



Registration User Guide

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



Registration Guide for Registrants and Employers

Purpose of this guide

This document provides an outline of the procedure for registration on the Life Science Industry (LSI) National Credentialing Register.

Contents

	Page
Who needs to be on the LSI National Credentialing Register?	3
Registration process in outline	3
Registration Costs	3
New Applications	4
1. Personal Details	4
2. Tiers	4
3. Education & Training	6
Education & Training Framework Matrix	8
4. Background Checks	10
5. Declaration & Monitoring Information & Declaration	10
Annual Re-registration	10
GDPR Compliance	11
Annex 1	
The LSI Registration Process – Graphical representation	12

Who needs to be on the LSI National Credentialing Register?

Many staff from the life science industry engage with NHS staff and patients on a daily basis. It is important that these interactions take place within a professional, ethical and safe framework.

The Academy for Healthcare Science (AHCS), in collaboration with the life science industry and the NHS have developed a high-quality, accredited credentialing register for life science industry staff who routinely visit health-care facilities. This ensures that industry personnel are appropriately trained, immunised and background checked before they enter primary or secondary healthcare settings.

Any industry employee could be asked to provide evidence that they are on an accredited register for entry to an NHS premises, or when moving between areas within the premises. Hence if you are an NHS-facing employee who regularly enters these settings you may need to be on the Register.

The registration process in outline

The LSI National Credentialing Register, and information about it, can be found on the AHCS website www.ahcs.ac.uk.

Most individuals on the LSI Register will be acting as company representatives and the application process will require involvement of their employer. However, the system also allows registrations of those who are sole traders or who are self-employed.

You, or your, employer can start the registration process by contacting admin@ahcs.ac.uk.

A flowchart showing the LSI registration process is included as Annex 1.

What is the cost of registration?

The annual registration fee is £50.

New applicants

The following sections will help you to:

- understand the process,
- know what is required of you.

1. Personal Details

Some of these details may be submitted in advance by the employer:

- Full name (including middle names)
- Email
- Date of birth
- Home address
- Job title
- Company
- Photo

The photo you upload will need to be:

- clear and in focus
- not older than 2 years old
- of yourself, and not with other people and objects
- a forward-facing head-and-shoulders shot
- free of any obstructions (e.g. hats, scarves, masks, sunglasses)

For full details of requirements please read the [LSI Photo Guidance document](#).

2. Tiers

Individuals may register under one of the three risk-related Tiers. The appropriate Tier should be selected on the basis of the areas within health-care institutions the registrant expects to visit, the level of contact expected with patients and the types of clinical procedures that may be carried out in the registrant's presence.

The Tier selected will determine what training is expected of the registrant, the recommended immunisations and the type of criminal background check to be carried out.

A summary of the Tiers and the associated requirements, is given below:

	<i>Tier 1</i>	<i>Tier 2</i>	<i>Tier 3</i>
Role*	Interaction with healthcare professionals but no contact with patients and public other than incidentally in areas open to the general public	Interaction with healthcare professionals and with patients and public in areas where no invasive procedures are taking place	Interaction with healthcare professionals and with patients and public in areas where invasive procedures are taking place
DBS†	None	Basic	Basic
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 	<ul style="list-style-type: none"> • Tier 1 training • Infection Prevention and Control (clinical) • Environment, Health and Safety 	<ul style="list-style-type: none"> • Tier 1 & 2 training • Training for high-risk settings

	<i>Tier 1</i>	<i>Tier 2</i>	<i>Tier 3</i>
	<ul style="list-style-type: none"> Information Governance Competition and Procurement Infection Prevention and Control (non-clinical) 	<ul style="list-style-type: none"> Adverse Event Management 	
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>The normal course of 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. Additional training is required for this role due to the higher risk of infection transmission and additional concerns around patient confidentiality. 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 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.</p> <p>A Basic-level DBS check is required as well as Hepatitis B immunization, in addition to those recommended for Tier 2 registrants.</p>
Typical Roles	<p>Majority of Sales Representatives</p> <p>Marketing Manager</p> <p>Service/Installation Engineer</p>	<p>Nurse Adviser</p> <p>Clinical Research Adviser</p> <p>Some Sales Representatives</p>	<p>Sales support for some MedTech products</p> <p>Clinical Specialists</p>

***Informative Examples**

A service engineer who maintains or repairs equipment in non-patient areas – Tier 1 would be appropriate. If the equipment had to be repaired in an area where patients were present, then Tier 2 would be required.

A representative who provides support to surgeons in an operating theatre setting – Tier 3 would be required.

A sales representative with Tier 1 registration, who is asked by a healthcare professional to meet with them on a ward – the representative will have to explain that they cannot enter areas where patients are present.

†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. Any requirements will be 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 needed 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 Development (CPD). Training should take account of changes to regulation and guidance as well as to product updates and new product introductions.

3. Education & Training

Employees should have received training appropriate to their role, and a record of the dates of the training provided should be held on file by the company.

The Tier level will determine the training expected.

An employer may provide LSI with details of the training courses its employees have completed, or individuals may complete this information themselves. In the case of product training, a 'letter of competency' from the company is sufficient. Letters of competency should be uploaded by the employee.

Training may be delivered in-house or by an external training provider. Training may be face to face or online as appropriate.

Tier 3 employees are expected to have comprehensive and detailed knowledge in relation to their attendance in high-risk treatment settings. Ideally this would be via training delivered face-to-face or through other teaching methods such as video seminars, interactive on-line teaching etc. This comprehensive training may be supplemented by periodic online 'refresher' courses, but full training should be repeated on a regular basis (every 5 years is recommended).

Tier 3 personnel who are new to the role should always receive comprehensive and detailed training before attendance in applicable treatment settings; those who are new to the company, but who are already experienced, should receive periodic refresher training and full training should be repeated on a regular basis (every 5 years) to ensure compliance with any changes in best practice.

It is particularly important that employees receive refresher training when guidance changes and/or to take account of product updates and new product introductions.

Employers should have on record the details and dates of courses employees have completed, whether external or internal. They should also keep a schedule for when repeat or refresher training is required.

Training requirements, how they relate to the LSI National Credentialing Register Standards, the delivery options, and how completion of training can be confirmed to the Register are summarised on the following pages.

LSI National Credentialing 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 3rd 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 Settings ²	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
<p>Tier 1 Interaction with Healthcare Professionals but no contact with patients and public other than in areas open to the general public.</p> <p>Tier 2 Interaction with Healthcare Professionals and with patients and public in areas where no invasive procedures are taking place.</p> <p>Tier 3 Interaction with Healthcare Professionals and with patients and public 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.

4. Background-check documents

It is mandatory at first registration for Tiers 2 and 3 applicants to provide a DBS Certificate dated within the last 3 years (except Scotland – see below)

If neither you nor your employer have a DBS certificate, this can be obtained from the government's website <https://www.gov.uk/request-copy-criminal-record>.

For applicants from Scotland, employer confirmation that the individual is registered with Disclosure Scotland and that no issues of concern have been notified.

For applicants from the Republic of Ireland, employer confirmation that due diligence checks on the employee have been carried out and that no issues of concern have been discovered.

5. What other sections will I need to complete?

Good Character & Health

The character and health checks apply to all applicants to the LSI National Credentialing Register. Applicants are required to answer truthfully 'Yes' or 'No' to a series of statements. This section must be completed at every renewal.

Monitoring Information

Whilst completion of this section is compulsory, applicants have the option of selecting 'I do not wish to disclose'.

Collection of Monitoring Information is a requirement under the Equality Act 2010 in the United Kingdom; in Northern Ireland, the Disability Discrimination Acts 1995 and 2005 continue to apply. These Acts protect people from discrimination in the workplace and in wider society, including in respect of the following characteristics:

- Age
- Disability
- Gender
- Gender reassignment
- Pregnancy and maternity
- Ethnicity or nationality
- Religion or belief
- Sexual orientation.

The information collected under this section of the application form is not used as part of the assessment process and its provision is voluntary.

The information collected is only used for monitoring purposes in an anonymised format to assist the organisation in analysing the profile and make-up of the applicant population.

This section will need to be completed at every renewal.

Declaration

Applicants will be asked to confirm that the information provided by the company, and/or by the Applicant, is correct.

A declaration concerning the applicant's good character, fitness to practise and compliance with the expected standards has to be made by the applicant.

This section has to be completed at every renewal.

Annual re-registration

60 days before the renewal date, the LSI administration team will contact registrants with a reminder to prepare for re-registration.

Registrants are required to keep up to date in respect of their training and immunisation status. Please ensure the training dates provided for all Tier levels are within the last 3 years. If training dates exceed 3 years, application will be returned 'Further Information Required'.

There is no requirement for DBS certificates to be updated though other organisations, including hospitals, may require this. Current 'best practice' is to renew certificates every three years though there is no statutory requirement to do so (the status of those registered with Disclosure Scotland is continually checked so no renewal of certificates is necessary).

A registrant can be selected for audit by the AHCS at any time and will need to submit a written record of their training activities and any supporting evidence to show that the relevant training is up to date.

GDPR Compliance

The AHCS contracts out a number of functions which require it to share limited personal data with the companies concerned. The sharing of such data is strictly controlled according to necessity and always in compliance with GDPR. Organisations which support the work of the AHCS in this way are themselves contractually required to comply with GDPR where appropriate to the data concerned, particularly in relation to the use of sub-processors and they are also required to co-operate with any audits and inspections required by the AHCS.

Annex 1

The LSI Registration Process

