

Accredited Registers Programme

Accreditation Panel's Decision – Notification of Change

Notification from: Academy for Healthcare Science (the Academy)
Panel meeting: 20 October 2017 (change approved)

The [Professional Standards Authority](#) accredits registers of people working in a variety of health and social care occupations not regulated by law. To be accredited, organisations holding such registers must prove that they meet our demanding [Standards for Accredited Registers](#) (the Standards). Accreditation is reviewed every twelve months.

Once accreditation has been granted, significant changes to an Accredited Register need to be assessed by the Authority to ensure ongoing compliance with the Accreditation Standards. These are submitted to the Authority as a notification of change.

On 13 April 2017 the Academy submitted a notification of change for consideration.

The Accreditation Panel reviewed the notification of change submitted by the Academy. Panel members reviewed the notification of change form and a summary report from the Accreditation team. The Panel had to review the proposed changes and decide whether or not they would impact on the register's compliance with the Accreditation Standards. The Panel could make recommendations in the form of:

- **Conditions** – changes that must be made in order for the change to be approved.
- **Instructions** – actions that would improve practice but do not affect compliance with the Standards and that the Panel requires to be implemented and be satisfied of appropriate implementation within a given timeframe
- **Learning points** – actions that would benefit the operation of the register, the implementation of which would be verified during the annual review of accreditation.

The Panel considered the range of options available to it when making its decision.

The Panel noted the assessment carried out by the Accreditation team for the notification of change included:

- Documentary review (Notification of change form, risk matrix and supplementary documentation)
- Due Diligence checks
- Share Your Experience

There were no declarations of interest from members of the Panel. A summary of matters considered by the Panel is set out in the Annex. The summary is not intended to reflect all of the matters discussed by the Panel, but to record those that were most important in forming its decision.

Outcome

The Panel decided that the changes would not impact on the Academy's compliance with the Accreditation Standards so approved the change.

Conditions, Instructions and Learning Points

The Panel provided the following **Instructions**:

1. The Academy is to only announce accreditation of the Life Sciences Industry register when its website is fully functional, the register populated with registrants' details and it is available to the public.
2. The Academy is to provide progress reports on its quality assurance of Life Sciences Industry registrants' education and training to the Authority after 6 months and 12 months of publication of this report.

The Panel confirmed that no **Conditions** or **Learning Points** would be issued as a result of the notification of change.

Annex – Accreditation Panel’s Decision – notification of change

Organisation: Academy for Healthcare Science (the Academy)	Outcome:
Panel Meeting Date: 20 October 2017	Change Approved
Description of Proposed change – Life Sciences Industry credentialing register <p>The Academy proposed to launch a new ‘Credentialing Register’ for the Life Science Industry (LSI). The register will admit company representatives from the LSI who trade with and provide services to the National Health Service (NHS), and who may engage with NHS staff and patients directly. This may include contact with patients in settings where invasive procedures are taking place.</p> <p>The Academy’s Accredited Register currently admits practitioners working as Healthcare Science Practitioners, Medical Illustrators, and Higher Specialist Scientists, in fields such as biotechnology, pharmaceuticals, medical technologies, diagnostics, digital health services and regenerative medicine.</p> <p>The Academy stated the new register will ensure that the NHS, and other healthcare providers, have a quality-assured form of recognition for external representatives, so they can access appropriate areas within clinical settings. This will include the issuing of barcoded identification badges to registrants, compatible with NHS security protocols.</p> <p>The LSI includes areas such as biotechnology, pharmaceuticals, medical technologies, diagnostics, digital health services and regenerative medicine. The Academy informed that the sector <i>‘discovers or translates new science, materials and processes into patient treatments and products to improve UK healthcare outcomes, address global health challenges and improve health system efficiency’</i>. The Academy has worked with industry organisations to develop its work supporting the LSI register. The LSI group (https://lifescienceindustry.co.uk) comprises the following organisations:</p> <ul style="list-style-type: none"> • The Association of British Healthcare Industries (AHBI) • AXREM (formally known as the Association of X-ray Equipment Manufacturers) 	

<ul style="list-style-type: none"> • Barema; the Association of Anaesthetic and Respiratory Device Suppliers • The British Dental Industry Association (BDIA) • The British Healthcare Trades Association (BHTA) • The British In Vitro Diagnostics Association (BIVDA) <p>These organisations cover a wide range of workers who will be eligible for entry to the register, including clinical specialists, product managers, advisors, service engineers, sales representatives, instructors and trainers.</p> <p>The LSI register will be published on a separate website (https://lifescienceindustry.co.uk/) from the Academy’s current register and will have its own governance structure and standards. IT functions, administration and quality assurance will be provided by the Academy.</p>	
Standard 1: holds a voluntary register for people in health and/or social care occupations	
<p>The credentialing register will be published on the LSI website. The Academy stated that the main audience will be the NHS and related parties as part of their assurance processes.</p> <p>The Academy stated that the LSI register will operate a tiered system of assessment for its registrants, to ensure appropriate requirements based on a risk-based approach and to ensure that registrants are trained to an appropriate level. Work to develop the tier system was undertaken between NHS, LSI and Academy colleagues.</p> <p>The Tiers, based around levels of access, are:</p> <ul style="list-style-type: none"> • Tier 1: No interaction with patients or relatives • Tier 2: Possible interaction with patients or relatives in areas where no invasive procedures are taking place • Tier 3: Possible interaction with patients or relatives in areas where invasive procedures are taking place. 	<p>The Panel found that compliance with this Standard was not affected by the change.</p> <p>The Panel discussed the stated need for the register; to be able to assure the identity and suitability of external workers within the NHS and other healthcare settings.</p> <p>The Panel noted that registrants in occupations such as sales and marketing would be working within</p>

All registrants, including those at Tier 1, will have direct contact with healthcare professionals in a variety of areas, including '*Offices, public areas, reception, in practice manufacturing laboratories*'.

healthcare settings and either have direct contact with service users and/or healthcare professionals. Life Sciences workers who did not access healthcare settings and therefore have no contact with service users or healthcare professionals would not be admitted to the credentialing register.

The Panel noted that the Accredited Registers programme has flexibility to assess different models of registers for health workers, in line with the Authority's *Right-touch* approach. The Panel considered that LSI registrants, who have direct contact with service users and/or healthcare professionals, were in health and/or social care occupations and so within the remit of the programme.

<p>Standard 2: committed to protecting the public and promoting public confidence</p>	
<p>The Accreditation team suggested that the addition of the LSI register would not impact on compliance with this Standard.</p> <p>The Academy stated that a process of due diligence will be undertaken before considering any register to join the Academy's cluster model. This includes undertaking quality audits to ensure the Academy is satisfied that each register admits individual registrants appropriately. The Academy provided information about due diligence undertaken to ensure the organisations joining the LSI register are appropriate to do so.</p>	<p>The Panel found that compliance with this Standard would not be affected by the change, pending the launch of the register on the LSI website.</p>
<p>Standard 3: risks</p>	
<p>As part of its submission, the Academy provided an updated risk matrix, highlighting the risks associated with the occupations on the LSI register and mitigations in place to manage these.</p> <p>The Academy stated that the occupations that will sit on the LSI register pose a lower risk to service users than other occupations it registers, and as such the level of regulatory force exerted by the Academy will be proportionately lower.</p> <p>The Academy identified risks through workshops and stakeholder engagement events and noted a number of risk mitigations, including the creation of an Education and Training Advisory Group, the involvement of employers and the Academy's Quality Assurance Framework.</p>	<p>The Panel found that compliance with this Standard was not affected by the change.</p>

<p>Standard 4: Financial sustainability</p>	
<p>The addition of LSI occupations would mean that the Academy could have an increased number of registrants which would likely result in an increased revenue. The yearly fee for the LSI register will be £30 per registrant.</p> <p>The development of the register has been part funded by a coalition of industry associations and the Academy.</p> <p>The Academy stated it would employ a Head of Registration Services for the LSI register once a critical mass of 7,500 registrants has been achieved. Until that time, it will be managed by the Academy's main Head of Registration Services.</p>	<p>The Panel found that compliance with this Standard was not affected by the change.</p>
<p>Standard 5: capacity to inspire confidence</p>	
<p>The Accreditation team suggested that the addition of the LSI register will not impact on compliance with this Standard.</p>	<p>The Panel found that compliance with this Standard was not affected by the change</p> <p>The Panel noted that the Academy will produce photo ID badges, which will be validated by registrants' employers to verify the identity of those presenting them.</p>

<p>Standard 6: knowledge base</p>	
<p>Registrants on the LSI register will be working with equipment and products approved for use in NHS sites, providing training, installation and guidance. The wide range of equipment, products and techniques used will have been tested for their appropriate use in healthcare settings.</p> <p>The standards of competence for entry to the register have been adapted to the LSI to ensure safe working of registrants in healthcare settings. The Academy noted that it will monitor compliance with the standards as part of its quality assurance processes.</p> <p>The LSI <i>Standards expected of a Registrant on the Life Science Industry Credentialing Register</i> are published on the LSI website.</p>	<p>The Panel found that compliance with this Standard was not affected by the change.</p>
<p>Standard 7: governance</p>	
<p>The Academy proposed significant changes to its regulatory framework and governance structure to reflect the addition of the LSI register. Within the Academy’s cluster model, each register, or group of registers, will have its own Registration Council and education group. Each Registration Council will report into the overarching Regulation Board. The Academy will use shared functions for the administration of the LSI register and lay involvement. Lay involvement sits within the Regulation Board. The Education and Training Advisory Group will report to the Registration Council, which will in turn report to the Academy’s overarching Regulation Board.</p> <p>The Academy has made provisional appointments to its Registration Council and Education and Training Advisory Group.</p>	<p>The Panel found that compliance with this Standard was not affected by the change.</p>

<p>Standard 8: setting standards for registrants</p>	
<p>The Accreditation team suggested that the addition of the LSI register would not impact on compliance with this Standard.</p> <p>The Academy confirmed that <i>'All registrants to LSI will be required to have indemnity cover under their employers' arrangements.'</i></p>	<p>The Panel found that compliance with this Standard was not affected by the change.</p>
<p>Standard 9: education and training</p>	
<p>The Academy has produced Standards expected of a Registrant on the Life Science Industry Credentialing Register, which include standards of proficiency, conduct and continuing professional and personal development (CPPD). The Academy has also developed an Education and Training Framework Matrix and a Quality Assurance Framework. The Academy used its Register Standards and worked with its LSI Project Steering Group to ensure the matrix and framework are compatible with the credentialing requirements. The Academy held a series of workshops with stakeholders to develop the Standards.</p> <p>The Quality Assurance Framework outlines requisite training outcomes and who will deliver and validate these. This is publicly available on the LSI website.</p> <p>Training courses for entry to the register will be provided by employers and quality assured by the Academy, before being accepted by the LSI Education and Training Advisory Group. Some tier 3 courses will be provided by external providers. The Education and Training Advisory Group's remit includes to <i>'quality assure the Register's processes to ensure standards are maintained and met as defined in the Quality Assurance Framework.'</i></p> <p>The Academy confirmed it would not permit entry to the register through a grandparenting route; all registrants must meet agreed education and training requirements.</p>	<p>The Panel found that compliance with this Standard was not affected by the change.</p> <p>The Panel instructed the Academy to provide progress reports on its quality assurance of LSI registrants' education and training after 6 months and 12 months.</p> <p>The Panel noted the Academy's Education and Training Advisory Group would provide guidance on the suitability of courses for LSI workers.</p>

<p>Standard 10: the register</p>	
<p>The Academy stated that the introduction of the LSI register could greatly increase registrant numbers and has therefore reviewed its current IT platform and stress tested its administration system. The Academy has an implementation plan to bring in registrants, which it states may take up to two years depending on occupation.</p> <p>The LSI register CPPD standards require registrants to keep knowledge and training up to date, and to participate in appraisal. The Academy noted that <i>'it is expected that all groups will be able to demonstrate evidence of CPPD. This will sit within the Academy's audit of CPPD as one of the shared functions'</i>. The team will check how such audits have been applied to LSI registrants at future annual reviews as part of its regular assessment.</p> <p>The online version of the credentialing register was still under development at time of assessment. The Academy outlined the presentation and functions of the register. It provided screenshots and models of the application process and the planned presentation of the register.</p>	<p>The Panel found that compliance with this Standard was not affected by the change.</p> <p>In line with previous decisions, the Panel instructed the Academy to only announce accreditation when the new register website is fully functional, the register populated with registrants' details and made available to the public.</p>
<p>Standard 11: complaints and concerns</p>	
<p>The LSI register will utilise the Academy's current complaints process. The team noted that the Academy's Regulation Board states that <i>'decisions about fitness to practise at any stage are solely within the remit of the Regulation Board and cannot be overturned by any other body'</i> and that it will oversee all appeals. The Academy noted that in practice, its Regulation Board provides oversight of processes and delegates to each Registration Council the right to conduct Fitness to Practise panels and Investigation panels. The Registration Board will appoint Appeals panels and have oversight of these.</p> <p>The team asked whether the Academy perceived it will receive an increase in the number of complaints through the new LSI register and if so, whether it had the capacity to manage these. The Academy reported that due to a proportionate increase of registrants, it will likely receive an increased number of complaints. However, the Academy stated it has sufficient support from its LSI Registration Council and administrative team to manage this.</p>	<p>The Panel found that compliance with this Standard was not affected by the change.</p> <p>The Panel noted the Academy's assurance that it would signpost links to complaints procedures about complainants and about itself on the LSI</p>

<p>The Academy reported that it will have processed in place with employers and the NHS to notify the Academy of any complaints or disciplinary procedures:</p> <p><i>'This is will be detailed on the Life Science Industry Credentialing Register website and will be followed up through communications with all Trusts and through the LSI Organisations newsletters and websites. The Academy has similar processes for other parts of its Register which have proven to be robust and fit for purpose.'</i></p> <p>The register will include mechanisms to restrict access of registrants under sanction. Registration will be tied to current employment and not transferrable to other employers, should the registrant be dismissed.</p>	<p>register website when the register was launched.</p>
<p>Share your experience</p>	
<p>The Accreditation team did not receive any responses from the share your experience process.</p>	<p>The Panel considers Share Your Experience responses when making decision.</p>
<p>Equality duty under the Equality Act 2010</p>	
<p>The Panel must consider the Authority's equality duty under the Equality Act 2010 when considering the notification of change.</p>	<p>The Panel had regard to its duty under the Equality Act 2010 when considering this notification of change.</p>
<p>Impact Assessment</p>	
<p>The Academy states that the introduction of the LSI register is likely to greatly increase the number of registrants over a two-year period. The Academy has introduced arrangements to manage a much higher</p>	<p>The Panel noted and took account of the impact of its</p>

number of registrants, including updating its governance structure, planning shared functions across the organisation and planning the introduction of a dedicated Head of Registration Services for the LSI register.

Registration fees will be set at £30 per registrant per year, plus the cost of a badge. It is envisaged that this cost will be met by the employers of registrants.

The Academy highlighted a response from an LSI member when reporting whether it had considered the impact of the cost of the register to the NHS:

'It is expected that having a standardised national approach to credentialing, as opposed to the current proliferation of local schemes, will offset any marginal costs associated with additional training requirements. We expect no additional costs to the NHS related to the process of credentialing of Life Science industry employees.'

decision to approve the change.

The Panel noted that if registration became required by the NHS it could restrict opportunities, to those not on the register. The register was developed with the assistance of professional trade bodies in this field, whose members would make up the first intake. The Panel noted however that sole traders, and employees of companies not aligned with those bodies, could also apply to join the register by demonstrating they meet its standards.