



Life Science Industry National Register

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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Author(s)	David Bennett, Janet Monkman, Alun Williams, Rachel Myers, Kerry Tinkler, Clive Powell, Edmund Proffitt Andrew Davies, Alan Birks, Nicki Dill, Sarah Jones, Darren Clark, Phillip Woodward
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For further information please contact the Academy for Healthcare Science:

Academy for Healthcare Science -
Registration 6 The Terrace,
Rugby Road,
Lutterworth,
Leicestershire
LE17 4BW
Registered Company No: 778365

Introduction

Patients Public and Registrants

There are many ways in which Patients and the Public can be protected from harm, this can be in direct care situations and from a general health and safety perspective.

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 and they have sought, on a Trust by Trust basis, a variety of means to address this challenge, leading to variable practices in the standards and processes used within the NHS to check the status of industry staff on site.

The purpose of this Quality Assurance Framework is to outline the agreed mechanism for oversight and maintenance of new training and education standards to address this problem. These standards are aimed at protecting both patient and registrant safety. Organisations that meet these standards will be recognised by the Life Science Industry (LSI) National Register. Training requirements are set out in the LSI National Register Standards.

Individuals who have successfully met the relevant training and other requirements will be eligible to apply to join the LSI National Register for life sciences industry personnel who interact with NHS front-line staff and/or patients. The LSI National Register is overseen by the LSI Registration Council, established in accordance with the governance arrangements of the Academy for Healthcare Sciences (AHCS) and subject to oversight by the AHCS Regulation Board).

The LSI National Register Registrar and the LSI Registration Council:

- Ensure that Life Science Industry Standards of Training and Education are fit for purpose.

- Have 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 NHS values and is properly trained to protect patient safety. Further to the communications that went out to all Trusts in August 2014, an initial consultation and 'call for evidence' was undertaken, the findings of which were considered by a Review Steering Group and directly informed the development of agreed national standards (see Appendix 1).

Quality Assurance Roles and Responsibilities

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

Level 1: Quality Assurance of the UK system, 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.

Registration, Regulation and Fitness to Practise

All the standards described in Appendix 1 are required for the Registration Council to make judgements on individuals for entry to and removal from the Register. Appeals will be managed by the AHCS Regulation Board. Registration is important for 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.

Life Science Industry Register - Education & Training Framework Matrix

Training	Applies to	Outcome	Related Standard of Proficiency	Delivery options	Confirmation of delivery ¹
Product	Tier 1	To understand and apply appropriate knowledge of your area/product its function and application.	2.1	In House	Applicant or employer confirmation of training (Employer’s letter of competency)
		Where appropriate be an effective communicator/trainer of the functions and safe use of the product.	2.1, 7.1		
		Know, understand and work within your remit.	3.1, 3.2		
		Have the knowledge to carry out your role safely and effectively and when to seek help.	3.3		
NHS Values and Behaviours	Tier 1	To understand and comply with NHS values and behaviours, including the NHS constitution - the NHS 7 key principles, values, rights and responsibilities.	4.1, 4.3, 4.4	In House or 3rd party	Applicant or employer confirmation of training details & dates
		Understand and adopt appropriate and effective written and verbal communication skills relevant to your role.	7.1		
Code of Business Practice	Tier1	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 3 rd party	Applicant or employer confirmation of training details & dates
Information Governance	Tier 1	Understand and comply with the Data Protection Act 1998 and Caldicott principles relevant to your role.	4.2, 6.2	In House or 3 rd party	Applicant or employer confirmation of training details & dates
Competition and Procurement	Tier 1	To understand and comply with The Bribery Act 2010, competition law and public contracts regulation.	6.1	In House or 3 rd party	Applicant or employer confirmation of training details & dates

¹ 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
Protection of Self, Public and Patients		Tier 1	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
Protection of Self, Public and Patients (enhanced)	Environmental Health & Safety	Tier 2	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
	Adverse Event Management					
	Infection Prevention & Control					
High-Risk Settings²	Theatre Access	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
	Training for other High-Risk Settings					
	Hand Hygiene					
<p>Tier 1 Interaction with Healthcare Professionals but no contact with patients or relatives other than incidentally in areas open to the general public</p> <p>Tier 2 Interaction with Healthcare Professionals and with patients or relatives in areas where no invasive procedures are taking place</p> <p>Tier 3 Interaction with Healthcare Professionals and with patients or relatives in areas where invasive procedures are taking place</p>						

² 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.

Academy principles in the development of Standards and Quality Assurance processes

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