

How To Be A Good Registrant:

Guidance on Application of the LSI National Credentialing Register Standards

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Introduction: The LSI National Credentialing Register & Fitness to Practise

Life science industry staff routinely engage with NHS staff and patients. It is important that these interactions take place within a professional, ethical and safe framework.

The LSI National Credentialing Register allows NHS staff to interact with registrants in the confidence that they meet expected professional and ethical standards. Application of and adherence to these standards would also be expected by patients and the public.

To be registered and to remain on the LSI National Credentialing Register a registrant must demonstrate that they are 'fit to practise'. Fitness to practise means having the skills, knowledge, character and capacity to carry out a role safely and effectively. This should be the case both on their first day of registration and throughout their career. To demonstrate fitness to practise, registrants must meet certain standards. These include:

Standards of Proficiency - the basic education and training outcomes that someone must achieve before they can be accepted on to the LSI National Credentialing Register.

Standards of Conduct – the standards to be achieved through application of the Standards of Training when present in healthcare facilities and when dealing with healthcare staff, patients and the public.

The Standards were developed in consultation with the NHS, the main life science industry associations and other experts to create a coherent system for regulation. The Standards are written so as to be appropriate for the many occupations and roles across the life science industry. They should be applied in the context of the individual registrant's role and scope of practice.

The Standards were produced by identifying:

- The potential risks posed by registrants to NHS staff, patients and the public
- The professional standards expected by the NHS
- The key learning outcomes and body of knowledge necessary for safe and effective practice

This document provides guidance for registrants and employers as to how individuals can attain the appropriate skills, knowledge, character and capacity to carry out their role safely and effectively within the NHS and, where appropriate, the wider healthcare system. As such, it serves as guidance not only on the Standards but it sets out how individuals can ensure they are 'Fit to Practise' in relation to their registration.

Registrants must register for one of the following Tiers based on where they will visit and likely levels of patient interaction:

- Tier 1** Interaction with healthcare professionals but no contact with patients and public other than incidentally in areas open to the general public
- Tier 2** Interaction with healthcare professionals and with patients and public in areas where no invasive procedures are taking place
- Tier 3** Interaction with healthcare professionals and with patients and public in areas where invasive procedures are taking place

Summary requirements for each Tier of the LSI National Credentialing Register

	Tier 1	Tier 2	Tier 3
DBS (or equivalent)*	None	Basic Level	Basic Level
Recommended Immunisations to protect individuals[†]	<ul style="list-style-type: none"> Seasonal flu 	<ul style="list-style-type: none"> Seasonal flu TB Tetanus Polio MMR 	<ul style="list-style-type: none"> Seasonal flu TB Tetanus Polio MMR Hep B
Training[‡]	<ul style="list-style-type: none"> Product NHS Values and Behaviours Code of Business Practice Information Governance Competition and Procurement Infection Prevention and Control (non-clinical) 	<ul style="list-style-type: none"> Product NHS Values and Behaviours Code of Business Practice Information Governance Competition and Procurement Infection Prevention and Control (clinical) Environment, Health and Safety Adverse Event Management 	<ul style="list-style-type: none"> Product NHS Values and Behaviours Code of Business Practice Information Governance Competition and Procurement Infection Prevention and Control (clinical) Environment, Health and Safety Adverse Event Management Training for high-risk settings
Additional information	<p>In the normal course of your role there is no requirement or expectation that there will be any interaction with patients and public, other than incidentally while moving around public areas. hence a DBS check is not required. The only recommended immunisation is for seasonal flu.</p> <p>Specific training is required to ensure you meet the standards expected for interaction with healthcare professionals.</p>	<p>Your role involves or is likely to involve interactions with patients and public, for example you might need to talk to patients or go onto wards within the hospital.</p> <p>Additional training is required for this role due to the higher risk of infection transmission and additional concerns around patient confidentiality.</p> <p>A basic-level DBS check is required, and additional immunisations are recommended.</p>	<p>In the course of your work you are likely to enter facilities such as intensive care units, post-operation recovery areas or operating theatres which are in use. Additional training is required for this role due to the higher risk of infection transmission and additional concerns around patient confidentiality as well as requirements for specific knowledge in order to be present in these high-risk settings.</p> <p>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</p>

			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. A basic-level DBS check is required as well as Hepatitis B immunisation in addition to those recommended for Tier 2 registrants.
Roles	Majority of Sales Representatives Marketing Manager Service/Installation Engineer	Nurse Adviser Clinical Research Adviser Some Sales Representatives	Product support for some MedTech products Clinical Specialists

*DBS Check Levels

The LSI DBS levels have been set on the basis of what seems to be appropriate for each of the three Tiers. However, registrants should be aware that this is based on broad categories and in the context of a 'typical' general hospital. There may be cases where registrants are faced with demands for higher level checks by hospitals on the basis of the type of facility and/or categories of patients. Registrants and their companies will need to deal with any such demands directly with the hospital concerned. The LSI Register has no powers to intervene in the event of a dispute between health-care providers and life science companies.

†Recommended Immunisations

The LSI Register does not place strict requirements on registrants in relation to immunisations. Requirements are set by individual hospitals or groups of hospitals. Those recommended here should be sufficient to satisfy the demands of most facilities, but additional immunisations may be required in some cases. There may be medical reasons why certain immunisations are not appropriate for an individual registrant.

*Training

The training undertaken by registrants should be relevant to their role and a record of the subject and dates of that training provided should be held on file by the employer. Refresher courses should be routinely provided as part of the individual's Continued Professional & Personal Development (CPPD). Training should take account of changes to regulation and guidance as well as to product updates and new product introductions.

Standards of Proficiency

These set out the minimum standards to be met before anyone is accepted on to the LSI National Credentialing Register. They cover education and training on:

- Products
- NHS Values & Behaviours
- Industry Codes of Practice
- Information Governance
- Competition & Procurement
- Environment, Health and Safety
- Adverse Event Management
- Infection Prevention and Control
- High-Risk Areas such as theatres, ICUs, HDUs and cardiac labs.

In addition to demonstrating that they meet these standards at their first application, registrants must annually renew their registration and provide evidence that they continue to achieve the expected levels. The Standards require the registrant only to work within their area(s) of competence and the legal and ethical boundaries of their remit. Specifically, individuals should:

- Understand their professional remit as an employee of a life sciences company and be aware of the agreed scope of practice for lawful, safe and effective practice.
- Understand the limits of their personal competence and the tasks and roles for which they are competent.
- Know the limits of their role and understand when to refer to another professional.

Registrants should receive training to ensure that they can meet the specific standards required by the register.

The LSI Register's Education & Training Framework Matrix (Annex 1 of this document) provides further details on training to meet the requirements set out in the Standards of Training.

Standards of Conduct

Standards of Conduct set out the minimum requirements expected of registrants in their everyday professional lives. They are aligned with the Standards of Proficiency such that they set out what is required by way of application of those standards in practice.

The Standards of Conduct are laid out in the LSI National Credentialing Register Standards. Registrants are expected to:

- Adhere to industry ethical and professional standards.
- Maintain up to date knowledge to undertake their role.
- Work within their area(s) of competence and remit.
- Understand, respect and comply with the values and behaviours of the NHS.
- Protect the safety, health and wellbeing of self, staff, patients, carers and others
- Comply with the legal, ethical and policy requirements relevant to the healthcare sector appropriate to the role being undertaken
- Communicate appropriately and effectively.

Guidance on the Standards of Conduct

The following expands on the Standards to provide guidance on the knowledge and understanding that a registrant should gain through undertaking appropriate training.

Standard 1. Adhere to industry ethical and professional standards

Registrants must:

- 1.1. Comply with the codes of business practice/conduct relevant to your sector and function relevant to your employment

Individuals on the LSI National Credentialing Register are required to adhere to industry ethical and professional standards. They should understand and comply with the Standards of Conduct and know and understand their company, industry and trade association codes of business practice.

New employees should be made aware of and should receive appropriate training to aid their understanding of the company code of business practice (where it exists). Those working in a customer-facing role should also be aware of, and fully compliant with any relevant industry or trade association codes of practice. For example, the following Trade Associations have detailed codes of practice, which member companies agree to comply with as part of their membership of those associations.

- Association of British HealthTech Industries (ABHI) [Code of Ethical Business Practice 2019](#)
- Association of the British Pharmaceutical Industry (ABPI) [Code of Practice for the Pharmaceutical Industry 2021](#)
- Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care (AXREM) [Code of Conduct - AXREM](#)
- British Dental Industry Association (BDIA) [BDIA - Code of Practice](#)
- British Healthcare Trades Association (BHTA) [Code of Practice – British Healthcare Trades Association](#)
- British In Vitro Diagnostics Association (BIVDA) [BDIA Code of Ethical Business Practice](#)

If companies are not members of a relevant industry association, they may still choose to utilise suitable codes of conduct where they exist. Training on a relevant industry code is a requirement for applicants to join the LSI Register.

NHS England also has policies relating to standards of business conduct for employees and for Clinical Commissioning Groups, in which their guidance on management of conflicts of interest was revised in June 2017 ([NHS England » Standards of Business Conduct Policy](#)).

Guidance is provided on a number of areas including:

- receipt of gifts and hospitality
- sponsored events
- registers of interest
- managing conflicts of interest at meetings and in the commissioning cycle
- internal audit and raising concerns.

Standard 2. Maintain up to date knowledge to undertake their role

- 2.1.** Ensure your knowledge, understanding, skills and abilities for your role are fully up to date.

Registrants should ensure they keep fully abreast of developments in their area of competence and that they participate in all company-provided training in relation to their product area. They should also ensure that any other relevant specialist training is kept up to date.

If Registrants are also part of another relevant professional register in either the regulated or non-regulated sectors, they should ensure they continue to keep their knowledge up to date to maintain such registrations.

Standard 3. Work within your area(s) of competence and remit

Registrants must:

- 3.1 Work within the limits of your personal knowledge and competence.
- 3.2 Work within your remit for lawful, safe and effective practice.

It is important that registrants should be aware of limits that apply to their scope of practice. This will serve to protect the registrants themselves and also their companies through avoiding situations where they might be compromised in the event of an adverse incident. Registrants should feel empowered to decline to engage in interactions that are beyond the limits of their training.

Standard 4. Understand, respect and comply with the values and behaviours of the NHS

Registrants must:

- 4.1 Maintain patient confidentiality and not disclose information without relevant consent, except where such disclosure is required by law.
- 4.2 Never discriminate against an individual.
- 4.3 Work in a collaborative and respectful manner with healthcare professionals and patients.
- 4.4 Be open, honest and act with integrity at all times.
- 4.5 Protect patients from risk or harm presented by another person's conduct, performance or health. Follow whistleblowing processes where these are available.
- 4.6 Uphold the duty of candour owed to customers, NHS staff, patients and the public and act accordingly.
- 4.7 Treat everyone as an individual, respect their dignity, confidentiality, rights and values.
- 4.8. Maintain professional relationships with customers, NHS staff, patients and the public.

The NHS is founded on a common set of principles and values that bind together the communities and people it serves – patients and public – and the staff who work for it.

- The NHS provides a comprehensive service available to all
- Access to NHS services is based on clinical need, not on an individual's ability to pay
- The NHS aspires to the highest standards of excellence and professionalism.
- The NHS aspires to put patients at the heart of everything it does.
- The NHS works across organisational boundaries and in partnership with other organisations in the interest of patients, local communities and the wider population.
- The NHS is committed to providing best value for taxpayers' money and the most effective, fair and sustainable use of finite resources.
- The NHS is accountable to the public, communities and patients that it serves.

These are principles underpinned by core NHS values, which have been derived from extensive discussions with staff, patients and the public. NHS values are set out in the [NHS Constitution for England](#) under the following headings:

- Working together for patients
- Respect and dignity
- Commitment to quality of care
- Compassion
- Improving lives
- Everyone counts.

It is important that life science industry staff are familiar with these NHS principles and values and that they are respected at all times. Training for all registrants should cover this.

Standard 5. Protect the safety, health and wellbeing of self, staff, patients, carers and others

Registrants must:

- 5.1 Identify and employ safe working practices and ensure compliance with legislation and NHS policies such as infection control and health and safety.
- 5.2 Ensure their own personal health and safety and make appropriate changes to how they practise if their physical or mental health may affect their performance (including relevant immunisations).

Entry on the LSI National Credentialing Register requires an understanding of relevant local and national policies and processes to protect safety, health and wellbeing, including infection control risks and complying with the principles of good hand hygiene.

All LSI registrants have a responsibility to understand and comply with the procedures for reporting Adverse Events to the appropriate authorities. All registrants should be aware of the processes for reporting safety information, so they know what to do if they become aware of a safety concern.

Individuals on the LSI National Credentialing Register must ensure that they familiarise themselves with the local policies of the hospitals that they will visit to ensure that they also comply with those requirements.

Registrants should ensure that they are aware of and comply with national and local NHS requirements with regard to immunisations.

All professionals who have contact with children and vulnerable adults are an important part of the wider safeguarding community. Safeguarding and promoting the welfare of others includes (but is not limited to): protecting others from maltreatment; preventing impairment of health or development; ensuring that children/vulnerable adults experience circumstances consistent with the provision of safe and effective care; taking action to enable all children and vulnerable adults to have the best outcomes.

Further information can be found in the [NHS England Safeguarding Policy](#).

Standard 6. Compliance with legal, ethical and policy requirements relevant to the healthcare sector appropriate to the role being undertaken

Registrants must:

- 6.1 Adhere to the Bribery Act, NHS Conflict of Interest Rules, UK Competition Law and Procurement Regulations and any related local requirements.
- 6.2 Comply with Data Protection Legislation and Caldicott Principles.

The life science industry in the UK and Europe, in common with other industries, is subject to national and supranational laws, which govern many aspects of their business operations.

The [Bribery Act 2010](#) makes it a criminal offence to give or offer a bribe, or to request, offer to receive or accept a bribe. The Act reformed the criminal law of bribery, making it easier to tackle this offence proactively in both the public and private sectors. It introduced a corporate offence, which means that commercial organisations, including NHS bodies, will be exposed to criminal liability, punishable by an unlimited fine, for failing to prevent bribery. The government has published [Bribery Act Guidance](#).

Competition law aims to promote healthy competition. It bans anticompetitive agreements between firms such as agreements to fix prices or to carve up markets, and it makes it illegal for businesses to abuse a dominant market position. Companies and their representatives must make every effort to observe UK and EU competition and procurement laws in all their interactions with healthcare institutions in both the public and private sectors.

Competition law seeks to curb practices that would undermine or restrict competition to the detriment of consumers: the abuse of a dominant market position by a firm, anticompetitive agreements between firms, and mergers or takeovers which, if allowed, would result in a substantial lessening of competition. The scope of the law includes the following areas:

- Anti-competitive agreements
- Abusive behaviour
- Mergers
- Public restrictions of competition.

Life science industry employees need to be aware of the main rules to avoid breaking the law or becoming a victim of others' anti-competitive practices. Companies should ensure that their representatives are aware of their responsibilities in relation to competition and procurement legislation. The level of training required will depend on the individual's role.

Information Governance ensures necessary safeguards for, and appropriate use of, patient and personal information. The LSI Standards require that registrants comply with the legal requirements relevant to the healthcare sector and to know and understand the risks and processes relevant to their role, including information governance and patient safety.

Life science industry employees are expected to operate in accordance with the UK [Data Protection Act 2018](#) and maintain the confidentiality of information of any type, including but not restricted to patient information, personal information relating to their colleagues and business contacts and commercial information provided to them in confidence.

The [Caldicott Principles](#) were developed in 1997 following a review of how patient information was handled across the NHS and were revised in 2013. They relate to patient-identifiable information and provide guidance on how and when such data should be used and shared. Industry employees with access to patient information need to be aware of, and comply with, these principles:

- Principle 1 - Justify the purpose(s) for using confidential information.
- Principle 2 - Don't use personal confidential data unless it is absolutely necessary.
- Principle 3 - Use the minimum necessary personal confidential data.
- Principle 4 - Access to personal confidential data should be on a strict need-to-know basis.
- Principle 5 - Everyone with access to personal confidential data should be aware of their responsibilities.
- Principle 6 - Comply with the law.
- Principle 7 - The duty to share information can be as important as the duty to protect patient confidentiality. More detailed information about the review and the principles can be found here: [The Caldicott Principles – UKCGC](#).

Standard 7 Communicate effectively and appropriately

Registrants must:

- 7.1 Apply effective and appropriate skills in communicating information, advice and instruction. Listen to customers, NHS staff, patients and the public and communicate in a way they can understand.
- 7.2 Communicate the LSI Standards that they work within, such as the standards of Conduct, clarifying their role and the boundaries of that role.
- 7.3 Where appropriate, keep accurate, comprehensive records in accordance with legislation, protocols and guidelines.

Registrants should be suitably trained to allow them to communicate effectively with healthcare professionals and, where relevant, patients and members of the public. Registrants should be aware of how to tailor their messages such that they are appropriate to the audience. They should be able to explain any limits to their remit and role in the event that this is necessary.

Many company and industry sector codes of practice provide guidance on appropriate communication and registrants are expected to know, understand and adhere to their company, industry and trade association codes of business practice as appropriate.

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
Infection Prevention & Control (non-clinical)		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
Environmental Health & Safety Adverse Event Management Infection Prevention & Control (clinical)		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
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					
Tier 1 Interaction with Healthcare Professionals but no contact with patients and public other than in areas open to the general public.						
Tier 2 Interaction with Healthcare Professionals and with patients and public in areas where no invasive procedures are taking place.						
Tier 3 Interaction with Healthcare Professionals and with patients and public in areas where invasive procedures are taking place.						

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.