AHCS
Regulation Board

Regulatory Framework
And
Governance Structures

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Regulatory Framework and Governance Structures

Introduction to the Academy for Healthcare Science (AHCS) Regulatory Framework

The AHCS has managed a Professional Standards Authority (PSA) accredited Register since late 2014, initially for practitioners and then higher specialist scientists. This has been overseen by a Regulation Council, initially in shadow form and from April 2015 at full strength.

During the intervening years, a wide range of professions and occupations in or closely linked to the healthcare science community in the UK engaged in a dialogue about becoming part of the accredited Register, or in another form of regulated relationship. At the same time workforce issues and funding challenges have become increasingly urgent and high profile for service delivery in the NHS and the leaders of the healthcare education and training in the four countries. Statutory and non-statutory regulation of healthcare workers has been the focus of wide-spread debate and this is ongoing, particularly in England.

In early 2017, the Management Board of the AHCS agreed to move to a more flexible approach set within a framework supported by a reconfigured structure and processes for governance of regulation. This Framework (see Diagram 1 below) reflects the principles of better regulation and one that has learnt the lessons of the past, including avoidance of over enthusiastic regulation.

The advantages of an overarching Framework are:

1. a less fragmented and confusing regulatory landscape for the public, professionals, registrants and service users.
2. a larger proportion of the practitioner workforce to be regulated via an accredited Register. Small organisations are unlikely to be able to submit an accreditation application on their own. By joining under a single umbrella, the accredited Register coverage would be maximised.
3. increased coverage within a shorter time. It is clear from discussions that each of the currently accredited Registers and applicant organisations have been required to make changes to their structure, standards and processes as part of the accreditation process. Managing these changes as a single project is likely to result in faster progress for cognate professions and occupations than having several stand-alone organisations running such projects.
4. a Regulation Board covering, for example, over 5,000 registrants or individuals will gain more experience and credibility than a single Register with under 500 registrants.
5. keeping costs to a minimum.

The Framework is a non-statutory structure, which must use persuasion and good argument to help professions and occupations to sign up to be registered, for employers to seek such proof of improved likelihood of safety for patients and service users, and for the public to see the value.

Diagram 1

[1] For scientists, the Code is met through Good Scientific Practice, other professions may use their own good practice guidelines – all must be articulated and monitored through the Registration Councils.

Regulation

Regulation is defined as the totality of purpose, structures and processes by which AHCS aim to keep service users and the public safe; registration is the main, but not only, tool by which we undertake regulation of individuals.

Contemporary thinking about UK regulation is that it should not be about "punishing the wicked" but much more about protecting the public and service users pro-actively through well-articulated standards, clear guidance and plain language so Registers are accessible and easily understood. Eligibility to enter the Register should be robust but not complicated. Permanent or temporary removal from the Register should be an important but judicially used strategy when necessary; the goal should be working with and through other organisations to enable the registrant to do the work they aspire to and to the standards that protect recipients of that work.

The goal of the Regulation Framework is to protect the health and wellbeing of those using or needing the services of registrants.

Standards

The standards that are applicable to the varied type and level of registrant will be proportionate to the risk posed by the regulated work force to service users. However, all will have some form of standard/s applied, e.g. presently to be a higher specialist the professional must already be registered with the HCPC as a clinical scientist and s/he must meet the requirements set out for entry to a PSA accredited Register. An accredited credentialing register may apply the standard to be safe to enter healthcare settings to one that is about being sufficiently safe to interact with professionals and service users e.g. successful outcome from the DBS with subsequent certification.

The standards that are applicable to the registrants on a PSA accredited Register:

- individuals must demonstrate that they meet the standards for proficiency (SOPs) (either through an approved programme or through an approved process of equivalence)
- individuals must demonstrate that they maintain their competencies and learning through the continuing professional development (CPD) standards
- individuals must work to a code of conduct, ethics and performance by reflecting the standards set out in Good Scientific Practice (GSP) or its equivalent

The standards that applicable to programmes of study:

- standards of education and training (SETs)

PSA Accredited Registers

Registers are the contemporaneous recognition that those named are fit to deal with service users and the public, directly or indirectly. The Registers need to be accessible and understandable to an untrained eye, making clear how much trust service users and the public can place in those on the Register.

The PSA Accreditation quality mark signifies that the AHCS has met the PSA's high standards in governance, standard-setting, education and training, management of the register, complaints handling and information, assuring the public and employers.

Under the Accredited Registers programme, practitioners on the register are able to display the Accredited Register quality mark, a sign that they belong to a register which meets the Professional Standards Authority's robust standards. Service users, the public and employers are encouraged to look for this quality mark.

Parts

Parts of a Register encompass the discrete group of professionals who have met and continue to meet the required and specific standards, education and conduct set out by the AHCS. The Part is indicated by a role title or titles. Not all registers have Parts. All Parts are within one AHCS Register.
In the Healthcare Science Register there are presently four Parts: Practitioner, Higher Specialist Scientist, Medical Illustrators and Clinical Physiologists.
In the Life Science Industries (LSI) Credentialing Register there are presently no Parts.

PSA Accredited Credentialing Registers

AHCS credentialing means a Register that enables the outcomes of training and short courses in a specified field, or cognate areas, to be recognised formally. The credentialing Registers will ensure that the NHS and other healthcare employers have a quality assured and accredited form of validated recognition for these specific workers to access such settings.

The credentialing Registers require less regulatory force by the AHCS Regulation Framework than that used for professionals on other accredited (non-credential) Registers following successful completion of a recognised course or programme or equivalence process. AHCS is ensuring the registrants of the credentialing Register are assured as safe and fit to work in the NHS and in other healthcare settings, but their work will not be at the level and/or extent of potential harm to service users that other registered professionals may have.

The Life Sciences Industry (LSI) Accredited Credentialing Register is the first of its kind in the UK and sets national standards for healthcare professionals working in the life sciences industry providing reassurance to the NHS.

AHCS directories

Directories are a listing of individuals, there may be several types.

Directories exist at the "lightest touch" form of regulation such as basic employability and safety checks, but the regulation is always proportionate to the risk to patients and public.

Directories exist at their simplest as a list of names with no direct commitment to patient safety but a shared reason for existing e.g. alumni.

The Directory may require a specific 'community' for a specific purpose e.g. Institute of Decontamination Science directory or the NIHR directory.

Another type is where the workers and occupations already have an existing non-accredited register or list with some but not all characteristics of standards and codes of conduct.

The next stage on the continuum of proportionate regulation is an AHCS Register. Others may wish to move towards membership of an PSA accredited AHCS Register with concomitant professional and financial commitment.

Non- PSA Accredited Registers

For some Groups this may be an option. For a variety of reasons, the professional group may not meet all the requirements for entry to a PSA accredited register but their risk to service users and the public means they should meet the minimum requirements of a Register held by the AHCS. Time and other factors may mean that this then applies to become a Part of the AHCS PSA accredited register, or in concert with the AHCS they reduce their requirements so that they become a Directory.

Rules

The Regulation Board's rules and procedures set out the requirements that apply to all Registers and the directories. The day to day operation of the Registers is the responsibility of the Registration Councils, supported by the Registrar and Head/s of Registration services.

These include:

- Registration Rules (all routes including equivalence)
- Appeal Rules
- Fitness to practise rules (including investigation panels, interim order panels and fitness to practise panels)

The terms of reference for the Regulation Board and terms of reference for the Registration Councils and Directories set out the responsibilities for developing, approving and revising Rules.

Appeals

It is important that appeals in relation to fitness to practise are conducted by one body across all those being regulated. One of the lessons of the past is that the regulatory body should not be judge, jury and appeal court. There have been lessons identified clearly by the Council for Healthcare Regulatory Excellence, and now the PSA, in terms of inconsistency intra and inter profession. There also needs to be a willingness and openness to reconsider earlier decisions about a registrant's fitness to practise or in modern parlance for the registrant to "keep his or her licence".

The Regulation Board therefore will oversee all appeals and agree the membership and protocols of the Appeals Panels. Any recommendations of the panels will require ratification by the Board and it can require a Panel to reconsider its decision if there are concerns.

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.

Policies

The Regulation Board retains ultimate responsibility for all regulation policy matters, including strategy. The Regulation Board will determine and review the Terms of Reference for the Registration Councils and directories within the scheme of delegation for these bodies. The Education, Training & Professional Standards Committee or equivalent of each group will provide advice and support and challenge through the Director of Education and Quality.

The Regulation Board will determine the policies that apply across all or some of the Councils and Directories. These include issues around IT, website publication, confidentiality and outcomes of fitness to practise or similar panels. There will be policy decisions on the information available to registrants and the public which reflect the principles of openness, clarity and plain English.

Patient and public involvement will be a principle throughout and a practical ethos of the Framework. Membership of the Regulation board, presence on committees and panels, the roles of lay assessors, seeking and responding to external feedback are all essential parts of “walking the talk”.

Policies will also enable the work of the Regulation Board and the Registration Councils to follow the contemporaneous thinking and evidence-based recommendations about regulation in the UK. The Regulation Board will advise the AHCS Management Board on strategic direction of non-statutory and statutory regulation.

Education

The Director responsible for education and quality oversees standards, quality assurance and quality monitoring to ensure a coherent and consistent approach across all AHCS operations. The overarching requirement is that all education and training programmes align with and are mapped to the relevant standards and quality assurance statements, as approved by the PSA:

- For healthcare science, the Education, Training and Professional Standards Committee (ETPSC) provides guidance by ensuring that the Standards for Education and Training (SETs) and Good Scientific Practice (GSP) are maintained and applied rigorously. The ETPSC reports to the Regulation Board through the Director of Quality on any matters relating to regulation and registration (see ETPSC terms of reference 2017).
- For all other parts of the AHCS Registers, the Director of Quality oversees and reports on the work of each Education, Training and Standards Advisory Group (ETSAG). Each ETSAG has a similar function to the ETPSC for its own discrete area.

Regulatory Force

The Regulation Board will be responsible for determining the level and quantity of force required as new Parts of the Register or directory are populated. The principles of better regulation: consistency, accountability, targeting, transparency and proportionality will be used, as will agility. Only those restrictions and boundaries that are necessary to protect the public and service users should be put in place. The Councils and Directories report to the Regulation Board on a regular basis (see Terms of Reference) and one of the issues that will be monitored is any extension or expansion in terms of standards and requirements for the registrants.

The principle of agility is important and the goal is to make regulation more pro-active, rather than reactive. The latest term is for regulators to work "upstream", to act preventively so there are less fitness to practise problems and so less harm to service users that requires investigation. The focus is therefore on encouraging an individual's commitment to learning and development, as well as fostering a spirit of collaborative working and transparency with service users and their families.

Where there are still fitness to practise issues, then an approach of sanctions with consent will be explored as a priority for the Board.

Objectives for the Framework

The Framework must:

- **Have registers that are accreditable.** Each constituent Register or Part may show it can meet the standards for accreditation. Where this is not the case, the AHCS will want to agree with the relevant group a specific project plan and resources for achieving these standards within a given period or identify an alternative register or directory
- **Be viable.** The model must be viable, including financially. The model must be manageable over a three to five-year period
- **Be timely.** The process of negotiating and establishing a Register or Part should not delay or prevent the AHCS from accomplishing business as usual
- **Be quality assured**. There will need to be open and frank discussions, and quality audits, of any existing Register before it joins. The purpose of this is to ensure that the AHCS knows how each registrant joined the Register, that complaints are dealt with per established fitness to practise Rules and that all of this is auditable by the Regulation Board and so the PSA. It is essential that no party poses specific unacceptable risks to the Academy. A process of due diligence will need to be undertaken before any new or existing Register joins
- **Have closure of entry routes to pre-existing Registers**, that are to merge into and existing Register as part of the negotiations. The AHCS will want to discuss upfront whether and how these routes might be closed over a reasonable period.

The Framework adopted by the AHCS is cognisant of the current position of each of the entities in terms of their current and historic routes to registration, standards of proficiency, conduct and continuing professional development and fitness to practise regimes.

The Governance of a Regulatory Framework.

The healthcare science workforce is very diverse and increasingly heterogeneous. There are occupations and roles that traditionally "fit "in the science world. There are also disciplines developing in practice without a neat fit but with cognate bodies of knowledge and practice. This governance structure enables the AHCS to protect the public but through and with the relevant and expert professional and occupational bodies. Working together within a coherent and inclusive framework that reflects the principles of good regulation in the 21st century, the unique insights and understanding of such bodies and professionals are harnessed.

The governance structure that is adopted includes sharing of common standards, common registration and fitness to practise regimes, and back office administration.

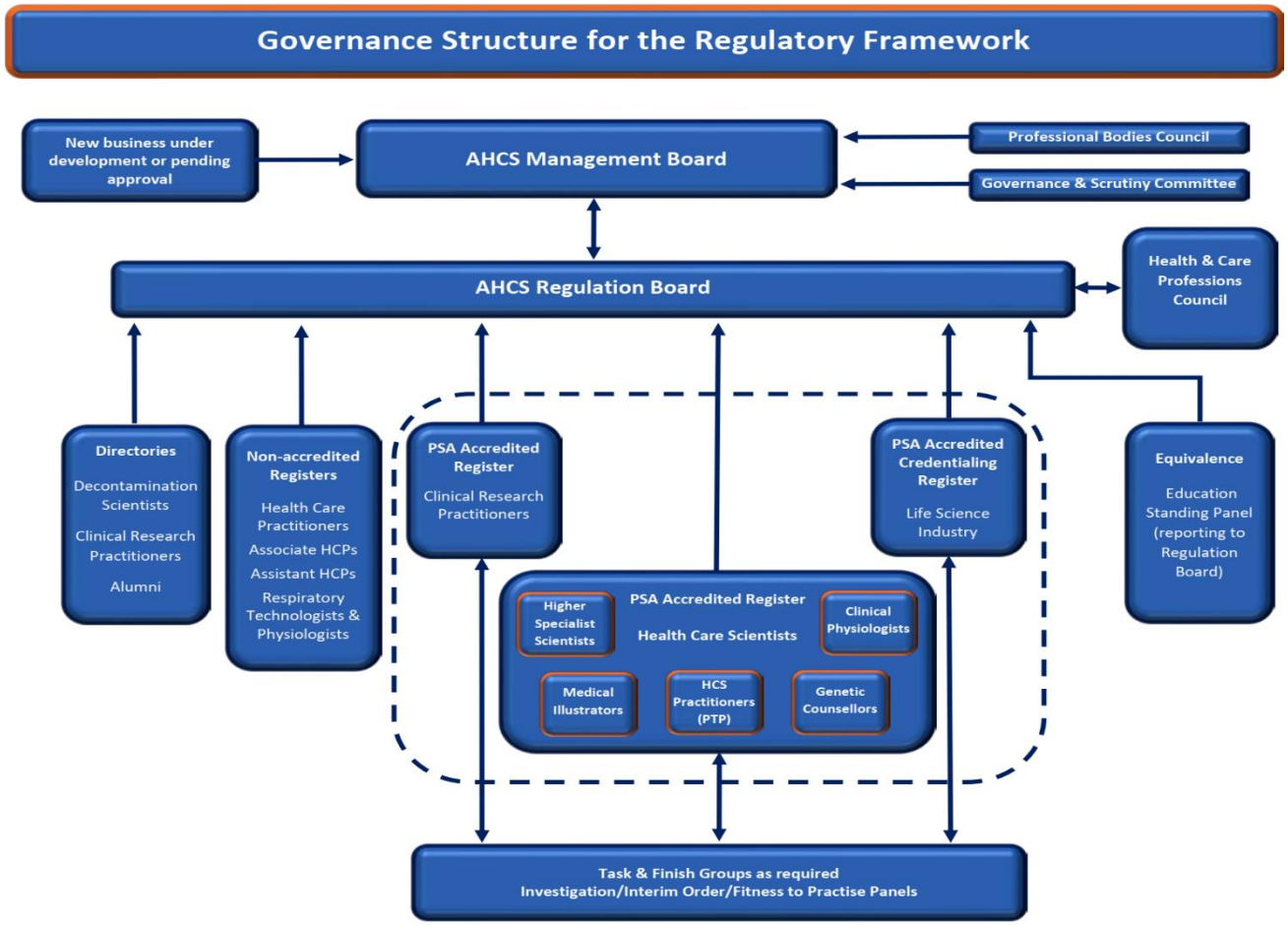
The Governance Structure

See Diagram 2 below

AHCS Academy for Healthcare Science

LSI

Governance Structure for the Regulatory Framework



professional standards authority
accredited register

LSI is the Life Sciences Industry.

Prof C is the Professional Council leading on One Voice for the healthcare science community.

GSC is the Governance and Scrutiny Committee which acts for and reports to the AHCS Management Board.

NIHR is the National Institute for Health Research.

HCPC is the Health and Care Professions Council.

The following role responsibilities outline those specific to the Regulatory Framework, and are not indicative of their total responsibilities.

Registrar

- Responsible to the Regulation Board, advising the Board on all aspects of its strategy, regulatory policy, and its roles and duties
- Ensures that the Regulation Framework is implemented fully
- Responsible for the preparation, upkeep and publication of the Register/s and its constituent Parts
- Ensuring probity and regularity in all the Board's business
- Reporting and liaising with PSA in relation to those registers that are accredited
- Acts as an expert guide and resource to the Head of Registration Services and other staff
- Liaison with relevant Professional Bodies or groups or organisations

Heads of Registration Services

- Responsibility for one or more Councils
- Manages the specific Registers, Parts of the Register or Directories on a day to day basis, including communication with registrants or aspiring registrants through whatever route
- Responsible for the administration staff and administrative work to support the effective and efficient management of the registrants' status and records in their scope
- Communicates with service users and the public through their media, including newsletters and websites
- Liaison with the Registrar
- Leadership of an improvement action plan where necessary