management has been developed by the Institute's Quality Management Advisory Committee in conjunction with the University of Ulster. The Institute will award a Certificate of Extended Practice in Quality Management on successful completion of the course. The Certificate of Quality Management recognises an area of specialist expertise in an area of biomedical science.

12.2 Poor performance

Raising concerns or 'whistleblowing' about the poor performance of healthcare professionals or a laboratory service can be one of the most delicate and difficult things to do as it can involve friends and work colleagues. However, all professionals, as part of their duty of care to the public, have the right and moral responsibility to bring to the attention of their manager any difficulties that may be encountered in the performance of their professional duties. This responsibility can be legally required by the HPC and is reinforced and covered by various government policies¹¹ and legislation. There may be circumstances where *not* raising concerns could be breaking national laws as well as terms of HPC registration.

Biomedical scientists can approach the Institute for advice and support in handling matters arising from poor performance of professionals and services.

All organisations should have policies and procedures for raising concerns which include a 'whistle blower policy'. It is expected that individual professionals will follow these and exhaust local and statutory procedures and consider the issues very seriously before considering making public any concerns. The *Public Interest Disclosure Act 1998* gives protection to employees who disclose information reasonably and responsibly in the public interest and who face victimisation or harassment as a result. The HPC requires registrants to inform them if they have important information about your conduct or competence, or about other registrants and health professionals you work with.

Types of concern can include:

- systemic failings that could result in compromising patient failings,
- inadequate or mal-functioning equipment,
- fraud or corruption,
- poor professional practice,
- health and safety issues,
- culture of violence, discrimination or bullying towards patients or colleagues,
- physical or mental illness affecting the performance of an individual professional to practise in a safe manner,
- substance and alcohol abuse affecting the performance of an individual professional to practise in a safe manner.

12.2.1 Poor performance: laboratory service

Most laboratory tests and all laboratories are now subject to sophisticated systems of quality control, quality assessment and total quality assurance.

However, the service delivery in a minority of laboratory services and departments can be compromised by poor performance, ineffective leadership and management, bad communication, low morale and dangerous practice.

Biomedical scientists with management responsibilities must ensure that systems are in place to allow colleagues to raise concerns.

12.2.2 Poor performance: individuals

A poorly performing biomedical scientist is one whose performance falls below minimum local or national professional standards of practice.

Fitness to practise as a registered healthcare professional may be impaired by:

- personal conduct: behaviour of biomedical scientists unrelated to the exercise of their professional skills (at any time),
- professional competence: inadequacy in the performance of biomedical scientists related to the exercising of their scientific and technical skills and professional judgement,
- health problems adversely affecting fitness to practise.

Identifying and managing the poor performer can be difficult and is invariably sensitive as it involves work colleagues and friends and can have serious consequences for the individual concerned.

In dealing with such cases, it is helpful to have clear objectives, which may be summarised as follows:

- always follow organisational policies relating to performance management,
- to protect patients from harm,
- always seek advice from a human resources representative,
- to ensure that the person is treated justly according to fair and open procedures,
- to provide opportunities for that individual to improve their performance according to properly managed processes such as quality assurance and/or personal appraisal systems.

12.2.3 How to raise concerns

All concerns and the steps taken to try to resolve them must be recorded in full detail for possible later reference. Raising concerns can be challenging but via the employer's policies and law you should be listened to without fear of consequence and you are supported by moral, legal, regulatory and statutory protections.

Employers can face heavy unlimited fines under the *Public Interest Disclosure Act* if they fail to protect or support employees who have raised concerns.

If a biomedical scientist has good reason to think that patient safety is or may be seriously compromised by poor performance and laboratory practice, they should in the first instance endeavour to correct the matter themselves.

An employer's policy would normally request that the next step is to raise concerns with the manager or next immediate superior. Biomedical scientists should:

- inform their accountable manager in a letter that specifies the areas and background in which there is concern,
- inform the relevant clinical colleagues responsible for sending samples for diagnostic opinions such that patients may be kept informed,
- develop and implement a scheme, in close consultation with relevant clinical and managerial colleagues, to reduce levels of activity to a level that ensures the provision of a safe service,

- regularly review the situation, strategy and any action plans that are in place for its satisfactory resolution.

If that is not possible an employer's policy should contain a formal and confidential procedure with a designated officer, although some issues such as bullying may be dealt with by other procedures. You should state if you wish to raise concerns in confidence. Your human resources department will have information on policies and local protocols.

If your concerns are not addressed you should contact the clinical director of pathology.

If you still feel that your concerns are not addressed you should contact the chief executive but the Medical Director must be aware that you have taken this step.

Biomedical scientists should only raise concerns externally after exhausting all workplace procedures and options. If however an employer still does not take adequate action, independent advice should be sought on taking the matter further.

Independent advice can be sought from the following:

- Institute of Biomedical Science – either by contacting the office or local Council member
- locally elected representative
- Care Quality Commission
- National Patient Safety Agency
- local Strategic Health Authority
- local health board or trust.

12.2.4 Taking action

Where there are suspicions of a colleague's performance, these should be raised via locally agreed policy procedures to the appropriate laboratory management level and, if appropriate, to the relevant healthcare regulator. Managers must be trained and emboldened to deal with such matters. In addition, reporting to the relevant healthcare regulator should be done at an early stage of suspicion or investigation, because failure to do so could put patients at continued risk.

Where a colleague from a different profession is involved, in most cases the appropriate reporting route will be via the clinical director of pathology.

12.2.5 Performance deficiencies in equipment or other medical devices

If defects or deficiencies are identified in medical devices or equipment, especially if CE marked, then the Medicines and Healthcare products Regulatory Agency must be informed in addition to any local reporting or error logging procedures. This may be done via the website at www.medical-devices.gov.uk.

The Medical Devices Directive covers any equipment or materials used to produce a diagnosis by placing obligations on manufacturers to ensure that their devices are safe and fit for their intended purpose before they are CE marked and placed on the market in any EC member state.

12.2.6 Assessment and introduction of new technology

Outdated, outmoded and discredited methodology represents a hazard to patients, clinicians and all others whom the profession serves. Laboratory services must embrace changes in technology and scientific practice with experienced professionals best suited to take a professional lead.

The introduction of all new equipment and technologies must only be put into service use, once a thorough testing and validation process has been successfully completed, documented and signed off by an appropriately qualified senior member of staff.

12.2.7 Performance: equipment and test procedures

Experienced professionals are best suited to taking the lead in the assessment and introduction of new technology and quality control of laboratory test procedures.

Components of quality control of test procedures include proficiency surveillance and ensuring strict adherence to written procedures. Laboratory staff are responsible for auditing the process and results.

Equipment control charts must be reviewed and archived for the recommended periods of time.

12.3 External and internal quality assessment

External Quality Assessment (EQA) results must be made available for examination by all laboratory staff and external assessors.

Internal quality control (IQC) is needed to maintain regular consistency of results to ensure a swift response to problems by checking results on control material for drift and imprecision.

Internal quality assessment (IQA) may be required and could include re-submitting anonymous specimens through the analytical process.

Results of IQA must be used for education of laboratory staff and inspection by assessors.

Both EAQ and IQA results must be kept for the prescribed period of time as laid down in the RCPATH/IBMS joint document on *The Retention and Storage of Pathological Records and Archives* (3rd edition, 2005).²⁴

12.4 Standard operating procedures (SOPs), forms and record sheets

SOPs must be in place for all test and most other procedures to guide and standardise working procedure, ensuring the reliability of results.

SOPs must be written in a standard format that is clear and easy to understand.

All forms and record sheets that are used in service delivery to detail any and all aspects of a procedure as laid down in a validated SOP must also follow the same quality management processes as used for the SOPs themselves.

Using a document control system all such quality managed documents must also be reviewed on a regular basis with details of the date of the revision recorded and the obsolete document being withdrawn, if appropriate.

The document control system must be in a format allowing for clear and demonstrable audit of the quality management system to take place.

13 INFORMATION TECHNOLOGY

It is desirable to have a specific person acting as a local data security officer responsible for maintaining an up-to-date register of installed software, hardware and communications changes and for keeping the data protection officer informed of any relevant changes.

13.1 Legislation & guidance

13.1.1 *Data Protection Act 1984*

The Act aims to ensure that all computers holding personal data are registered with the data protection registrar and those specific principles of security are adhered to (ref *Data Protection Act 1984 Schedule 1, Part 1*⁴²). The principles laid down in the Act are explained in Part 2 of the schedule; any lack of understanding should be clarified with the local data protection officer or the office of the Data Protection Registrar. The Caldicott principles should be followed.⁴³

13.1.2 Confidentiality

Although this is implicit in the *Data Protection Act*, the importance of data confidentiality cannot be stressed too highly. Patient information is provided specifically in relation to the investigations requested and to the collation of statistics, and cannot be used in an identifiable way for any other purposes. Failure to comply with this is a serious breach of trust and would almost certainly lead to disciplinary procedure, dismissal and possible prosecution, plus the prospect of sanction by the HPC.

13.1.3 *Computer Misuse Act 1990*

Under the Computer Misuse Act 1990⁴⁴ it is an offence punishable by law to gain unauthorised access into a computer system, and if the person gaining access alters either programs or data the fine is unlimited and imprisonment is possible. It is good practice therefore, to assume that without an official password into a system a biomedical scientist should not have or gain official access.

13.1.4 Caldicott

“The recommendations of the Caldicott Committee defined the confidentiality agenda for NHS organisations for a number of years. Central to the recommendations was the appointment in each NHS organisation of a “Guardian” of person-based clinical information to oversee the arrangements for the use and sharing of clinical information. Subsequent work extended the requirement to appoint Caldicott Guardians into Councils with Social Services Responsibilities [CSSRs]”⁴⁵

13.1.5 *Freedom of Information Act*

The *Freedom of Information Act 2000*⁴⁵ covers all public bodies, including those in the health service. It gives the public the right to access any information that is held particularly but not exclusively relating to how public bodies make decisions and run services. Information is defined legally as something that has already been recorded, including emails, and thus does not cover new explanation, opinion or further analysis. Advice and analysis are in any case not included. The Act specifies how requests for information must be handled, and it sets a time limit of twenty days for a full reply. The Act does not conflict with the duty to maintain patient confidentiality, and there are certain other exemptions, both absolute and qualified. Any member of the public can request information without having to explain why it has been requested. Information that is known to be part of an information request must not be deliberately altered or destroyed. The penalty is a personal fine of up to £5000.

Most public bodies will have appointed and trained a freedom of information (FOI) officer, or equivalent. A biomedical scientist receiving a request for information that is or appears to be made under the FOI Act must act immediately to refer the request to the FOI officer who is able to respond

in accordance with the Act. A written request must be forwarded. In the event of a verbal request the enquirer must be given the contact details of the FOI officer. In the event that the FOI officer refers a request for information to an employee because of his/her expertise in the subject, then he/she is responsible for responding within the time limits indicated by the FOI officer. If this is not possible the expert must contact the FOI officer to discuss the situation and how to proceed.

Routine requests for information relating to normal services are not affected and should be handled in the normal way.

13.2 Other considerations

13.2.1 IT, internet and email use

All biomedical scientists should be aware of and comply with local trust policies on the use of internet and email.

In addition, the NHS Chief Executive has directed that there should be no transfers of unencrypted person identifiable data held in electronic format across the NHS. This is the default position to ensure that patient and staff personal data are protected. Any data stored on a PC or other removable device in a non-secure area or on a portable device such as a laptop, PDA or mobile phone should also be encrypted. This is also now a requirement across all public sector organisations set by the Cabinet Secretary.

13.2.2 Licensed software

All commercial computer software is protected by licence, and failure to comply with the terms of the licence may well lead to prosecution. The use of 'pirated' software, which includes copying to additional machines without additional licences, is illegal, and individuals and/or the employing authority are liable under copyright law.

Faxes

The security of data transmitted by fax must be as protected as possible.⁴⁸ Transmission to an unknown destination could have serious consequences. All faxes should be preceded by an official header sheet containing the following:

- sender's name, fax number and telephone number,
- number of sheets, including the header,
- a request that the sender be informed immediately should the stated number of sheets not be received,
- name of the individual for whom the fax is intended.

It is expected that the receiving fax machine is in a secure position (safe haven). If receiving fax machine is not in a secure position:

1. ask for the request for information to be faxed to you on headed paper, detailing everything you will need to complete the request (patient details, their fax and telephone numbers etc),
2. telephone the requestor and inform them you are about to fax them,
3. ask them to acknowledge receipt of your fax,
4. double-check the fax number,
5. make sure the trust fax cover sheet states information as outlined above, and mark it "Private and Confidential",
6. if possible, request a report sheet to confirm transmission,
7. ensure that all faxed information is returned to a secure place.

Generally, faxed copies of results will have the same status as a report dispatched as a hard copy unless stated to the contrary. Obliteration of patients' names and the use of hospital numbers and/or NHS numbers as identification are essential.

13.2.3 Software viruses

Computer viruses of program codes and documents can be introduced into computers and damage systems or corrupt data. A common means of entry is by loading programmes from colleagues. Where possible, only new unopened licensed copies of software should be installed. In instances where this is not possible, for example with macro-viruses which infect documents, a suitable virus checker, regularly updated, should be used frequently to detect damaging code on hard and/or floppy disks or CDs.

14 FURTHER INFORMATION

The IBMS website provides an archive of updated good professional links referenced in this publication at www.ibms.org/goodprofessionalpractice.

Further information on the Institute's qualifications and diplomas is available at www.ibms.org/education. The Institute has produced a number of professional guidance publications, some of which have been cited in *Good Professional Practice*. Most of the Institute's range of guidance and publications is available to download at www.ibms.org/publications.

Articles, resources and further information on healthcare science role and getting involved in promoting the professions and s are available at www.ibms.org/getinvolved.

Information on the Institute's Continuing Professional Scheme is available at www.ibms.org/cpd.

There is a round-up of professional and healthcare science links at www.ibms.org/professional. IBMS members can use the web discussion panels in the members area of the Institute's website to exchange tips, information and discuss any issues raised by applying good professional practice in the workplace.

15 REFERENCES

1. HMSO. *The Health Professions Order 2001*
2. *HPC Standards of Proficiency*. July 2003.
 - 1a: Professional autonomy and accountability
 - 1b: Professional relationships
 - 2a: Identification and assessment of health and social care needs
 - 2b: Formulation and delivery of plans and strategies for meeting health and social care needs
 - 2c: Critical evaluation of the impact of, or response to, the registrant's actions
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16 USEFUL CONTACTS

British Standards Institution (BSI)

T: 020 8996 9000
E: cservices@bsigroup.com
W: www.bsigroup.com

Clinical Pathology Accreditation (UK) Ltd (CPA)

T: 0114 251 5800
E: office@cpa-uk.co.uk
W: www.cpa-uk.co.uk

Care Quality Commission

T: 03000 616161
E: enquiries@cqc.org.uk
W: www.cqc.org.uk

Health Professions Council (HPC)

T: 020 7582 0866
E: info@hpc-uk.org
W: www.hpc-uk.org

Health Protection Agency (HPA)

T: 020 8200 4400
E: HPA.enquiries@hpa.org.uk
W: www.hpa.org.uk

Health and Safety Executive

T: 0845 345 0055
E: hse.infoline@connaught.plc.uk
W: www.hse.gov.uk

Human Tissue Authority

T: 020 7211 3400
E: enquiries@hta.gov.uk
W: www.hta.gov.uk

International Organization for Standardization

T: +41 22 749 01 11
W: www.iso.org

Kings Fund

T: 020 7307 2400
W: www.kingsfund.org.uk

Medicines and Healthcare Products Regulatory Agency

T: 020 7084 2000
E: info@mhra.gsi.gov.uk
W: www.mhra.gov.uk

National External Quality Assessment Schemes

T: 0114 261 1689
E: office@ukneqas.org.uk
W: www.ukneqas.org.uk

National Pathology Benchmarking Service

W: www.keele.ac.uk/schools/pharm/General/NPBS

NHS Blood & Transplant

T: 01923 486800
W: www.nhsbt.nhs.uk

NHS Cancer Screening Programmes (including cervical and breast)

T: 0114 271 1060
E: info@cancerscreening.nhs.uk
W: www.cancerscreening.nhs.uk

NHS Litigation Authority

T: 020 7430 8761
W: www.nhsla.com

Public Concern at Work

T: 020 7404 6609
W: www.pcaw.co.uk

Skills for Health

T: 0117 922 1155
E: office@skillsforhealth.org.uk
W: www.skillsforhealth.org.uk

The Royal College of Pathologists

T: 020 7451 6700
E: info@rcpath.org
W: www.rcpath.org

The Science Council

T: 020 7922 7888
E: inquiries@sciencecouncil.org
W: www.sciencecouncil.org

UK National External Quality Assessment Scheme (NEQAS) Office

T: 0114 261 1689
E: office@ukneqas.org.uk
W: www.ukneqas.org.uk

17 IBMS VISION AND ROLES

The Institute of Biomedical Science (IBMS) is the professional body for those who work within the field of biomedical science. Its principal aims are to represent its members, set standards of behaviour for its members, enable career development, educate its members, promote biomedical science to the public and award qualifications appropriate to the collective knowledge and skill base of its members.

The Institute was founded in 1912 and represents over 19,000 members employed predominately within the healthcare arena, but also within university and veterinary laboratories, the National Blood Service, Health Protection Agency, Medical Research Council and Department for Environment, Food and Rural Affairs. Other members also work in related commercial fields and academia. Although most Institute members live and work in the United Kingdom and the Republic of Ireland, many other members are employed throughout the world.

IBMS roles

- To aid and support the development of biomedical science, both nationally and internationally.
- Influence and develop professional standards of practice to guide those who practice biomedical science.
- Assess competence to practise as Health Professions Council (HPC) registered biomedical scientists.
- Define an appropriate structure of membership and associated member benefits.
- Provide personal and professional support for members.
- Represent the interests of biomedical science, provide advice and work with UK governments, public & independent healthcare providers, media, universities, industry and commercial sector, professional organisations and all other partners.
- Develop appropriate education and training for its members enabling them to demonstrate multiple levels of competency
- Develop qualifications and diplomas to demonstrate varying levels of expertise enabling members to plan a career pathway.
- To enable members to achieve their potential through career options, career long learning and continuing professional development.
- Update and inform those who practice biomedical science through all available channels including: the media, professional publications, scientific meetings and events.
- Promote public awareness of biomedical science.
- Produce scientific and professional publications, guidance and other resources for members.
- Award the designation of Chartered Scientist to qualifying members.
- Fund research and support charitable causes in biomedical science.
- Maintain a historical archive of the Institute and biomedical science profession.

Why join the IBMS?

The Institute offers a package of membership benefits to help biomedical scientists develop their careers and scientific knowledge, and to provide personal and professional support.