



Life Science Industry National Credentialing Register

Fit for Practise Guidance Document

19 June 2020

Version 1.0

Review date: 19 June 2021

Doc Ref: #LSI015

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



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Foreword: Life Science Industry Credentialing Register – Fit for Practise

Staff from the Life Science Industry engage with NHS staff and patients daily, in the capacity of representatives of those Life Science industries that trade and provide services to the National Health Service. It is important that these interactions take place within a professional, ethical and safe framework.

The Life Science Industry (LSI) National Credentialing Register allows NHS staff to interact with an individual confidently, knowing that that individual meets the professional standards required by the NHS.

To be registered and to remain on the LSI National Credentialing Register a registrant must be able to demonstrate that they are 'fit to practise'. In this instance, fitness to practise means that someone has the skills, knowledge, character and capacity to carry out their role safely and effectively, both on their first day of registration and throughout their career interacting with the NHS and, where appropriate, the wider healthcare system. 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 registered with the LSI National Credentialing Register

Standards of Conduct - the minimum standards registrants must meet in their professional lives once registered

Standards of Continuing Personal and Professional Development - how registrants ensure that their knowledge, skills and behaviours to carry out their role are up-to-date.

The above Standards were developed in partnership with the NHS, Industry Associations and regulation experts to create a coherent system for regulation. The Standards are written in a way that enables them to be appropriate for the many occupations and roles across the Life Science Industry and they should be read in the context of the 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 required by the NHS
- The key learning outcomes and body of knowledge necessary for safe and effective practice by those newly registered
- The minimum standards required to remain fit to 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.

Registrants are able to select to register for one of the following Tiers; these will provide access into different areas of a hospital:

- **Tier 1** Interaction with Healthcare Professionals but no interaction or contact with patients or relatives other than in areas open to the general public
- **Tier 2** Interaction with Healthcare Professionals and with patients or relatives in areas where no invasive procedures are taking place
- **Tier 3** Interaction with Healthcare Professionals and with patients or relatives in areas where invasive procedures are taking place

A DBS check is not normally required for registration on Tier 1 as you will not be in contact with vulnerable adults or young people. A standard DBS check is required for entry onto Tiers 2 and 3 of the LSI National Credentialing Register.

The subject matter for the training provided to registrants should be relative to their role and a record of the dates of the training provided should be held on file. Refresher courses should be provided as part of the individual's Continued Personal and Professional Development (CPPD) when guidance changes and, for example, to take account of product updates and new product introductions.

Summary matrix of entry requirements for each Tier of the LSI National Credentialing Register

| | Tier 1 | Tier 2 | Tier 3 |
|---|--|---|---|
| DBS | None | Basic Level | Basic Level |
| Recommended Immunisations to protect individuals | Seasonal flu | Seasonal flu TB Tetanus Polio MMR | 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 Self, public and patient safety | <ul style="list-style-type: none"> Product NHS Values and Behaviours Code of Business Practice Information Governance Competition and Procurement Self, public and patient safety (enhanced) | <ul style="list-style-type: none"> Product NHS Values and Behaviours Code of Business Practice Information Governance Competition and Procurement Self, public and patient safety (enhanced) Training for high-risk settings |
| Additional information | In the normal course of your role there is no requirement or expectation that there will be any interaction with patients and their relatives, hence a DBS check is not required and the only recommended immunisation is for seasonal flu. Specific training is required to ensure you meet the standards expected for interaction with healthcare professionals. | In the normal course of your role this involves or is likely to involve interactions with patients and relatives, for example you might need to talk to patients or go onto wards within the hospital. In addition to the training required for Tier 1, a basic DBS check is required, and additional immunisations are recommended as well as enhanced training to ensure the safety of yourself, the public and patients. | In the course of your work you are likely to enter 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. |
| Roles | Majority of Sales Representatives Marketing Manager Service/Installation Engineer | Nurse Adviser Clinical Research Adviser Some Sales Representatives | Sales support for some MedTech products Clinical Specialists |

Standards of Proficiency

The LSI National Credentialing Register's Standards of Proficiency set out the minimum standards that a registrant must meet at the time they first register. These standards must be demonstrated through education and training.

The Standards require the registrant to work within the area(s) of competence and legal and ethical boundaries of their remit; specifically, individuals should:

- Know and work within their professional remit as an employee of a life sciences company working within their agreed scope of practice for lawful, safe and effective practice
- Know and work within the limits of their personal competence and only enter discussions or undertake tasks and roles for which they are competent, even if asked to do otherwise
- Know the limits of their role and when to refer to another professional.

The individual should receive training to ensure that they can meet this standard and the specific standards required by the register.

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

To be registered with the LSI National Credentialing Register you must demonstrate that you meet the basic standards. Registration at Tiers 2 and 3 requires additional training to meet the

Standard 1. Adhere to industry ethical and professional standards

- 1.1. Understand and comply with the LSI registrant's Standards of Conduct.
- 1.2. Understand and comply with the Codes of Business Practice relevant to your sector and function relevant to your employment.

standards.

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.

Standards of Conduct

Standards of Conduct set out the minimum requirements expected of you in your everyday professional life. As a registrant, you are personally responsible for the way you behave. The Standards of Conduct are laid out in the LSI National Credentialing Register Standards document and are closely related to the Standards of Proficiency. They cover the following areas:

- Adhere to industry ethical and professional standards
- Maintain up-to-date knowledge to undertake your role
- Work within your 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.

They are also available via the following link: <https://lifescienceindustry.co.uk>

Code 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 (if appropriate). 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 members agree to comply with:

- Association of British HealthTech Industries (**ABHI**)
<http://www.abhicodeofpractice.org.uk/cobp-documents.aspx>
- Association of the British Pharmaceutical Industry (**ABPI**)
<http://www.pmcpa.org.uk/thecode/Pages/Download-the-Code.aspx>
- Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care (**AXREM**)
<http://www.axrem.org.uk/resource/axrem-code-of-conduct/>
- Association of Anaesthetic and Respiratory Device Suppliers (**Barema**)
<http://www.barema.org.uk/content/constitution>
- British Dental Industry Association (**BDIA**)
<https://www.bdia.org.uk/cpd-code.html>
- British Healthcare Trades Association (**BHTA**)
<http://bhta.com/code-of-practice/>
- British In Vitro Diagnostics Association (**BIVDA**)
https://www.bivda.co.uk/Portals/0/Documents/BIVDA_CoC_leaflet.pdf

The NHS also has policies relating to standards of business conduct for NHS England employees (<https://www.england.nhs.uk/wp-content/uploads/2017/07/standards-of-business-conduct-v2.pdf>) and for CCGs, in which their guidance on management of conflicts of interest was revised in June 2017.

Guidance is provided on a number of areas including:

- provision 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

For the statutory guidance to CCGs see :<https://www.england.nhs.uk/publication/managing-conflicts-of-interest-revised-statutory-guidance-forccgs-2017/>

Standard 2 Understand the knowledge base relevant to your role and be appropriately qualified and up to date to undertake your role. See also Standard 5.

- 2.1 Know and understand your specialty area/product, its use/application, and where appropriate can impart knowledge of this use/application.
- 2.2 Know and understand infection control risks and processes appropriate to your role

The following Standard of Proficiency relates to Tiers 2 & 3

- 2.3 Know and understand the risks and processes relevant to your role, including information governance and patient safety.

The following Standard of Proficiency relates to Tier 3:

- 2.4 Know and understand risks, roles and responsibilities, etiquette, protocols and processes for high risk settings, e.g. theatre, cardiac labs, critical care and paediatric wards.

Standard 3 Work within the area(s) of competence and legal and ethical boundaries of your remit

- 3.1 Know and work within your professional remit as an employee of a life sciences company working within your agreed scope of practice for lawful, safe and effective practice.
- 3.2 Know and work within the limits of your personal competence and only enter discussions or undertake tasks and roles for which you are competent, even if asked to do otherwise.
- 3.3 Know the limits of your role and when to refer to another professional

The LSI National Credentialing Register standards require registrants to understand the knowledge base relevant to their role, be appropriately qualified and up-to-date to undertake their role.

Within their role / area of responsibility, individuals on the LSI National Credentialing Register need to be able to understand and apply appropriate knowledge in regard to products they promote or support, their functions and their application.

Where appropriate, they need to be an effective communicator / trainer of the functions and safe use of the product.

They should have the knowledge to carry out their role safely and effectively and know when to seek help.

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

- 4.1 Understand the key principles, values and behaviours of working with the NHS.
- 4.2 Understand patient confidentiality and do not disclose information without relevant consent, except where such disclosure is required by law. See also section 6
- 4.3 Understand the need to respect and uphold the rights, dignity and confidentiality of patients and professionals.
- 4.4 Understand and respect the impact of culture, equality and diversity when interacting with others

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.

Principles:

- 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 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 under the following headings:

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

These principles and values are laid out in the following links:

<https://www.nhs.uk/NHSEngland/thenhs/about/Pages/nhscoreprinciples.aspx>

<https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england>

Individuals on the LSI Credentialing Register should also be aware of the Standards of Business Conduct Policy applicable to NHS England staff, which can be access from the following link:

<https://www.england.nhs.uk/publication/standards-of-business-conduct-policy//>

Individuals on the LSI National Credentialing Register must also be aware of the standards set out in the related Clinical Commissioning Groups Statutory Guidance on Conflicts of Interest:

<https://www.england.nhs.uk/publication/managing-conflicts-of-interest-revised-statutory-guidance-forccgs-2017/>

These two documents provide definitions and guidance on areas such as conflicts of interest, declarations of interest, gifts and hospitality, sponsorship, sponsored events etc.

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

- 5.1 Understand the relevant policies and processes to protect safety, health and wellbeing, for example infection prevention & control.
- 5.2 Understand the importance of maintaining your own health (including relevant immunisations).
- 5.3 Understand the need to maintain a safe working environment.

Entry onto 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 their requirements.

Whilst no immunisations are required for registration on the LSI National Credentialing Register, individuals should ensure that they are aware of and should comply with national and local NHS requirements.

Safeguarding children and vulnerable adults

A DBS check is not required for registration on Tier 1 as you will not be in contact with vulnerable adults or young people.

However, a standard DBS check is required for entry onto Tiers 2 and 3 of the LSI National Credentialing Register.

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.

The NSPCC and Government Departments (including the Departments for Education and of Health & Social Care) provide valuable safeguarding resources and literature to support the protection of children and vulnerable adults. The NHS England Safeguarding Policy is available here: <https://www.england.nhs.uk/wp-content/uploads/2015/07/safeguard-policy.pdf>

Those registering for Tiers 2 and 3 must meet an additional standard:

- 2.3 Know and understand the risks and processes relevant to your role, including information governance and patient safety.

Those registering for Tier 3 must meet an additional standard:

2.4 Know and understand risks, roles and responsibilities, etiquette, protocols and processes for high risk settings, e.g. theatre, cardiac labs, critical care and paediatric wards.

In settings where especially vulnerable patients may be encountered, such as theatre, cardiac labs, critical care and paediatric wards registrants must understand the high risks and:

- 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
- Take standard precautions to reduce the risk of infection through appropriate hand washing/scrubbing and aseptic techniques
- Communicate effectively with all members of the team
- Be aware of the legal requirements appropriate to their role including consent and confidentiality, product liability, medical negligence and duty of care.

Tier 3 registrants are required to have gained a thorough understanding of these and other appropriate knowledge and skills through a Theatre Access training course.

Standard 6 Compliance with legal requirements relevant to the healthcare sector

6.1 Know the legal requirements that apply specifically to your professional activities, such as the Bribery Act, Competition Law and Procurement Regulations.

6.2 Understand Data Protection legislation and Caldicott Principles relevant to your role.

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.

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.

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.

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.

In the UK the responsibility for enforcing competition law lies with the independent Competition & Markets Authority (CMA). The legislative framework for the UK regime is established by the Competition Act 1998 and the Enterprise Act 2002, as amended by the Enterprise and Regulatory Reform Act 2013, which created the CMA.

<https://www.gov.uk/government/collections/cma-consumer-enforcement-guidance>

Although the Office of Fair Trading is no longer the responsible organisation for this area, their publication on competition and consumer laws for business is a useful guide.

<https://www.gov.uk/government/publications/competition-and-consumer-laws-for-business>

The European Commission also provides a number of different publications on competition policy http://ec.europa.eu/competition/publications/brochures_en.html.

Information Governance ensures necessary safeguards for, and appropriate use of, patient and personal information. The Standards for the LSI National Credentialing Register require a registrant to 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 **Data Protection Act 1998** 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. In May 2018 this will be superseded by the new EU **General Data Protection Regulation** (GDPR) legislation. This strengthens data protection legislation, introduces tougher enforcement measures and gives people more control over how their personal data is used. The legislation also makes data protection law identical throughout the EU single market. Individuals on the LSI National Credentialing Register are expected to have knowledge of data protection relevant to their role, including the more stringent requirements of GDPR.

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:

<https://www.igt.hscic.gov.uk/Caldicott2Principles.aspx>.

Standard 7 Can communicate effectively

7.1 Understand and apply appropriate and effective written and verbal communication skills.

Appropriate training should be given to enable the LSI registrant to communicate with healthcare professionals and, where relevant, patients and members of the public.

Many company and industry sector codes of practice provide guidance on appropriate communication with these groups and individuals on the LSI Credentialing Register are required to know, understand and adhere to their company, industry and trade association codes of business practice.