Quality Assurance Framework

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This document is one of a suite of policies and procedures which are part of the Academy for Healthcare Science

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Introduction

Patients Public and Registrants

NHS Trusts need to be able to confirm the identity, credentials and training status of individuals who visit their sites. The responsibility for this lies with each Trust. The LSI National Credentialing Register provides the only system for confirming these details that has accreditation from the Public Standards Authority for Health and Social Care (PSA). In addition there is a robust procedure for dealing with complaints about individual registrants.

The purpose of this Quality Assurance Framework is to outline the agreed mechanism for oversight and maintenance of the training and education Standards that underpin the LSI Register. These standards are aimed at ensuring both patient and registrant safety. Training providers can use the Standards to shape their training such that it is suitable for those wishing to join the Register. The Standards of Proficiency and Standards of Conduct expected of registrants are available in document LSI008.

Individuals who have successfully met the relevant training and other requirements will be eligible to apply to join the LSI Register.

The Register is overseen by the Academy for Healthcare Sciences Regulation Board).

The AHCS Registrar:

- Ensures that Life Science Industry Standards of Training and Education are fit for purpose.
- Has oversight and ownership of the Life Science Industry Quality Assurance Framework

Professional Registration of Industry Personnel: The Mission

The Life Science Industry has worked closely with NHS England to develop a single national professional registration scheme for industry personnel that will ensure the workforce is appropriately educated and trained in order to to protect patient safety.

Registrants must complete relevant training on:

- The company's products/services
- NHS Values and Behaviour
- Industry Codes of Business Practice
- Information Governance
- Competition and Procurement Law
- Non-clinical Infection Prevention & Control
- Environmental Health & Safety (Tiers 2 & 3 only)
- Adverse Event Management (Tiers 2 & 3 only)
- Clinical Infection Prevention & Control (Tiers 2 & 3 only)
- Training for High-risk Settings (Tier 3 only)[1]

[1] See Education & Training Matrix in Appendix 1 for further details of training requirements and explanation of the three Tiers

Quality Assurance Roles and Responsibilities

In Life Science Industry (LSI) training and education there are three levels of quality assurance:

Level 1: **Quality Assurance** carried out by the Academy for Healthcare Science using a 'right-touch', proportionate approach that is fit for purpose. The AHCS Regulation Board will produce annual reports for the Professional Standards Authority (PSA).

Level 2: **Quality Management** carried out by the Employer.

Level 3: **Quality Control** carried out in-house by the Employer or sub-contracted by the Employer to a third party.

AHCS Approach to setting Standards and QA processes

There are six principles in the development of both standards and quality assurance processes. These are:

- Proportionality
- Accountability
- Consistency
- Transparency
- Targeting
- Agility.

The table in the Appendix 2 summarises how these principles are applied to setting standards and quality assurance processes.

Standards, Registration and Fitness to Practise

All the standards described in Appendix 1 are required to assess individual's suitability for acceptance on the LSI Register or in the context of Fitness to Practise cases. Compliance with the Standards and Registration helps ensure the protection of patients and is increasingly viewed as essential by employers, providers, commissioners and patients themselves.

The Academy for Healthcare Science (AHCS) commitment to driving up the quality of education and training

The Academy for Healthcare Science will continue to:

- Work closely with the NHS, patients, public and registrants to maintain focus in what we do.
- Value stakeholder feedback evaluation from the service. This evaluation will inform decisions on the further targeting of quality assurance activities and on the further development of standards.
- Drive forward scientific excellence and strong leadership through fulfilment of its quality assurance role.

- Be committed to working closely with professional and other relevant bodies and to playing a pro-active role in national networks.
- Support the integration of new knowledge into practice.
- Analyse information from a wide variety of sources to learn from experience, improve performance and drive up standards.
- Carry out regular monitoring against performance indicators to measure progress in achieving quality improvement aims and objectives.
- Share information on best practice with a range of organisations, including employers and the Professional Standards Authority. We are all working towards better standards across the board. Feedback provides us with good intelligence on areas that need to be improved. By critically assessing evidence of what works and what does not work, we can focus our communications on specific approaches that are most likely to have a positive impact on raising standards.

Appendix 1

Life Science Industry Register - Education & Training Framework Matrix

Training	Applies to	Outcome	Related Standard of Proficiency	Delivery options	Confirmation of delivery[2]
Product	Tiers 1, 2 & 3	To understand and apply appropriate knowledge of your area/product its function and application. Where appropriate be an effective communicator/trainer of the functions and safe use of the product. Know, understand and work within your remit. Have the knowledge to carry out your role safely and effectively and when to seek help.	2.1 2.1, 7.1 3.1, 3.2 3.3	In House	Applicant or employer confirmation of training (Employer's letter of competency)
NHS Values and Behaviours	Tiers 1, 2 & 3	To understand and comply with NHS values and behaviours, including the NHS constitution - the NHS 7 key principles, values, rights and responsibilities. Understand and adopt appropriate and effective written and verbal communication skills relevant to your role.	4.1, 4.3, 4.4 7.1	In House or 3rd party	Applicant or employer confirmation of training details & dates
Code of Business Practice	Tiers 1, 2 & 3	Know and understand your company/industry/trade association code of business practice and the standards of conduct of the Register.	1.1, 1.2	In House or 3rd party	Applicant or employer confirmation of training details & dates
Information Governance	Tiers 1, 2 & 3	Understand and comply with the Data Protection Act 1998 and Caldicott principles relevant to your role.	4.2, 6.2	In House or 3rd party	Applicant or employer confirmation of training details & dates
Competition and Procurement	Tiers 1, 2 & 3	To understand and comply with The Bribery Act 2010, competition law and public contracts regulation.	6.1	In House or 3rd party	Applicant or employer confirmation of training details & dates

[2] In order to complete the registration process, applicants need to provide confirmation that they have completed the necessary training.
For product training, this may be verified by a 'letter of competency' where the employer confirms the individual has been fully trained on all relevant aspects of the products that fall within their role, otherwise applicants simply enter details and dates of their training.
For the remaining Tier 1 standards, the applicant may complete in-house or third-party training course and enter the details and dates.
For the Tier 2 and 3 elements, many companies will use third-party training either online or in person. Again, certification may be uploaded on to the LSI system. However, this does not preclude such training being provided in-house, in which case confirmation of successful completion from the employer must be provided.
Employers can provide the training information in a format discussed with and approved by the Registrar..

Training		Applies to	Outcome	Related Standard of Proficiency	Delivery options	Verification of delivery
Infection Prevention & Control (non-clinical)		Tiers 1, 2 & 3	Understand relevant local and national policies and processes to protect safety, health and wellbeing, including infection control risks.	2.2, 5.1, 5.3	In House or 3rd party	Applicant or employer confirmation of training details & dates
Environmental Health & Safety **Adverse Event Management** **Infection Prevention & Control (clinical)**		Tiers 2 & 3	To understand and apply a duty of care regarding environmental health and safety including infection prevention and control, adverse event management and maintaining one's own health through immunisation.	2.3, 5.2	In House or 3rd party	Applicant or employer confirmation of course details & dates
High-Risk Settings[3]	**Theatre Access** **Training for other High-Risk Settings** **Hand Hygiene**	Tier 3	In settings, such as theatre, cardiac labs, critical care and paediatric wards understand the high risks: use personal protective equipment appropriate to the setting; understand the etiquette, roles, responsibilities and protocols in high-risk settings; carry out risk assessment including hazards, decontamination requirements, precautions etc. relevant to the setting; communicate effectively with all members of the team.	2.4	In House or 3rd party	Applicant or employer confirmation of course details & dates

Tier 1 Interaction with Healthcare Professionals but no contact with patients or public other than incidentally in areas open to the general public.

Tier 2 Interaction with Healthcare Professionals and with patients or public in areas where no invasive procedures are taking place.

Tier 3 Interaction with Healthcare Professionals and with patients or public in areas where invasive procedures are taking place.

[3] Training for high-risk settings should be appropriate to the role. For example, registrants who attend in areas such as ICU or HDU are not required to complete a course on theatre access but they should complete training on aspects specific to the areas they visit. Such courses may be specific to the area or may cover more general aspects such as PPE, clinical waste management or behaviour when in the presence of critically ill patients. Companies should select the appropriate level of training for each employee.

Appendix 2

Academy principles in the development of Standards and Quality Assurance processes

Principle	Standards	Quality Assurance Processes
Proportionality ('Right touch')	The burden created to comply with standards should be proportionate to the risks presented. Standards are normally expressed as outcome statements, to allow a diversity of approaches to meeting them. As far as possible, standards will be applicable across the disciplines and roles of the healthcare science workforce.	It is a requirement that organisations and individuals undertake activities that help to mitigate risk. Processes must call on evidence that already exists as much as possible.
Accountability	In producing and revising standards, there will always be appropriate public consultation. Standards will be reviewed periodically to ensure that they remain fit for purpose.	The Academy is accountable to the regulator, the Professional Standards Authority (PSA).
Consistency	Adherence to standards must be measurable.	It is a requirement that individuals involved in QA are trained and developed, to ensure consistency. QA decisions will be evidence- based.
Transparency	The purpose of standards will be transparent and they will be available on the Academy's website.	QA processes will be transparent to all organisations and the individuals who must use them, including members of the public. The outcomes from QA activities will be publicly accessible via the AHCS web site.
Targeting	Standards are targeted at areas of risk. When standards are reviewed, the creation of new standards or revisions to existing standards will be based in part on the evidence of risk.	QA processes will identify risk and prioritise areas of high risk over areas of low risk. Where other bodies operate QA processes in the same setting, targeting will be used to prevent the duplication of evidence collection.
Agility	Standards will not inhibit the development of a profession or service, provided all risks have been reasonably mitigated. Standards will be reviewed periodically to mitigate new and emerging risks, amended where evidence suggests that existing standards require it, or removed if they lack continued relevance.	Wherever possible QA will be pro-active and with an emphasis on risk prevention.