Council, 25 September 2014

Results of profession-specific standards of proficiency consultation for biomedical scientists

Executive summary and recommendations

Introduction

We are currently reviewing the profession-specific standards of proficiency for the professions we regulate. The review of the profession-specific standards follows from the Council's approval of new generic standards of proficiency in March 2011.

To ensure the process is manageable, we are reviewing the profession-specific standards in small groups of professions at a time. At the start of each review, we contact each of the professional bodies for the relevant professions and ask for their suggestions on any changes that they consider necessary. We then use their suggestions to revise the standards for public consultation.

Following a review of the standards by the professional body for biomedical scientists – the Institute of Biomedical Science – we publically consulted on the draft standards between 31 March 2014 and 20 June 2014.

The attached consultation response analysis document and revised draft standards of proficiency for biomedical scientists were considered and recommended to Council by the Education and Training Committee at its meeting in September 2014. We have made a minor editing amendment to the consultation response analysis document for clarity post the Education and Training Committee's meeting as a result of formal legal scrutiny. The attached papers are for the Council's consideration and approval for publication.

Decision

The Council is invited to:

- discuss the attached paper;
- agree the revised standards of proficiency for biomedical scientists as set out in appendix one (subject to minor editing amendments and formal legal scrutiny); and
- agree the text of the consultation response analysis document (subject to minor editing amendments and formal legal scrutiny).

Background information

- Paper for Education and Training Committee, 6 March 2014, (enclosure 3 at www.hpc-uk.org/aboutus/committees/archive/index.asp?id=661)
- Paper agreed by Council, 27 March 2014, (enclosure 7 at www.hpc-uk.org/aboutus/committees/archive/index.asp?id=665)
- Paper for Education and Training Committee, 11 September 2014, (enclosure 8 at www.hcpc-uk.org/aboutus/committees/educationandtraining/index.asp?id=676)

Resource implications

The resource implications of this round of consultation are accounted for in the Policy and Standards Department planning for 2014/15. The resource implications of the ongoing process of review and eventual publication of the revised standards of proficiency have been taken into account in the Policy and Standards work plan for 2014/15, and will continue to be taken into account in future years.

Financial implications

The financial implications include the costs associated with a series of public consultations on new draft standards and publication of new standards for 15 professions. These costs are accounted in department planning for 2014/15.
We anticipate further costs in 2015/16 for further consultations and publication of further revised standards.

Appendices

- Appendix one: Revised standards of proficiency for biomedical scientists following the consultation
- Appendix two: List of additional standards suggested by respondents to the consultation
- Appendix three: List of amendments to the standards suggested by respondents to the consultation

Date of paper

11 September 2014

Consultation on changes to the profession-specific standards of proficiency for biomedical scientists

Analysis of responses to the consultation on proposed profession-specific standards of proficiency for biomedical scientists, and our decisions resulting from responses received

1. Introduction

About the consultation

1.1 We consulted between 31 March 2014 and 20 June 2014 on proposed changes to the profession-specific standards of proficiency for biomedical scientists.

1.2 The standards of proficiency set out what we expect professionals on our Register—known as 'registrants'—to know, understand, and be able to do when they apply to join our Register. We consulted on proposed changes to the standards as part of our regular periodic review of the standards.

1.3 We informed a range of stakeholders about the consultation including professional bodies, employers, and education and training providers, advertised the consultation on our website, and issued a press release.

1.4 We would like to thank all those who took the time to respond to the consultation document. You can download the consultation document and a copy of this responses document from our website: www.hcpc-uk.org/aboutus/consultations/closed.

About us

1.5 We are a regulator and were set up to protect the public. To do this, we keep a register of health and care professionals who meet our standards for their professional skills and behaviour. Individuals on our register are called "registrants".

1.6 We currently regulate 16 health and care professions:
- Arts therapists
- Biomedical scientists
- Chiropodists / podiatrists
- Clinical scientists
- Dietitians
- Hearing aid dispensers
- Occupational therapists
- Operating department practitioners
- Orthoptists
- Paramedics
- Physiotherapists
- Practitioner psychologists
- Prosthetists / orthotists
- Radiographers
- Social workers in England
- Speech and language therapists

Reviewing the standards of proficiency

1.7 The standards of proficiency for biomedical scientists set standards for the safe and effective practice of the profession. They do so by describing what professionals must know, understand, and be able to do in order to apply to join our Register.

1.8 The standards play an important role in public protection. When a professional applies for or renews their registration, or if concerns are raised about their competence while they are registered with us, we use the standards of proficiency in checking whether they have the necessary knowledge and skills to be able to practise their profession safely and effectively.

1.9 The standards are divided into generic standards, which apply to all the professions on our Register, and standards specific to each individual profession. Under the new structure, most of the standards of proficiency will be profession-specific, listed under 15 new generic standards.

1.10 The purpose of the generic standards is to recognise commonality across all the professions that we regulate, while the purpose of the profession-specific standards is to set out additional standards for biomedical scientists related to the generic standard.

1.11 We consulted on changes to the generic standards of proficiency between July and October 2010.[1] The new generic standards have now been agreed by our Council and were not the subject of this consultation.

1.12 The review of the profession-specific standards is an opportunity to make sure the standards of proficiency are relevant to each profession. We regularly review the standards of proficiency to:

- reflect current practice or changes in the scope of practice of each profession;
- update the language where needed to ensure it is relevant to the practice of each profession and to reflect current terminology;
- reflect the standard content of pre-registration education programmes;
- clarify the intention of existing standards; and
- correct omissions or avoid duplication.

1.13 Our initial revision of the profession-specific standards was informed by discussions with the professional body for biomedical scientists – the Institute of Biomedical Science. We then consulted on these draft revisions.

[1] You can find more information about the consultation on our website here: www.hcpc-uk.org/aboutus/consultations/closed/index.asp?id=110

1.14 In consulting on proposed changes to the standards, we asked our stakeholders to consider whether the changes we have suggested to the profession-specific standards of proficiency for each profession are appropriate, and whether other changes are necessary. We have used the responses we received to help us decide if any further amendments are needed.

1.15 Once the final sets of standards are approved, they will be published and become effective. We will then work with education providers to implement the new standards after they are published.

About this document

1.16 This document summarises the responses we received to the consultation. The results of this consultation have been used to revise the proposed standards of proficiency for biomedical scientists.

1.17 The document is divided into the following sections.

- **Section two** explains how we handled and analysed the responses we received, providing some overall statistics from the responses.
- **Section three** summarises the general comments we received in response to the consultation.
- **Section four** outlines the comments we received in relation to specific questions within the consultation.
- **Section five** outlines our responses to the comments we received and the changes we are making as a result.
- **Section six** lists the organisations which responded to the consultation.

1.18 This paper also has three appendices.

- Appendix one lists the standards after consultation (subject to minor editing amendments and legal scrutiny).
- Appendix two lists all the comments we received suggesting additional standards.
- Appendix three lists all the comments we received suggesting amendments to the draft standards.

1.19 In this document, ‘you’ or ‘your’ is a reference to respondents to the consultation, ‘we’, ‘us’ and ‘our’ are references to the HCPC.

2. Analysing your responses

2.1 Now that the consultation has ended, we have analysed all the responses we received. Whilst we cannot include all of the responses in this document, a summary of responses can be found in sections three and four.

Method of recording and analysis

2.2 The majority of respondents used our online survey tool to respond to the consultation. They self-selected whether their response was an individual or an organisation response, and, where answered, selected their response to each question (eg yes; no; partly; don't know). Where we received responses by email or by letter, we recorded each response in a similar manner.

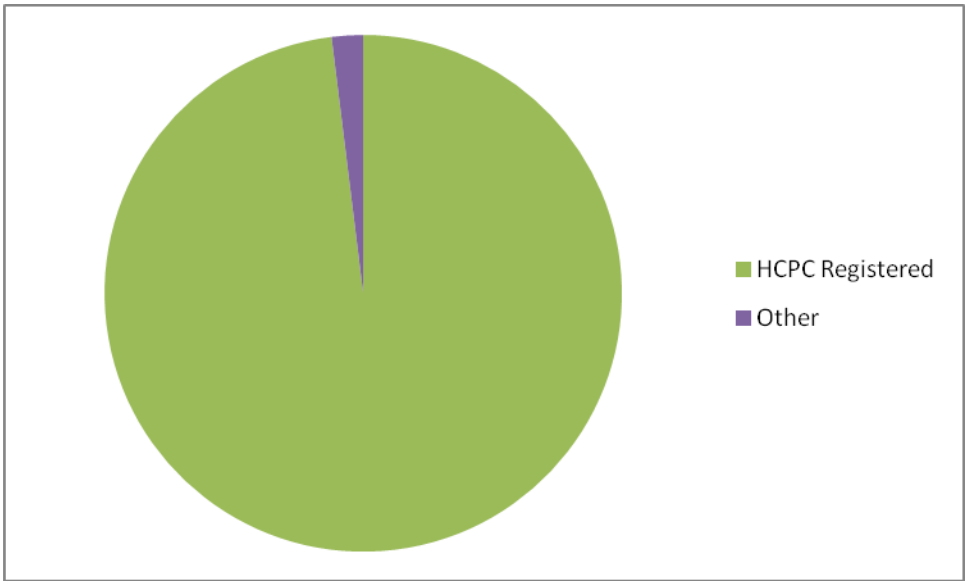
2.3 When deciding what information to include in this document, we assessed the frequency of the comments made and identified themes. This document summarises the common themes across all responses, and indicates the frequency of arguments and comments made by respondents.

Statistics

2.4 We received 63 responses to the consultation. 51 (81 per cent) of responses were received from individuals and 12 (19 per cent) from organisations. Of the 51 individual responses, 50 (98 per cent) were from HCPC registered professionals.

2.5 The breakdown of respondents and of responses to each question is shown in the graphs and tables which follow.

Graph 1 – Breakdown of individual responses



Graph 2 – Breakdown of organisation responses

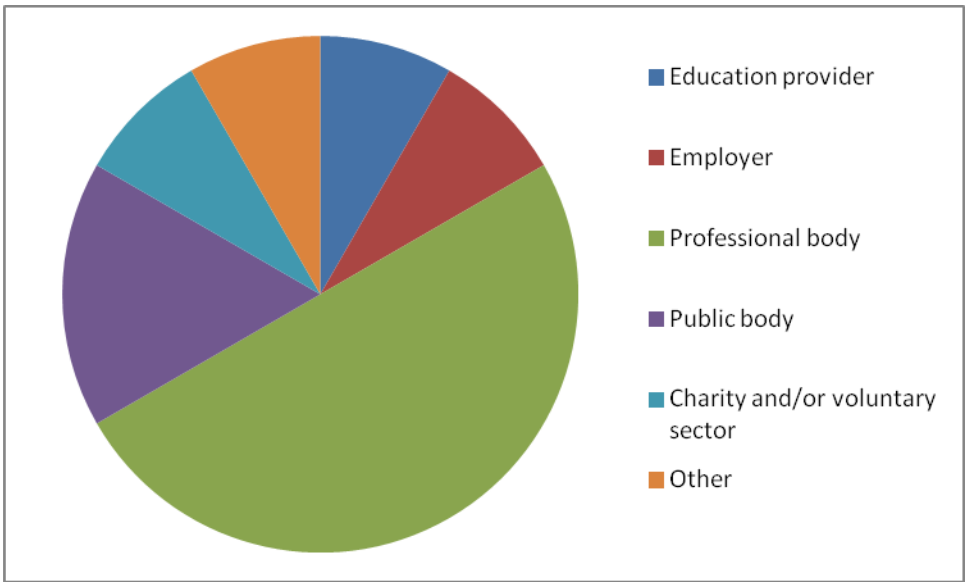


Table 1 – Breakdown of responses to each question

Questions	Yes	No	Partly	Don't know
1. Do you think the standards are at a threshold level necessary for safe and effective practice?	48 (76%)	0 (0%)	13 (21%)	2 (3%)
2. Do you think any additional standards are necessary?	9 (14%)	47 (75%)	N/A	7 (11%)
3. Do you think there are any standards which should be reworded or removed?	24 (38%)	25 (40%)	N/A	14 (22%)
4. Do you have any comments about the language used in the standards?	12 (19%)	46 (73%)	N/A	5 (8%)

Table 2 – Breakdown of responses by respondent type

	Individuals					Organisations			
	Yes	No	Partly	Don't Know		Yes	No	Partly	Don't Know
Question 1	37 (73%)	0 (0%)	12 (24%)	2 (4%)		11 (92%)	0 (0%)	1 (8%)	0 (0%)
Question 2	5 (10%)	39 (76%)	N/A	7 (14%)		4 (33%)	8 (67%)	N/A	0 (0%)
Question 3	18 (35%)	19 (37%)	N/A	14 (27%)		6 (50%)	6 (50%)	N/A	0 (0%)
Question 4	10 (20%)	36 (71%)	N/A	5 (10%)		2 (17%)	10 (83%)	N/A	0 (0%)

- Percentages in the tables above have been rounded to the nearest whole number and therefore may not add to 100 per cent.
- Question five invited any further comments rather than a 'yes' or 'no' answers so it is not included in the above tables.

3. General comments

3.1 This section outlines the general themes that arose from the responses we received to the consultation.

Interaction with other frameworks

3.2 A few respondents mentioned other frameworks which outline recommendations and good practice for both biomedical scientists and other healthcare professions. They subsequently sought some reference to these in the revised standards. Some of these included:

- the National School of Healthcare Science's life science curricula and learning guides which refer to additional specialisms;
- the International Organisation for Standardization's (ISO) standards and terminology (including ISO 15189);
- other regulatory bodies' standards and compliance with them, for example the Medicines and Healthcare Products Regulatory Agency (MHRA);
- the NHS Practitioner Training Programme (PTP) curricula; and
- the Academy for Healthcare Science's *Good Scientific Practice* document which summarises professional standards across healthcare science.

Content of individual standards

3.3 Several respondents were concerned about the content of individual standards and / or pointed to possible omissions. The following provides an overview of some of the main concerns voiced by respondents.

3.4 A few respondents commented on communication issues within the standards. There was general support for strengthening the communication requirements in a number of spheres. These included:

- reference to co-morbidity, its impact on communication and placing an onus on registrants to assist further with individual communication requirements;
- communicating with colleagues both within and outside of their profession;
- communicating the outcome of a biomedical procedure to a recipient (including a service user) to 'unambiguous standards';
- utilising assistive technology to aid communication;
- adapting communication requirements to take account of sensory loss; and
- communicating with carers and relatives.

3.5 Other respondents sought the inclusion of additional profession-specific standards and detail in a number of areas. These included:

- practising in a non-discriminatory manner;

- adhering to immunisation requirements;
- maintaining a safe practice environment;
- keeping up-to-date with scientific developments;
- record keeping;
- utilising departmental resources effectively;
- referring to the role of pathology in diagnosis and treatment;
- referring to additional terms and specialisms in the standards; and
- participating in service accreditation schemes.

3.6 A few respondents proposed the reinstatement of a number of existing standards and / or content which had either been subsumed into existing standards or amended to form new profession-specific standards. These included:

- Standard 2b.3 – be able to identify the cause of procedural anomalies and implement remedies;
- Standard 2c.2 – understanding the principles of quality control and quality assurance;
- Standards 1b.1 and 1b.3 – reference to both working in partnership and communicating information to 'relatives and carers';
- Standard 2a.4 – reference to presenting data in graph and table format;
- Standard 2b.4 – reference to being aware of 'near-patient testing';
- Standard 3a.3 – understand sources of hazard in the workplace, including specimens, raw materials, clinical waste and equipment;
- Standard 3a.3 – know the correct principles and applications of disinfectants, methods for sterilisation and decontamination, and for dealing with waste and spillages correctly; and
- Standard 3a.3 – know the use and application of engineering controls, eg mechanical ventilation systems such as fume cupboards or microbiological safety cabinets.

'Be able to' / 'understand' etc

3.7 Whilst some respondents supported the use of such phrases as 'know', 'be able to', 'be aware of' and 'understand' which made the standards more accessible and usable, a number of other respondents were concerned about this choice of construction. There was a variety of views on this point.

3.8 Those respondents who voiced some concern about the wording and construction of the standards included:

- questioning how we would measure the requirement; and
- substituting the requirement with a stronger expectation, for example, define.

3.9 Stronger emphasis was sought by some respondents in the following standards:

- Standard 1.1 – know the limits of their practice and when to seek advice or refer to another professional; and

- Standard 9.5 – be aware of the impact of pathology services on the patient care pathway.

3.10 However, support for strengthening the expectations contained in the standards was not universal. One respondent was concerned that the requirement contained in standard 2.6 – to be aware of the British, European and International Standards that govern and affect pathology laboratory practice – was too strong an expectation for most registrants. They supported a more general approach being adopted whereby registrants would be required to understand their duties, tasks, responsibilities and be able to obtain additional information, as required.

Employer tensions, nature of the role and meeting the standards

3.11 A few respondents were concerned about the ability of all registrants to meet the standards of proficiency for biomedical scientists and provide evidence for same. These concerns included:

- questioning the applicability of the standards for all registrants; and
- arguing that the nature of the role did not cater for much direct patient contact.

3.12 Three respondents commented on the issue of informed consent. They noted the difficulty for registrants of directly obtaining informed consent from service users and pointed to a reliance on other healthcare professionals obtaining this. They were particularly concerned with the reference to 'be able to' in this context. However, two of the respondents supported registrants being required to have an 'understanding' of informed consent.

3.13 Two respondents commented on standard 4.2 – be able to make reasoned decisions to initiate, continue, modify or cease treatment or the use of techniques or procedures, and record the decisions and reasoning appropriately. Both respondents were concerned with the reference to treatment in the standard which they argued would be difficult to be assessed against and / or questioned its applicability for all registrants particularly in the initiation of treatment.

3.14 Other respondents questioned the applicability of a variety of standards and / or terminology used therein for registrants. These included:

- Standard 2.4 – recognise that relationships with service users should be based on mutual respect and trust, and be able to maintain high standards of care even in situations of personal incompatibility;
- Standard 2.6 – be aware of the British, European and International Standards that govern and affect pathology laboratory practice;
- Standard 4.5 – be able to make and receive appropriate referrals;

- Standard 13.6 – understand the theoretical basis of, and variety of approaches to, assessment and intervention;
- Standard 14.6 – be able to demonstrate proficiency in liquid handling methodologies, including preparation of standard solutions and buffers; and
- Standard 14.25 – be able to investigate and monitor disease processes and normal states.

3.15 Other suggestions for improving the applicability of the standards for all registrants included combining or ensuring that the standards of proficiency for both biomedical scientists and clinical scientists were as similar as possible.

3.16 One respondent voiced some unease about the interaction of our standards and meeting their employer's expectations and requirements. They were concerned with registrants being required to adhere to our standards of proficiency, which could result in some tensions with their employer particularly in relation to standard 4.4 – be able to initiate resolution of problems and be able to exercise personal initiative.

4. Comments in response to specific questions

4.1 This section contains comments made in response to specific questions within the consultation document.

Question 1. Do you think the standards are at a threshold level necessary for safe and effective practice?

4.2 The vast majority of respondents (76 per cent) agreed that the draft standards were set at a threshold level necessary for safe and effective practice.

4.3 Some of these respondents commented that the standards:
- were appropriate and used clearer wording and sentence structure;
- referred to additional requirements in a number of spheres and clarified our expectations; and
- were sufficiently detailed and applicable to a registrant's particular role and the wider profession (including taking account of new developments).

4.4 Two respondents commented on the enforcement of the standards via the self-declaration procedure which is linked to the biannual registration renewal cycle. One respondent questioned whether this procedure was sufficient and supported its substitution with an alternative model to ensure compliance. However, the second respondent welcomed the revised standards of proficiency in order to aid a registrant's understanding when completing such a declaration.

4.5 A number of respondents only **partly** agreed that the standards were set at a threshold level necessary for safe and effective practice (twenty-one per cent).

4.6 Some of these respondents proposed further areas for consideration in order to strengthen the standards. These included:
- clarifying the role of the standards of proficiency;
- providing reference to understanding the principles and frameworks of good governance; and
- providing more explicit references to patient safety and patient experience, knowledge of quality improvement (QI) strategies, and the appropriate storage of data in the standards.

Question 2. Do you think any additional standards are necessary?

4.7 The majority of respondents did not think that any additional standards were necessary. With 75 per cent stating this to be the case, as opposed to only 14 per cent stating that additional standards were necessary.

4.8 The reasons provided by respondents for not proposing additional standards included:

- pointing to the applicability of the standards for the profession; and
- voicing some concerns about widening the standards and the resultant difficulty of registrants meeting them.

4.9 A minority of respondents suggested that additional standards were necessary. 33 per cent of organisations who responded thought that additional standards were necessary, but only 10 per cent of individual respondents thought additional standards were necessary.

4.10 All of the additional standards suggested by respondents are set out in appendix two. The main areas suggested by respondents included additional standards relating to:

- learning from colleagues and other health and care professionals;
- clarifying our expectations with regard to confidentiality and safeguarding issues;
- testing English language competency;
- providing more detailed reference to health and safety legislation; and
- referring to additional profession-specific terminology.

Question 3. Do you think there are any standards which should be reworded or removed?

4.11 Some 40 per cent of respondents did not think that any standards needed to be reworded or removed. However, a significant minority of respondents (38 per cent) thought that some standards needed to be reworded or removed.

4.12 Some of the suggestions we received were based on concerns about the general use of language in the standards; these concerns have been summarised in response to question four below.

4.13 We have listed all the proposed amendments to the standards in appendix three. Respondents suggested changes to the standards for a number of reasons including, to:

- strengthen and clarify our expectations and requirements for registrants;
- provide clearer reference to the scope of practice in the standards; and
- aid comprehension and measure compliance.

Question 4. Do you have any comments about the language used in the standards?

4.14 The majority of respondents (73 per cent) indicated that they had no comments to make about the language used in the standards.

4.15 Those respondents who commented on this issue were generally supportive of the language used in the standards. They observed that the language used:

- was appropriate, clear, comprehensive, concise, simple, straightforward and unambiguous; and
- marked an improvement on previous versions.

4.16 Other respondents suggested that the language used in the standards could be further strengthened and improved. These included:

- questioning whether the language used in the standards could be understood by registrants whose first language was not English;
- softening the language used in order to aid comprehension and compliance (but without weakening the requirement itself); and
- pointing to the use of subjective rather than objective language in the standards.

Question 5: Do you have any other comments on the standards?

4.17 Several respondents indicated that they had other comments to make regarding the standards. To avoid duplication, some of those comments have not been included here if they have been addressed elsewhere in this document. Some respondents:

- commented that the adoption of a ‘one size fits all’ approach made for unnecessary standards;
- questioned the standards relationship to, relevance and impact on the Institute of Biomedical Science’s (IBMS) certificate of competence and in verifying portfolios;
- questioned whether the standards could be adapted to the required competencies for practising the profession within different settings;
- pointed to the difficulty in meeting some of the standards in both high pressure and short staffed environments;
- argued that the standards of proficiency for biomedical scientists were biased towards laboratory practice rather than clinical practice;
- sought further clarification of our requirements for continuing professional development (CPD); and
- suggested greater involvement of other stakeholders connected with the profession in the pre-review process.

5. Our responses

5.1 We received a range of comments about the standards during the consultation process, including suggested amendments and possible additional standards, which we have carefully considered. The following section outlines our responses to these comments and suggestions including the changes we will make to the draft standards.

Level of detail in the standards

5.2 A number of comments we received suggested additional standards and amendments to provide more prescriptive detail about the requirements for registrant biomedical scientists.

5.3 We considered the following in deciding whether we should make suggested changes or amendments:

- Is the standard necessary for safe and effective practice?
- Is the standard set at the threshold level for entry to the Register?
- Does the standard reflect existing requirements for biomedical scientists on entry into the profession?
- Does the standard reflect existing education and training?
- Is the standard written in a broad and flexible way so that it can apply to the different environments in which biomedical scientists might practise or the different groups that they might work with?

5.4 The standards set out the proficiencies necessary to practise the profession. However, the standards are not a curriculum document nor are they intended to be a list of activities which registrants must undertake in any situation. For example, a registrant needs to ‘be able to maintain confidentiality’ on entry to the Register. However, this is an ability and does not mean that there will not be situations where information might need to be shared with, or disclosed to others for the benefit of service users or in the public interest.

5.5 Part of our focus for the review of the standards is to ensure that the standards are relevant to the scope of practice of the biomedical scientist profession. When making decisions about whether to make changes to the standards, we must therefore consider whether the changes would make the standards too specific or would limit the scope of the standards.

5.6 We also aim to avoid duplication in the standards, to ensure they are clearly worded, and maintain consistency between different professions’ standards wherever possible and appropriate.

The standards and scope of practice

5.7 Some respondents sought further reference to scope of practice in the standards and clearer guidance for more experienced registrants who have specialised in a particular area of practice who subsequently may or may not be able to meet all of the standards of proficiency.

5.8 The standards set out the threshold proficiencies required of applicants when they first apply to join the Register. Once on the Register, every time registrants renew their registration, they are asked to confirm that they continue to meet the standards of proficiency that apply to their own scope of practice - the area of their profession in which they have the knowledge, skills and experience to practise safely and effectively.

5.9 We recognise that a registrant's scope of practice will change over time and that the practice of experienced registrants may become more focused and specialised than that of newly registered colleagues. However, the standards are intended to set the threshold knowledge, understanding and skills required by a registrant for entry to our Register. Therefore, we do not outline or stipulate competencies above a threshold level.

Use of 'be able to' and 'understand' etc

5.10 We intentionally use phrases such as 'understand', 'know', 'be aware of' and 'be able to' rather than 'must'. This is so the standards remain applicable to current registrants in maintaining their fitness to practise, as well as prospective registrants who have not yet started practising and are applying to be registered for the first time. It also makes sure that the standards are written in a similar way to the learning outcomes set for pre-registration education programmes.

5.11 It is important to note the current standards of proficiency use verbs and starting phrases in the same way as the proposed new profession-specific standards of proficiency. We have not experienced any difficulty in applying the current wording of the standards of proficiency in the way some respondents have anticipated.

Comments on specific standards

5.12 A few respondents were concerned with the removal or amendment of a number of existing profession-specific standards and / or content from the proposed standards.

5.13 These included:

- being aware of immunisation requirements;
- working in partnership and communicating with relatives and carers;
- understanding the principles of quality control and assurance;

- being aware of near-patient testing;
- being able to use statistical packages and present data as graphs and tables; and
- providing additional prescriptive detail on the maintenance of a safe practice environment in the workplace.

5.14 With regard to the latter suggestion, this would include the following:
- understanding the sources of hazard;
- knowing the correct principles and applications of disinfectants and other methods of sterilisation; and
- knowing how to use and apply engineering controls.

5.15 However, these requirements have either been subsumed into existing standards or amended to form new profession-specific standards. These include:
- standard 3.2 which refers to the importance of registrants maintaining their own health;
- standards 8.2 and 9.1 refers to 'others' which could include relatives and carers where appropriate;
- standards 12.3 and 14.13 details the general principles of quality control and quality assurance;
- standard 14.16 refers to the role and responsibility of the laboratory for near-patient testing;
- standard 14.27 refers to the use of statistical packages and presenting data in an 'appropriate format'; and
- standards 13.11 and 15.3 – 15.5 refers to the general requirements for the maintenance of a safe practice environment.

5.16 We have noted the above concerns; however, we are satisfied that nothing has been lost with regard to these minor amendments to the proposed standards.

5.17 We have noted the comments we received for strengthening the communication requirements for registrants in a number of spheres.

5.18 We have noted the concern expressed by some respondents on the ability of all registrants to meet the standards of proficiency due the nature of the role and / or questioning their applicability and relevance for an individual registrant's scope of practice.

5.19 We acknowledge that employers and other organisations such as the International Organisation for Standardisation (ISO) produce specific guidance and policies in a number of spheres which can be used in conjunction with our standards.

5.20 We have carefully considered and noted the comments above. However, we have concluded that, on balance, we are satisfied that the revised standards do reflect the threshold entry requirements for entry to the Register as a biomedical scientist.

Our decisions

5.21 The proposed standards had a very high approval rating overall among respondents which included 76 per cent of respondents indicating that they were set at the threshold level necessary for safe and effective practice.

5.22 Also some of the changes suggested by respondents were not included because we felt that they would duplicate content already contained within the standards we set, or they would not make our requirements clearer.

5.23 We have made three change to the standards based on the comments we received in consultation as summarised below. The revised standards following consultation can be found in appendix one.

- We have made a minor change to standards 13.8 and 14.7 to amend the reference from ‘cell science’ to ‘cellular science’ which is a more reflective of current terminology for the profession and is wider than traditional cellular pathology.
- We have made some minor editing amendments to individual standards to correct mistakes and / or omissions.

6. List of respondents

Below is a list of all the organisations that responded to the consultation.

Association of Biomedical Healthcare Scientists (ABHS)
Academy for Healthcare Science (AHCS)
British Blood Transfusion Society
British Society of Clinical Immunology and Allergy Section
Centre for the Advancement of Interprofessional Education (CAIPE)
Council of Healthcare Science in Higher Education
Institute of Biomedical Science (IBMS)
Liverpool John Moores University
National Blood Bank
NHS Education for Scotland
Public Health England
Royal College of Pathologists

Appendix 1: Draft standards of proficiency for biomedical scientists

New standards and amendments to standards are shown in **bold and underlined**. Deletions are shown in ~~strikethrough~~. The standards in this section are subject to legal scrutiny and may be subject to minor editing amendments prior to publication.

No.	Standard
1	**be able to practise safely and effectively within their scope of practice**
1.1	know the limits of their practice and when to seek advice or refer to another professional
1.2	recognise the need to manage their own workload and resources effectively and be able to practise accordingly
2	**be able to practise within the legal and ethical boundaries of their profession**
2.1	understand the need to act in the best interests of service users at all times
2.2	understand what is required of them by the Health and Care Professions Council
2.3	understand the need to respect and uphold the rights, dignity, values, and autonomy of service users including their role in the diagnostic and therapeutic process and in maintaining health and wellbeing
2.4	recognise that relationships with service users should be based on mutual respect and trust, and be able to maintain high standards of care even in situations of personal incompatibility
2.5	know about current legislation applicable to the work of their profession
2.6	be aware of the British, European and International Standards that govern and affect pathology laboratory practice
2.7	understand the importance of and be able to obtain informed consent
2.8	be able to exercise a professional duty of care

3	**be able to maintain fitness to practise**
3.1	understand the need to maintain high standards of personal and professional conduct
3.2	understand the importance of maintaining their own health
3.3	understand both the need to keep skills and knowledge up to date and the importance of career-long learning
4	**be able to practise as an autonomous professional, exercising their own professional judgement**
4.1	be able to assess a professional situation, determine the nature and severity of the problem and call upon the required knowledge and experience to deal with the problem
4.2	be able to make reasoned decisions to initiate, continue, modify or cease treatment or the use of techniques or procedures, and record the decisions and reasoning appropriately
4.3	be able to initiate resolution of problems and be able to exercise personal initiative
4.4	recognise that they are personally responsible for and must be able to justify their decisions
4.5	be able to make and receive appropriate referrals
4.6	understand the importance of participation in training, supervision and mentoring
5	**be aware of the impact of culture, equality and diversity on practice**
5.1	understand the requirement to adapt practice to meet the needs of different groups and individuals
6	**be able to practise in a non-discriminatory manner**
7	**understand the importance of and be able to maintain confidentiality**
7.1	be aware of the limits of the concept of confidentiality

7.2	understand the principles of information governance and be aware of the safe and effective use of health and social care information
7.3	be able to recognise and respond appropriately to situations where it is necessary to share information to safeguard service users or the wider public
8	**be able to communicate effectively**
8.1	be able to communicate in English to the standard equivalent to level 7 of the International English Language Testing System, with no element below 6.5[2]
8.2	be able to demonstrate effective and appropriate verbal and non-verbal skills in communicating information, advice, instruction and professional opinion to service users, colleagues and others
8.3	understand how communication skills affect assessment of**,** and engagement with**,** service users and how the means of communication should be modified to address and take account of factors such as age, capacity, learning ability and physical ability
8.4	be able to communicate **the** outcomes of biomedical procedures
8.5	be able to select, move between and use appropriate forms of verbal and non-verbal communication with service users and others
8.6	be aware of the characteristics and consequences of verbal and non-verbal communication and how this can be affected by factors such as age, culture, ethnicity, gender, socio-economic status and spiritual or religious beliefs
8.7	understand the need to provide service users or people acting on their behalf with the information necessary to enable them to make informed decisions

[2] The International English Language Testing System (IELTS) tests competence in the English language. Applicants who have qualified outside of the UK, whose first language is not English and who are not nationals of a country within the European Economic Area (EEA) or Switzerland, must provide evidence that they have reached the necessary standard. Please visit our website for more information.

8.8	understand the need to assist the communication needs of service users such as through the use of an appropriate interpreter, wherever possible
8.9	recognise the need to use interpersonal skills to encourage the active participation of service users
9	**be able to work appropriately with others**
9.1	be able to work, where appropriate, in partnership with service users, other professionals, support staff and others
9.2	understand the need to build and sustain professional relationships as both an independent practitioner and collaboratively as a member of a team
9.3	understand the need to engage service users and carers in planning and evaluating diagnostics, treatments and interventions to meet their needs and goals
9.4	be able to contribute effectively to work undertaken as part of a multi-disciplinary team
9.5	be aware of the impact of pathology services on the patient care pathway
10	**be able to maintain records appropriately**
10.1	be able to keep accurate, comprehensive and comprehensible records in accordance with applicable legislation, protocols and guidelines
10.2	recognise the need to manage records and all other information in accordance with applicable legislation, protocols and guidelines
10.3	be able to recognise, communicate and understand the risks and possible serious consequences of errors and omissions in both requests for, and results of, laboratory investigations
10.4	be able to use systems for the accurate and correct identification of patients and laboratory specimens
10.5	understand the need to adhere to protocols of specimen identification, including bar coding and electronic tag systems
10.6	understand the importance of backup storage of electronic data

11	**be able to reflect on and review practice**
11.1	understand the value of reflection on practice and the need to record the outcome of such reflection
11.2	recognise the value of case conferences and other methods of review
12	**be able to assure the quality of their practice**
12.1	be able to engage in evidence-based practice, evaluate practice systematically and participate in audit procedures
12.2	be able to gather information, including qualitative and quantitative data, that helps to evaluate the responses of service users to their care
12.3	be aware of the role of audit and review in quality management, including quality control, quality assurance and the use of appropriate outcome measures
12.4	be able to maintain an effective audit trail and work towards continual improvement
12.5	be aware of, and be able to participate in, quality assurance programmes, where appropriate
12.6	be able to evaluate intervention plans using recognised outcome measures and revise the plans as necessary in conjunction with the service user
12.7	recognise the need to monitor and evaluate the quality of practice and the value of contributing to the generation of data for quality assurance and improvement programmes
12.8	be able to select and apply quality and process control measures
12.9	be able to identify and respond appropriately to abnormal outcomes from quality indicators
13	**understand the key concepts of the knowledge base relevant to their profession**
13.1	understand the structure and function of the human body, together with knowledge of health, disease, disorder and dysfunction relevant to their profession

13.2	be aware of the principles and applications of scientific enquiry, including the evaluation of treatment efficacy and the research process
13.3	recognise the role of other professions in health and social care
13.4	understand the structure and function of health and social care services in the UK
13.5	understand the concept of leadership and its application to practice
13.6	understand the theoretical basis of, and the variety of approaches to, assessment and intervention
13.7	be able to demonstrate knowledge of underpinning scientific principles of investigations provided by clinical laboratory services
13.8	understand the role of the following specialisms in the diagnosis, treatment and management of disease: ~~cell~~ **cellular** science, blood science, infection science, molecular and genetic science and reproductive science
13.9	be able to evaluate analyses using qualitative and quantitative methods to aid the diagnosis, screening and monitoring of health and disorders
13.10	understand the techniques and associated instrumentation used in the practice of biomedical science
13.11	understand the biological hazards groups and associated containment levels
14	**be able to draw on appropriate knowledge and skills to inform practice**
14.1	be able to change their practice as needed to take account of new developments or changing contexts
14.2	be able to conduct appropriate diagnostic or monitoring procedures, treatment, therapy or other actions safely and effectively
14.3	be able to perform and supervise procedures in clinical laboratory investigations to reproducible standards
14.4	be able to operate and utilise specialist equipment according to their discipline
14.5	be able to validate scientific and technical data and observations according to pre-determined quality standards

14.6	be able to demonstrate proficiency in liquid handling methodologies, including preparation of standard solutions and buffers
14.7	be able to demonstrate proficiency in practical skills in ~~cell~~ **cellular** science, blood science, infection science, molecular and genetic science and reproductive science where appropriate to the discipline
14.8	be able to demonstrate practical skills in the processing and analysis of specimens including specimen identification, the effect of storage on specimens and the safe retrieval of specimens
14.9	be able to demonstrate practical skills in the investigation of disease processes
14.10	be able to work in conformance with standard operating procedures and conditions
14.11	be able to work with accuracy and precision
14.12	be able to prepare reagents accurately and consistently
14.13	be able to perform calibration and quality control checks
14.14	be able to demonstrate operational management of laboratory equipment to check that equipment is functioning within its specifications and to respond appropriately to abnormalities
14.15	understand the implications of non-analytical errors
14.16	know the extent of the role and responsibility of the laboratory with respect to the quality management of hospital, primary care and community based laboratory services for near-patient testing and non-invasive techniques
14.17	be able to formulate specific and appropriate management plans including the setting of timescales
14.18	be able to gather appropriate information
14.19	be able to select suitable specimens and procedures relevant to patients' clinical needs, including collection and preparation of specimens as and when appropriate
14.20	be able to select and use appropriate assessment techniques
14.21	be able to undertake and record a thorough, sensitive and detailed assessment, using appropriate techniques and equipment

14.22	be aware of the need and be able to assess and evaluate new procedures prior to routine use
14.23	be able to undertake or arrange investigations as appropriate
14.24	be able to analyse and critically evaluate the information collected
14.25	be able to investigate and monitor disease processes and normal states
14.26	be able to use standard operating procedures for analyses including point of care in vitro diagnostic devices
14.27	be able to use statistical packages and present data in an appropriate format
14.28	be able to demonstrate a logical and systematic approach to problem solving
14.29	be able to use research, reasoning and problem solving skills to determine appropriate actions
14.30	recognise the value of research to the critical evaluation of practice
14.31	be aware of a range of research methodologies
14.32	be able to evaluate research and other evidence to inform their own practice
14.33	be able to design experiments, report, interpret and present data using scientific convention, including application of SI units and other units used in biomedical science
14.34	be able to use information and communication technologies appropriate to their practice
15	**understand the need to establish and maintain a safe practice environment**
15.1	understand the need to maintain the safety of both service users and those involved in their care
15.2	be aware of applicable health and safety legislation, and any relevant safety policies and procedures in force at the workplace, such as incident reporting, and be able to act in accordance with these

15.3	be able to work safely, including being able to select appropriate hazard control and risk management, reduction or elimination techniques in a safe manner and in accordance with health and safety legislation
15.4	be able to select appropriate personal protective equipment and use it correctly
15.5	be able to establish safe environments for practice, which minimise risks to service users, those treating them and others, including the use of hazard control and particularly infection control
15.6	understand the application of principles of good laboratory practice

Appendix 2: Suggested additional standards

No.	Standard	Suggested additional standards
1.	be able to practise safely and effectively within their scope of practice	
2.	be able to practise within the legal and ethical boundaries of their profession	
3.	be able to maintain fitness to practise	One respondent suggested the inclusion of an additional standard under this standard: • engage in learning with, from and about colleagues in other branches of health and social care, to fully understand both their own and others role within health and social care.
4.	be able to practise as an autonomous professional, exercising their own professional judgement	
5.	be aware of the impact of culture, equality, and diversity on practice	
6.	be able to practise in a non-discriminatory manner	
7.	Understand the importance of and be able to maintain confidentiality	One respondent suggested the inclusion of an additional standard under this standard: • understand the need to liaise appropriately with colleagues if you have any concerns about confidentiality or where safeguarding is relevant.
8.	be able to communicate effectively	One respondent sought an additional standard for testing the English language competency of registrants whose first language is not English.

9.	be able to work appropriately with others	
10.	be able to maintain records appropriately	One respondent suggested the inclusion of an additional standard under this standard: • registrants must ensure that data is held securely to ensure compliance with current data protection requirements, and to maintain necessary standards of confidentiality.
11.	be able to reflect on and review practice	
12.	be able to assure the quality of their practice	Two respondents sought additional standards under generic standard 12. One respondent suggested reinstating the existing standard 2c2 as this is a significant feature of the work undertaken by registrants: • understand the principles of quality control and quality assurance. However, the other respondent sought an additional standard on quality improvement (QI) methodologies.
13.	understand the key concepts of the knowledge base relevant to their profession	
14.	be able to draw on appropriate knowledge and skills to inform practice	Two respondents sought additional standards under this standard. One respondent suggested reinstating the existing standard 2b.3, as the work of registrants significantly involves the use of kits and other reagents, instruments and practical procedures: • be able to identify the cause of procedural anomalies and implement remedies However, the other respondent sought reference within the standard to an awareness of the terms of ‘verification’ or ‘validation’ and when this is necessary.

15.	understand the need to establish and maintain a safe practice environment	Two respondents suggested the reinstatement of the existing standard on immunisation under this standard: • be aware of immunisation requirements and the role of occupational health A few respondents supported strengthening the general requirements for registrants establishing and maintaining a safe practice environment. One respondent suggested reinstating a number of existing standards from standard 3a.3. These included: • understand sources of hazard in the workplace, including specimens, raw materials, clinical waste and equipment; • know the correct principles and applications of disinfectants, methods for sterilisation and decontamination, and for dealing with waste and spillages correctly; and • know the use and application of engineering controls, eg mechanical ventilation systems such as fume cupboards or microbiological safety cabinets. Whereas another respondent supported the inclusion of an additional standard on safety management under generic standards 2, 14 or 15. This respondent identified the following areas for inclusion: • safe waste disposal (which would include solid waste); and • avoiding potentially hazardous or polluting discharges to the environment. They pointed to a number of benefits for including such an additional standard. These included: • replacing standard 13.11 which may not be understood by all registrants; • ensuring such a standard would be more wide-ranging and apply to various environments and circumstances; and • strengthening the role of Trusts in providing relevant training to their staff for safe working. Finally, the third respondent sought an additional standard on spillage training and / or the involvement of the Environment Agency in hospital waste management.

Appendix 3: Detailed comments on the draft standards

Respondents' proposed deletions are indicated in the text by ~~strikethrough~~ whilst additions are shown in **bold.**

This section does not include comments received about the generic standards, as they were not within the scope of the consultation.

No.	Standard	Comments
1	**be able to practise safely and effectively within their scope of practice**	
1.1	know the limits of their practice and when to seek advice or refer to another professional	One respondent suggested amending this standard to the following wording: • **can define** ~~know~~ the limits of their practice and when to seek advice or refer to another professional
1.2	recognise the need to manage their own workload and resources effectively and be able to practise accordingly	
2	**be able to practise within the legal and ethical boundaries of their profession**	
2.1	understand the need to act in the best interests of service users at all times	
2.2	understand what is required of them by the Health and Care Professions Council	

2.3	understand the need to respect and uphold the rights, dignity, values, and autonomy of service users including their role in the diagnostic and therapeutic process and in maintaining health and wellbeing	
2.4	recognise that relationships with service users should be based on mutual respect and trust, and be able to maintain high standards of care even in situations of personal incompatibility	Two respondents commented on this standard. One respondent suggested amending this standard to the following wording: • recognise that relationships with service users should be based on mutual respect and trust, and be able to maintain high standards of care **at all times** ~~even in situations of personal incompatibility~~ One respondent was concerned that the wording of this standard made it difficult for all registrants to meet this requirement and provide evidence for this due to the nature of the role. They also identified the following additional standards where they had this concern: 2.7, 4.2, 4.5, 8.7, 9.3, 12.2 and 13.6.
2.5	know about current legislation applicable to the work of their profession	One respondent suggested amending this standard to the following wording: • know about current **UK** legislation applicable to the work of their profession

2.6	be aware of the British, European and International Standards that govern and affect pathology laboratory practice	Two respondents commented on this standard. One respondent suggested amending this standard to the following wording: • be aware of the British, European and International Standards that govern and affect ~~pathology~~ **clinical** laboratory practice In contrast, the second respondent commented that this standard was not applicable to the majority of registrants and would be difficult to assess compliance against particularly in relation to fitness to practise (FTP).
2.7	understand the importance of and be able to obtain informed consent	Three respondents commented on this standard. One respondent suggested amending this standard to the following wording: • understand the importance of ~~and be able to obtain~~ informed consent These respondents were concerned that registrants might not be able to obtain informed consent due to the nature of their role and / or a reliance on other healthcare professionals or the requestor of tests to obtain it.
2.8	be able to exercise a professional duty of care	
3	**be able to maintain fitness to practise**	
3.1	understand the need to maintain high standards of personal and professional conduct	
3.2	understand the importance of maintaining their own health	

3.3	understand both the need to keep skills and knowledge up to date and the importance of career-long learning	
4	**be able to practise as an autonomous professional, exercising their own professional judgement**	
4.1	be able to assess a professional situation, determine the nature and severity of the problem and call upon the required knowledge and experience to deal with the problem	
4.2	be able to make reasoned decisions to initiate, continue, modify or cease treatment or the use of techniques or procedures, and record the decisions and reasoning appropriately	Two respondents commented on this standard. Both respondents were concerned with the reference to treatment in the standard which they observed may be difficult for registrants to be assessed against and / or questioned its applicability for all registrants particularly in the initiation of treatment.
4.3	be able to initiate resolution of problems and be able to exercise personal initiative	One respondent suggested amending this standard to the following wording: • be able to**, within their scope of practice,** initiate resolution of problems and be able to exercise personal initiative
4.4	recognise that they are personally responsible for and must be able to justify their decisions	
4.5	be able to make and receive appropriate referrals	One respondent commented that referrals are not initiated or received by biomedical scientists.

4.6	understand the importance of participation in training, supervision, and mentoring	One respondent supported the inclusion of training in this standard.
5	**be aware of the impact of culture, equality, and diversity on practice**	
5.1	understand the requirement to adapt practice to meet the needs of different groups and individuals	One respondent commented that the wording of this standard was more appropriate than the existing standard.
6	**be able to practise in a non-discriminatory manner**	Two respondents commented on this standard. One respondent sought a clearer distinction and definition for the required behaviours contained in this standard and how it differentiates from our expectations for registrants under generic standard five. Whereas the second respondent sought the inclusion of standards 2.3 and 8.6 under generic standard six.
7	**understand the importance of and be able to maintain confidentiality**	
7.1	be aware of the limits of the concept of confidentiality	One respondent supported the widening of standards 7.1 – 7.3.
7.2	understand the principles of information governance and be aware of the safe and effective use of health and social care information	
7.3	be able to recognise and respond appropriately to situations where it is necessary to share information to safeguard service users or the wider public	One respondent supported the widening of this standard from the previous version.
8	**be able to communicate effectively**	

8.1	be able to communicate in English to the standard equivalent to level 7 of the International English Language Testing System, with no element below 6.5[3]	One respondent commented on this requirement and its impact on communicating in Welsh.
8.2	be able to demonstrate effective and appropriate verbal and non-verbal skills in communicating information, advice, instruction and professional opinion to service users, colleagues and others	One respondent sought clarity on the reference to colleagues in this standard. They questioned whether this requirement referred only to colleagues in one's own profession or to colleagues in other professions?
8.3	understand how communication skills affect assessment of, and engagement with, service users and how the means of communication should be modified to address and take account of factors such as age, capacity, learning ability and physical ability	One respondent suggested amending this standard to the following wording: • understand how communication skills affect assessment of, and engagement with, service users and how the means of communication should be modified to address and take account of factors such as age, capacity, **co-morbidity,** learning ability and physical ability
8.4	be able to communicate outcomes of biomedical procedures	
8.5	be able to select, move between and use appropriate forms of verbal and non-verbal communication with service users and others	
8.6	be aware of the characteristics and consequences of verbal and non-verbal communication and how this can be affected by factors such as age, culture, ethnicity, gender, socio-economic status and spiritual or religious beliefs	

[3] The International English Language Testing System (IELTS) tests competence in the English language. Applicants who have qualified outside of the UK, whose first language is not English and who are not nationals of a country within the European Economic Area (EEA) or Switzerland, must provide evidence that they have reached the necessary standard. Please visit our website for more information.

8.7	understand the need to provide service users or people acting on their behalf with the information necessary to enable them to make informed decisions	
8.8	understand the need to assist the communication needs of service users such as through the use of an appropriate interpreter, wherever possible	One respondent suggested amending this standard to the following wording: • understand the need to assist the communication needs of service users such as through the use of an appropriate interpreter **and / or assistive technology**, wherever possible
8.9	recognise the need to use interpersonal skills to encourage the active participation of service users	
9	**be able to work appropriately with others**	One respondent sought reference in this standard to working appropriately with others in order to improve outcomes for patients and others. They also suggested extending the standard so that biomedical scientists are able to achieve this.
9.1	be able to work, where appropriate, in partnership with service users, other professionals, support staff and others	Three respondents commented on this standard. One respondent suggested amending this standard to the following wording: • be able to work~~, where appropriate,~~ in partnership with service users, other professionals, support staff and others The second respondent sought a stronger reference to support workers in the standards. Whereas the third respondent sought reference to relatives and carers within the standard in order for their views to be considered in the provision of medical treatment.
9.2	understand the need to build and sustain professional relationships as both an independent practitioner and collaboratively as a member of a team	

9.3	understand the need to engage service users and carers in planning and evaluating diagnostics, treatments and interventions to meet their needs and goals	
9.4	be able to contribute effectively to work undertaken as part of a multi-disciplinary team	One respondent suggested amending the standard to the following wording: • be able to ~~contribute effectively to work undertaken as part of a multi-disciplinary~~ **lead and follow within the inter-professional** team**, as appropriate**
9.5	be aware of the impact of pathology services on the patient care pathway	Three respondents commented on this standard. One respondent suggested amending this standard to the following wording to encompass all specialisms within the profession: • be aware of the impact of ~~pathology~~ **clinical laboratory** services on the patient care pathway Whereas another respondent supported the inclusion of this standard as it acknowledged the significant role of pathology in diagnosis and treatment.
10	**be able to maintain records appropriately**	

10.1	be able to keep accurate, comprehensive and comprehensible records in accordance with applicable legislation, protocols and guidelines	Two respondents commented on this standard. One respondent suggested amending this standard in order to include the requirement that registrants ensure that their records are accessible to colleagues so as not to hinder further action and impair effective service delivery: • be able to keep **accessible,** accurate, comprehensive and comprehensible records in accordance with applicable legislation, protocols and guidelines Whereas the second respondent suggested re-ordering standards 10.1 and 10.2 or combining both of them. They also supported reference to 'legible' within the standard.
10.2	recognise the need to manage records and all other information in accordance with applicable legislation, protocols and guidelines	One respondent was concerned that this standard in its current format may not be easily understood or measured. Whereas another respondent supported the reinstatement of 'legible' in the standard.
10.3	be able to recognise, communicate and understand the risks and possible serious consequences of errors and omissions in both requests for, and results of, laboratory investigations	
10.4	be able to use systems for the accurate and correct identification of patients and laboratory specimens	
10.5	understand the need to adhere to protocols of specimen identification, including bar coding and electronic tag systems	
10.6	understand the importance of backup storage of electronic data	One respondent supported reference in the standard to the storage of data which would take account of future developments in technology.
11	**be able to reflect on and review practice**	
11.1	understand the value of reflection on practice and the need to record the outcome of such reflection	

11.2	recognise the value of case conferences and other methods of review	One respondent questioned the specific reference to ‘case conferences’ in this standard. They supported the incorporation of reflection into professional development as an alternative to case conferences, for example, clinical supervision and maintaining a professional portfolio.
12	**be able to assure the quality of their practice**	
12.1	be able to engage in evidence-based practice, evaluate practice systematically and participate in audit procedures	
12.2	be able to gather information, including qualitative and quantitative data, that helps to evaluate the responses of service users to their care	
12.3	be aware of the role of audit and review in quality management, including quality control, quality assurance and the use of appropriate outcome measures	
12.4	be able to maintain an effective audit trail and work towards continual improvement	
12.5	be aware of, and be able to participate in, quality assurance programmes, where appropriate	One respondent supported reference to participation in service accreditation schemes, for example, Clinical Pathology Accreditation (CPA) in this standard.
12.6	be able to evaluate intervention plans using recognised outcome measures and revise the plans as necessary in conjunction with the service user	

12.7	recognise the need to monitor and evaluate the quality of practice and the value of contributing to the generation of data for quality assurance and improvement programmes	
12.8	be able to select and apply quality and process control measures	One respondent suggested amending this standard to the following wording: • be able to select and apply quality and process control measures **including restorative action**
12.9	be able to identify and respond appropriately to abnormal outcomes from quality indicators	
13	**understand the key concepts of the knowledge base relevant to their profession**	One respondent supported the inclusion of reference to understanding the role of a registrant within the wider healthcare team. However, they did not identify the standard in question.
13.1	understand the structure and function of the human body, together with knowledge of health, disease, disorder and dysfunction relevant to their profession	One respondent commented that this standard is somewhat vague and open ended.
13.2	be aware of the principles and applications of scientific enquiry, including the evaluation of treatment efficacy and the research process	
13.3	recognise the role of other professions in health and social care	Two respondents commented on this standard. One respondent suggested amending this standard to the following wording: • recognise**, reflect upon, and respect** the role**s and responsibilities** of other professions in health and social care Whereas the second respondent suggested widening this standard to consider the interdependency of all health and social care professions in delivering high-quality care. This would improve outcomes for both service users and others.

13.4	understand the structure and function of health and social care services in the UK	One respondent questioned whether registrants understand the new NHS structure.
13.5	understand the concept of leadership and its application to practice	One respondent welcomed the reference to leadership in the standard.
13.6	understand the theoretical basis of, and the variety of approaches to, assessment and intervention	Two respondents commented on this standard. One respondent questioned its applicability for all registrants. They also sought further clarity on the theoretical basis and variety of approaches referred to in the standard. Whereas the second respondent identified this standard as requiring rewording or removal.
13.7	be able to demonstrate knowledge of underpinning scientific principles of investigations provided by clinical laboratory services	One respondent supported the new wording of this standard.
13.8	understand the role of the following specialisms in the diagnosis, treatment and management of disease: cell science, blood science, infection science, molecular and genetic science and reproductive science	Three respondents commented on this standard. One respondent suggested amending this standard to the following wording: • understand the role of the following specialisms in the diagnosis, treatment and management of disease: cell science, blood science**, immunological science**, infection science, molecular and genetic science and reproductive science Whereas the second respondent questioned whether reference to 'cell science' in this standard could be reworded to 'cellular pathology'. The third respondent supported the inclusion of an additional specialism in the standard – transfusion and transplantation science.
13.9	be able to evaluate analyses using qualitative and quantitative methods to aid the diagnosis, screening and monitoring of health and disorders	
13.10	understand the techniques and associated instrumentation used in the practice of biomedical science	

13.11	understand the biological hazards groups and associated containment levels	Two respondents commented on this standard. One respondent suggested amending this standard to the following wording: • **have an** understand**ing of chemical and** ~~the~~ biological hazards **and methods of safe working and control, to protect yourself, your colleagues and others,** ~~groups~~ and **to ensure appropriate environmental protection** ~~associated containment levels~~ Whereas the second respondent suggested moving this standard to generic standard 15 which covers the issue of health and safety.
14	**be able to draw on appropriate knowledge and skills to inform practice**	One respondent supported amending the order of the standards listed under generic standard 14. They recommended the adoption of a more chronological approach reflecting the order of how specific tasks are undertaken and starting with standards 14.2, 14.20, 14.6, and 14.8. Standard 14.1 would subsequently be located further down the list of standards.
14.1	be able to change practice as needed to take account of new developments or changing contexts	Two respondents commented on this standard. One respondent suggested amending this standard to the following wording: • be able to **operate and utilise routine analytical processes and equipment according to their discipline** ~~change practice as needed to take account of new developments or changing contexts~~ Whereas the second respondent sought reference to registrants keeping up-to-date with scientific developments as per generic standard 11 and profession-specific standard 14.32.
14.2	be able to conduct appropriate diagnostic or monitoring procedures, treatment, therapy or other actions safely and effectively	One respondent suggested including reference to liaising with other professional colleagues in order to achieve this requirement.

14.3	be able to perform and supervise procedures in clinical laboratory investigations to reproducible standards	Two respondents commented on this standard. One respondent suggested amending this standard to the following wording: • be able to perform and supervise**, as delegated,** procedures in clinical laboratory investigations to reproducible standards Whereas the second respondent observed that the amended standard was more inclusive.
14.4	be able to operate and utilise specialist equipment according to their discipline	
14.5	be able to validate scientific and technical data and observations according to pre-determined quality standards	
14.6	be able to demonstrate proficiency in liquid handling methodologies, including preparation of standard solutions and buffers	Three respondents commented on this standard. One respondent suggested amending this standard to the following wording: • be able to demonstrate proficiency in liquid handling methodologies~~, including preparation of standard solutions and buffers~~ Whereas the second respondent questioned this standard's applicability for all registrants and whether the requirement is a component of approved education and training programmes. But they also argued that the requirement in general is covered in standards 14.11, 14.12 and 14.13 for those registrants for whom this skill is necessary. Finally, the third respondent identified this standard as requiring rewording or removal due to its basic nature which they felt was more applicable for support workers.

14.7	be able to demonstrate proficiency in practical skills in cell science, blood science, infection science, molecular and genetic science and reproductive science where appropriate to the discipline	Five respondents commented on this standard. Two respondents suggested amending this standard: • be able to demonstrate proficiency in practical skills ~~in cell science, blood science, infection science, molecular and genetic science and reproductive science~~ where appropriate to the discipline; or • be able to demonstrate ~~proficiency in~~ practical skills in **instrumentation etc.** ~~cell science, blood science, infection science, molecular and genetic science and reproductive science where appropriate to the discipline~~ The latter respondent commented that the previous list of methodologies, which had been amended for the draft standards, were out-dated and not available in many hospital laboratories. Whereas the third respondent questioned whether reference to 'cell science' in this standard could be reworded to 'cellular pathology'. The fourth respondent welcomed the amending of this standard which made it more relevant for practising the profession. The last respondent supported the inclusion of an additional specialism in the standard – transfusion and transplantation science.
14.8	be able to demonstrate practical skills in the processing and analysis of specimens including specimen identification, the effect of storage on specimens and the safe retrieval of specimens	One respondent identified this standard as requiring rewording or removal due to its basic nature which they felt was more applicable for supporter workers.
14.9	be able to demonstrate practical skills in the investigation of disease processes	
14.10	be able to work in conformance with standard operating procedures and conditions	
14.11	be able to work with accuracy and precision	
14.12	be able to prepare reagents accurately and consistently	

14.13	be able to perform calibration and quality control checks	
14.14	be able to demonstrate operational management of laboratory equipment to check that equipment is functioning within its specifications and to respond appropriately to abnormalities	
14.15	understand the implications of non-analytical errors	
14.16	know the extent of the role and responsibility of the laboratory with respect to the quality management of hospital, primary care and community based laboratory services for near-patient testing and non-invasive techniques	Two respondents commented on this standard. One respondent commented on the removal of 'be aware of' in relation to near patient testing as per existing standard 2b.4. They commented that although 'near-patient testing' is an expanding area, that there are also areas where it is difficult to apply it. They also questioned whether it could be difficult to comply with this requirement in some laboratory settings. Whereas the second respondent commented that this standard is subject to change at ISO level, which would make it difficult to assess histology when meeting standard 14.27.
14.17	be able to formulate specific and appropriate management plans including the setting of timescales	
14.18	be able to gather appropriate information	One respondent suggested including reference to communicating with other professional colleagues in order to achieve this requirement.
14.19	be able to select suitable specimens and procedures relevant to patients‟ clinical needs, including collection and preparation of specimens as and when appropriate	
14.20	be able to select and use appropriate assessment techniques	
14.21	be able to undertake and record a thorough, sensitive and detailed assessment, using appropriate techniques and equipment	

14.22	be aware of the need and be able to assess and evaluate new procedures prior to routine use	One respondent supported the reference to diagnostics in the standard which made it clearer.
14.23	be able to undertake or arrange investigations as appropriate	
14.24	be able to analyse and critically evaluate the information collected	One respondent commented that this standard requires further elaboration.
14.25	be able to investigate and monitor disease processes and normal states	One respondent questioned this standard's applicability for most registrants. They subsequently supported its removal as they observed that the overarching principles are already contained in other standards.
14.26	be able to use standard operating procedures for analyses including point of care in vitro diagnostic devices	
14.27	be able to use statistical packages and present data in an appropriate format	Two respondents commented on this standard. One respondent was concerned that the current wording only implies the relevance of statistics in meeting this requirement and not the presentation of data in other formats, i.e. graphs and tables. They supported the reinstatement of reference to these formats in the standard. In contrast the second respondent commented that there was too much detail in the standards in general and identified this standard as a case in point. This respondent: • questioned the specific reference to statistical package software; and • claimed that few registrants knew how to operate this particular software. However, they also supported identifying other software programmes that registrants regularly use.
14.28	be able to demonstrate a logical and systematic approach to problem solving	

14.29	be able to use research, reasoning and problem solving skills to determine appropriate actions	
14.30	recognise the value of research to the critical evaluation of practice	
14.31	be aware of a range of research methodologies	One respondent suggested amending this standard to the following wording: • be aware of a range of research methodologies **and their application**
14.32	be able to evaluate research and other evidence to inform their own practice	
14.33	be able to design experiments, report, interpret and present data using scientific convention, including application of SI units and other units used in biomedical science	Two respondents commented on this standard. One respondent commented that this standard was above the threshold level necessary for safe and effective practice. The second respondent supported the removal of this standard.
14.34	be able to use information and communication technologies appropriate to their practice	One respondent supported this new profession-specific standard as they felt it also encompassed reference to social media.
15	**understand the need to establish and maintain a safe practice environment**	One respondent sought the inclusion of additional health and safety standards similar to those included in the proposed profession-specific standards for clinical scientists. These refer to understanding the sources of hazard in the workplace; awareness of immunisation requirements and the role of occupational health; and the correct principles and applications of disinfectants and other methods of sterilisation in the workplace.

15.1	understand the need to maintain the safety of both service users and those involved in their care	Two respondents commented on this standard. One respondent suggested amending this standard to the following wording: • understand the need to maintain the safety of ~~both~~ **colleagues, visitors,** service users and **patients** ~~those involved in their care~~ Whereas the second respondent supported specific reference to carers and other professionals in the standard.
15.2	be aware of applicable health and safety legislation, and any relevant safety policies and procedures in force at the workplace, such as incident reporting, and be able to act in accordance with these	
15.3	be able to work safely, including being able to select appropriate hazard control and risk management, reduction or elimination techniques in a safe manner and in accordance with health and safety legislation	
15.4	be able to select appropriate personal protective equipment and use it correctly	
15.5	be able to establish safe environments for practice, which minimise risks to service users, those treating them and others, including the use of hazard control and particularly infection control	
15.6	understand the application of principles of good laboratory practice	