*For consultation*

**Education and Training Requirements for GOC-Approved Qualifications for Specialist Entry to the GOC Register in Additional Supply, Supplementary Prescribing and/or Independent Prescribing Categories**

**Introduction**

This document describes our requirements for approval of qualifications for specialist entry to the GOC register in additional supply (AS), supplementary prescribing (SP) and/or independent prescribing (IP) categories. It is divided into the following sections:

* **Section 1:** **Outcomes for Approved Qualifications for Specialist Entry to the GOC Register** **(Additional Supply, Supplementary Prescribing and Independent Prescribing)** (‘outcomes for approved qualifications’) describes the expected knowledge, skills and behaviours an optometrist must have for the award of an approved qualification for specialist entry to the GOC register in AS, SP and/or IP categories.
* **Section 2: Standards for Approved Qualifications for Specialist Entry to** **the GOC Register** **(Additional Supply, Supplementary Prescribing and Independent Prescribing)** (‘standards for approved qualifications’) describes the expected context for the delivery and assessment of the outcomes leading to an award of an approved qualification for specialist entry to the GOC register in the AS, SP and/or IP categories.
* **Section 3:** **Quality Assurance and Enhancement Method** **for Specialist Entry to the GOC Register** (AS, SP and IP) describes how we will gather evidence to decide in accordance with the Opticians Act 1989 (‘the Act’) whether a qualification for specialist entry to the GOC register in the AS, SP and/or IP categories meets our outcomes for approved qualificationsand standards for approved qualifications. This method statement is common to qualifications for specialist entry to the GOC register.

**What do these documents replace?**

Together, the outcomes and standards for approved qualifications for specialist entry to the GOC register (AS, SP and IP) will replace ‘A Handbook for Optometry Specialist Registration in Therapeutic Prescribing’ (published in July 2008) and the ‘Competency Framework for Independent Prescribing’ (published in 2011), including the list of required core competences, the numerical requirements for trainees’ practical experiences, education policies and guidance contained within the handbooks, and our policies on supervision and recognition of prior learning (published separately).

Together these new documents will ensure the specialist post-registration qualifications we approve are responsive to a rapidly changing landscape in the delivery of eye-care services and fit for purpose in each of the UK nations. The documents allow for the changing needs of patients and service-users, enhanced roles for dispensing opticians within new models of service delivery (not least as a result of the COVID-19 emergency), and increased expectations of trainees and their employers, so as to ensure that the qualifications we approve are fit for purpose.

**What have we consulted on previously?**

These proposals are based on our analysis of our responses to our Call for Evidence, Concepts and Principles Consultation 2017-2018, feedback from our 2018-2019 consultation on proposals stemming from the Education Strategic Review (ESR) and associated research, and our public consultation held in July-September 2020. For more information, please see the GOC’s consultation hub.

**Pre-registration qualifications**

We also approve two pre-registration qualifications for entry to the GOC register as either a dispensing optician or an optometrist. Our updated requirements for these qualifications (see our [Requirements for Approved Qualifications in Optometry or Dispensing Optics: Outcomes for Registration; Standards for Approved Qualifications; Quality Assurance and Enhancement Method](https://www.optical.org/download.cfm?docid=11293C0A-0DE9-4135-B42DCE6680E8CBC4)) were approved by the GOC’s Council (‘Council’) on 10 February 2021.

**How have we developed our proposals?**

Our proposals have been guided by research and consultation and best practice from other regulators, professional and chartered bodies. You can read our research, background and briefing papers on our website.

In preparing this document we were advised by an Expert Advisory Group (EAG) and feedback from a range of stakeholder groups including our Education Visitors, our Advisory Panel (including Education and Standards Committee) the optical sector and sight-loss charities.

We would like to thank everyone who took the time to help us develop our proposals to ensure they protect and benefit the public, safeguard patients and help to secure the health of service-users. You can read the EAG’s terms of reference and membership on our website.

**Arrangements for current providers of GOC-approved and provisionally qualifications**

From January 2022 we will begin working with each provider of GOC-approved and provisionally approved post-registration qualifications to understand at what pace providers will be able to adapt their existing qualifications or develop new qualifications to meet the new outcomes and standards.

We anticipate most providers will work towards admitting trainees to approved qualifications that meet the outcomes and standards from July 2022*.*

Separate arrangements will be made with The College of Optometrists to ensure that for trainees who graduate from qualifications approved before 2021, their route to specialist entry to the GOC register is maintained.

**Section 1: Outcomes for Approved Qualifications for Specialist Entry to the GOC Register (Additional Supply, Supplementary Supply and Independent Prescribing)**

**Introduction**

The **outcomes for approved qualifications for specialist entry to the GOC register (AS, SP and IP)** describe the expected knowledge, skills and behaviours an optometrist must have to be awarded an approved qualification for specialist entry to the GOC register in the AS, SP and/or IP categories.

Wewill use the **outcomes for approved qualifications,** **standards for approved qualifications** and **quality assurance and enhancement method** together to decide whether to approve a qualification for specialist entry to the GOC register in the AS, SP and/or IP categories.

GOC-approved qualifications[[1]](#footnote-1) will prepare trainees to meet these outcomes for specialist entry to the GOC register.

The outcomes are organised into six categories:

1. Uphold professional standards

2. Person centred care

3. Establishes and manages patient options

4. Prescribing practice

5. Ethics and standards

6. Manages risk

7. Learning and development

Each category includes an overarching statement and outcomes which must be met if a trainee is to be awarded the approved qualification. Each outcome is described using a level based on an established competence and assessment hierarchy known as ‘Miller’s Pyramid of Clinical Competence’[[2]](#footnote-2) (knows; knows how; shows how; and does).We have provided a note on Miller’s Pyramid on page 11 of this document.

The number of outcomes in each category varies; some categories have fewer outcomes than others. The number of outcomes in each category and their order within the category is not an indication of weight and/or volume of assessment, teaching and learning when providers design qualifications.

Approved qualifications for specialist entry to the GOC register in the additional supply category must meet the outcomes indicated with ‘(AS)’.

Approved qualifications for specialist entry to the GOC register in the supplementary prescribing category must meet the outcomes indicated with ‘(SP)’.

Approved qualifications for specialist entry to the GOC register in the independent prescribing category must meet outcomes indicated with ‘(IP)’.

Outcomes which incorporate the updated Royal Pharmaceutical Society’s (RPS) Competency Framework for all Prescribers (2021) which is currently subject to a public consultation[[3]](#footnote-3) are indicated by a corresponding reference to the updated RPS Competency Framework (e.g. [Revised RPS-9.3]) and the previous GOC Competency Framework for Independent Prescribing (2011) is also referenced where appropriate (e.g. GOC Framework).

**Outcomes for Approved Qualifications Leading to Specialist Entry to the GOC Register (Additional Supply, Supplementary Supply and Independent Prescribing)**

*Registered optometrists make the care of patients their primary concern. They take responsibility for their own actions and apply the knowledge, skills and behaviours required to practise effectively, safely and professionally.*

**1. Uphold professional standards**

*Registered optical professionals establish relationships with other professionals based on professional understanding and respect; acting as part of a multidisciplinary team they ensure that continuity of care across care settings is not compromised.*

O1.1 Works collaboratively as part of a wider multidisciplinary eye-care team to ensure that the transfer and continuity of care (within and across all care settings) is developed and not compromised. (Revised RPS-10.1) (IP) (SP) (AS) [Does]

O1.2 Establishes relationships with other professionals based on understanding, trust and respect for each other’s roles in relation to prescribing. (Revised RPS-10.2) (IP) (SP) (AS) [Does]

O1.3 Undertakes the consultation in an appropriate setting, taking account of confidentiality, consent, dignity and respect in line with regulatory practice and contractual requirements. (Revised RPS-1.1/1.2) (IP) (SP) (AS) [Does]

O1.4 Assesses the communication needs of the patient/carer and adapts consultation appropriately (e.g. for language, age, capacity, physical or sensory impairments). (Revised RPS-1.4) (IP) (SP) (AS)

O1.5 Introduces self and prescribing role to the patient/carer and confirms patient/carer identity. (Revised RPS-1.3) (IP) (SP) (AS) [Does]

**2. Person centred care**

*An optometrist with a specialist entry to the GOC register (AS, SP and IP) must have a person centred approach, be adaptive and work collaboratively with others in the best interest of the patient, exercising initiative and personal responsibility, and understanding their role in the prescribing process.*

O2.1 Demonstrates good consultation skills and builds rapport with the patient/carer. (Revised RPS-1.5) (IP) (SP) (AS) [Does]

O2.2 Actively involves and works with the patient/carer in partnership to make informed choices, agreeing a plan that respects the patient’s/carer’s preferences including their right to refuse or limit treatment. (Revised RPS-3.1) (IP) (SP) (AS) [Does]

O2.3 Explores the patient’s/carer’s understanding of a consultation and aims for a satisfactory outcome for the patient/carer and prescriber. (Revised RPS-3.6) (IP) (SP) (AS) [Does]

O2.4 Respects patient diversity, equality, personal values and beliefs about their health, treatment and medicines in line with appropriate legislation. (Revised RPS-3.2) (IP) (SP) (AS) [Shows how]

O2.5 Makes prescribing decisions based on the needs of patients and not the prescriber’s personal preferences. (Revised RPS-8.4) (IP) (SP) (AS) [Shows how]

O2.6 Identifies and minimises potential risks associated with prescribing via remote methods. (Revised RPS-7.3) (IP) (SP) (AS) [Shows how]

O2.7 Explains the material risks and benefits, and rationale behind management options in a way the patient/carer understands, so that they can make an informed choice. (Revised RPS-3.3) (IP) (SP) (AS) [Does]

O2.8 Builds a relationship which encourages appropriate prescribing and not the expectation that a prescription will be supplied. (Revised RPS-3.5) (IP) (SP) (AS) [Shows how]

O2.9 Assesses health literacy of the patient/carer and adapts appropriately to provide clear, understandable and accessible information. (Revised RPS-5.2) (IP) (SP) (AS) [Does]

O2.10 Guides the patient/carer on how to identify reliable sources of information about their medicines and treatment. (Revised RPS-5.3) (IP) (SP) (AS) [Does]

O2.11 Checks the patient’s/carer’s understanding of the discussions had, actions needed and their commitment to the management plan. (Revised RPS-5.2) (IP) (SP) (AS) [Does]

O2.12 Ensures the patient/carer knows what to do if there are any concerns about the management of their condition, if the condition deteriorates or if there is no improvement in a specific timeframe. (Revised RPS-5.4) (IP) (SP) (AS) [Does]

**3. Establishes patient management options**

**Options**

*An optometrist with a specialist entry to the GOC register (AS, SP and IP) assesses the patient to establish a diagnosis (sometimes in complex and unpredictable situations), determine and maintain an informed management plan for reviewing the patient’s treatment, arrange appropriate aftercare and prescribe if necessary (within their individual scope of practice).*

O3.1 Demonstrates appropriate consultation techniques and takes an appropriate medical, social and medication history including allergies and intolerances. (Revised RPS-1.6) (IP) (SP) (AS) [Does]

O3.2 Undertakes and documents an appropriate clinical assessment. (Revised RPS-1.7) (IP) (SP) (AS) [Does]

O3.3 Identifies and addresses potential vulnerabilities that may be causing the patient/carer to seek treatment. (Revised RPS-1.8) (IP) (SP) (AS) [Does]

O3.4 Accesses and interprets all available and relevant patient records to ensure knowledge of the patient’s management to date. (Revised RPS-1.9) (IP) (SP) (AS) [Does]

O3.5 Requests and interprets appropriate investigations necessary to inform treatment options. (Revised RPS-1.10) (IP) (SP) [Knows how]

O3.6 Makes, confirms or understands, and documents the working or final diagnosis by systematically considering the differential diagnosis. (Revised RPS-1.11) (IP) (SP) (AS) [Does]

O3.7 Recognises and understands the condition(s) being treated, their natural progression and how to assess their severity, deterioration and anticipated response to treatment. (Revised RPS-1.12) (IP) (SP) (AS) [Does]

O3.8 Reviews adherence to, and effectiveness of, current medicines. (Revised RPS-1.13) (IP) (SP) (AS) [Does]

O3.9 Assesses adherence in a non-judgemental way, understands the different reasons for non-adherence (intentional or non-intentional) and how best to support the patient/carer. (Revised RPS-3.4) (IP) (SP) (AS) [Shows how]

O3.10 Recognises when and where to refer appropriately or seek guidance from another member of the healthcare team, a specialist or appropriate information source when necessary. (Revised RPS-1.14) (IP) (SP) (AS) [Does]

O3.11 Considers both non-pharmacological (including no treatment) and pharmacological approaches. (Revised RPS-2.1) (IP) (SP) (AS) [Does]

O3.12 Considers all pharmacological treatment options including optimising doses as well as stopping treatment (appropriate polypharmacy, de-prescribing). (Revised RPS-2.2) (IP) (SP) (AS) [Does]

O3.13 Assesses and manages the risks and benefits associated with prescribing decisions including using or not using treatment. (Revised RPS-2.3) (IP) (SP) (AS) [Does]

O3.14 Applies understanding of the mode of action, pharmacokinetics and pharmacodynamics of medicines, and how these may be altered by individual patient factors. (Revised RPS-2.4) (IP) (SP) (AS) [Does]

O3.15 Assesses how co-morbidities, existing medicines, allergies, contraindications and quality of life impact on management options. (Revised RPS-2.5) (IP) (SP) (AS) [Does]

O3.16 Considers any relevant patient factors and their potential impact on the choice and formulation of medicines, and the route of administration. (Revised RPS-2.6) (IP) (SP) (AS) [Does]

O3.17 Encourages and supports the patient/carer to take responsibility for their medicines and self-manage their condition. (Revised RPS-5.5) (IP) (SP) (AS) [Does]

03.18 Adapts the management plan in response to on-going monitoring and review of the patient’s condition and preferences. (Revised RPS-6.3) (IP) (SP) (AS) [Does]

**4. Prescribing practice**

*An optometrist with a specialist entry to the GOC register (AS, SP and IP) is responsible for their role as a prescriber in achieving desired patient outcomes, prescribing safely, appropriately and in context. Working within their limits of competence and exercising professional judgement, they engage in evidence-informed clinical decision-making for all patients and can demonstrate self-direction in solving problems.*

O4.1 Understands and uses available tools to improve prescribing practice (such as supervision, workplace competency-based assessments, questionnaires, prescribing data analysis, audits, and actively seeking patient and peer feedback). (Revised RPS-9.3) (IP) (SP) (AS)

O4.2 Prescribes a medicine or device with adequate, up-to-date awareness of its actions, indications, dose, contraindications, interactions, cautions and adverse effects. (Revised RPS-4.1) (IP) (SP) (AS) [Does]

O4.3 Understands the potential for adverse effects and takes steps to recognise, minimise risk and manage them. (Revised RPS-4.2) (IP) (SP) (AS) [Shows how]

O4.4 Establishes and maintains a plan to monitor the effectiveness of treatment and potential unwanted effects. (Revised RPS-6.2) (IP) (SP) (AS)[Does]

O4.5 Prescribes generic medicines where practical and safe for the patient, and knows when medicines should be prescribed by branded product. (IP) (SP) (AS) (Revised RPS-4.4) [Does]

O4.6 Accurately completes and routinely checks calculations relevant to prescribing and practical dosing. (Revised RPS-4.5) (IP) (SP) (AS) [Does]

O4.7 Prescribes appropriate quantities and at appropriate intervals necessary, to reduce the risk of unnecessary waste. (Revised RPS-4.6) (IP) (SP) (AS) [Does]

O4.8 Stays up-to-date in own area of practice and applies the principles of evidence-based practice. (Revised-RPS 2.8) (IP) (SP) (AS) [Does]

O4.9 Accesses, critically evaluates, and uses reliable and validated sources of information. (Revised RPS-2.7) (IP) (SP) (AS) [Does]

O4.10 Understands and prescribes within relevant national, regional and local frameworks for medicines use. (Revised RPS-4.3) (IP) (SP) (AS) [Shows how]

O4.11 Recognises when safe prescribing processes are not in place and acts to minimise risks. (Revised RPS-7.4) (IP) (SP) (AS) [Shows how]

O4.12 Applies the General Medical Council’s ‘Remote prescribing high level principles’ (co-authored by a range of healthcare regulators including the GOC) to ensure patients have effective safeguards in place to protect them when they receive advice and treatment remotely. (IP) (SP) (AS) [Shows how]

O4.13 Negotiates the appropriate level of support and/or supervision (including when working remotely) for their role as a prescriber. (Revised RPS-10.3) (IP) (SP) [Does]

O4.14 Provides support and advice to other prescribers or those involved in administration of medicines where appropriate. (Revised RPS-10.4) (IP) (SP) [Does]

O4.15 Uses up-to-date information about the availability, pack sizes, storage conditions, excipients and costs of prescribed medicines. (Revised RPS-4.8) (IP) (SP) (AS) [Does]

O4.16 Electronically generates and/or writes legible unambiguous and complete prescriptions which meet legal requirements. (Revised RPS-4.9) (IP) (SP) (AS) [Does]

O4.17 Effectively uses systems necessary to prescribe medicines. (Revised RPS-4.10) (IP) (SP) (AS) [Does]

O4.18 Documents accurate, legible and contemporaneous clinical records. (Revised RPS-4.13) (IP) (SP) (AS) [Does]

O4.19 Effectively communicates information to other healthcare professionals involved in the patient’s care when sharing or transferring care and prescribing responsibilities, within and across all care settings. (Revised RPS-4.14) (IP) (SP) (AS) [Shows how]

O4.20 Understands antimicrobial resistance and the roles of infection prevention and control. Applies antimicrobial stewardship measures e.g. considers alternative options and only prescribes antimicrobials when clinically appropriate. (Revised RPS-2.10) (IP) (SP) (AS) [Knows how]

**5. Ethics and standards**

*An optometrist with a specialist entry to the GOC register (AS, SP and IP) must uphold high professional standards and ethical responsibilities, and apply legislation and relevant policies and guidance that impact on their prescribing practice.*

O5.1 Accepts personal responsibility and accountability for prescribing, and understands the legal and ethical implications. (Revised RPS-8.1) (IP) (SP) (AS) [Does]

O5.2 Understands and works within legal and regulatory frameworks affecting own prescribing practice (e.g.prescribing controlled drugs, unlicensed and off label medicines, supplementary prescribing, and prescribing for self, close family and friends). (Revised RPS-8.3) (IP) (SP) (AS) [Knows how]

O5.3 Prescribes unlicensed and off-label medicines where legally permitted, and unlicensed medicines only if satisfied that an alternative licensed medicine would not meet the patient’s clinical needs. (Revised RPS-4.11) (IP) (SP) (AS) [Shows how]

O5.4 Follows appropriate safeguards if prescribing medicines are unlicensed, ‘off-label’, or outside standard practice. (Revised RPS-4.12) [Shows how] (IP) (SP) (AS)

O5.5 Works within the NHS, organisational, regulatory and other codes of conduct when interacting with the pharmaceutical industry. (Revised RPS-8.6) (IP) (SP) (AS) [Does]

O5.6 Knows how medicines are licensed, supplied and monitored. (GOC Framework) (IP) (SP) (AS) [Knows]

O5.7 Considers the wider perspective including the public health issues related to medicines and their use, and promoting health. (Revised RPS-2.9) (IP) (SP) (AS) [Knows]

**6. Manages risk**

*An optometrist with a specialist entry to the GOC register (AS, SP and IP) should be able to identify when people might be at risk and be candid when things have gone wrong. They should recognise when safe systems are not in place to support prescribing and act appropriately to ensure a safe environment for patients and the public.*

O6.1 Acts upon inappropriate or unsafe prescribing practice using appropriate processes. (Revised RPS-9.2) (IP) (SP) (AS) [Knows how]

O6.2 Recognises, minimises risk and manages potential misuse of medicines using appropriate processes. (Revised RPS-4.7) (IP) (SP) (AS) [Shows how]

O6.3 Knows about common types and causes of medication and prescribing errors, and how to minimise their risk. (Revised RPS-7.2) (IP) (SP) (AS) [Knows how]

O6.4 Recognises and reports suspected adverse reactions to medicines and medical devices using appropriate reporting systems. (Revised RPS-6.4) (IP) (SP) (AS) [Does]

O6.5 Reports near misses, critical incidents, medication and prescribing errors using appropriate reporting systems, and regularly reviews practice to prevent recurrence. (Revised RPS-7.6) (IP) (SP) (AS) [Shows how]

O6.6 Recognises and manages factors that might unduly influence prescribing (e.g. interactions with pharmaceutical industry, media, patient, colleagues, cognitive bias, prescribing incentives and targets). (Revised RPS-8.5) (IP) (SP) (AS) [Shows how]

**7. Learning and development**

*An optometrist with a specialist entry to the GOC register (AS, SP and IP) must maintain their clinical knowledge and skills appropriate to their scope of practice, make use of networks for support, reflection and learning, and be able to work within their area of expertise and competence to achieve desired patient outcomes.*

O7.1 Takes responsibility for own learning and continuing professional development (CPD) relevant to the prescribing role by continuously reviewing, reflecting, identifying gaps, planning, acting, applying and evidencing learning or competencies. (Revised RPS-9.4) (IP) (SP) (AS) [Does]

O7.2 Supports the learning and development of others with their prescribing practice and learning journey, by engaging in mentoring, leadership and workforce development. (Revised RPS-9.6) (IP) (SP) (AS) [Does]

O7.3 Ensures confidence and competence to prescribe are maintained. (Revised RPS-8.1) (IP) (SP) (AS) [Shows how]

O7.4 Improves by reflecting on own and others’ prescribing practice, and acting upon feedback and discussion. (Revised RPS-9.1) (IP) (SP) (AS) [Does]

O7.5 Prescribes within own competence and scope of practice, and recognises the limits of own knowledge and skill. (Revised RPS-7.1) (IP) (SP) (AS) [Does]

O7.6 Keeps up-to-date with emerging safety concerns related to prescribing. (Revised RPS-7.5) (IP) (SP) (AS) [Does]

Note on ‘Miller’s Pyramid of Clinical Competence’[[4]](#footnote-4)

**Knows** Knowledge that may be applied in the future.

(Assessments may include essays, unseen examinations, practical reports, oral examinations and multiple-choice questions (MCQs), etc.)

**Knows how** Knows how to apply knowledge and skills in a defined context or situation.

(Assessments may include essays, oral examinations, unseen examinations, short answer questions, multi-format MCQs (single best answer, extended matching questions), practical simulations, portfolios, workbooks and poster presentations, etc.)

**Shows how** Applies knowledge, skills and behaviour in a simulated environment or in real life repeatedly and reliably.

(Assessments may include objective structured clinical examinations (OSCEs), simulated patient assessments, oral and poster presentations, designing, conducting and reporting an experiment, dispensing tests and taking a patient history, unseen examinations involving patient cases, etc.)

**Does** Acting independently and consistently in a complex situation of an everyday or familiar context repeatedly and reliably.

*(Assessments may include OSCEs, simulated patient assessments and observed practice, case-based assessments, portfolios, sustained research project (thesis, poster and oral presentation), etc.)*

**Section 2:** **Standards for Approved Qualifications for Specialist Entry to the GOC Register (Additional Supply, Supplementary Supply and Independent Prescribing)**

**Introduction**

The **standards for approved qualifications for specialist entry to the GOC register (AS, SP and IP)** describe the expected context for the delivery and assessment of the outcomes leading to an award of an approved qualification for specialist entry to the GOC register in AS, SP and/or IP categories.

We will use the **outcomes for approved qualifications,** **standards for approved qualifications** and **quality assurance and enhancement method** together to decide whether to approve a qualification for specialist entry to the GOC register in the AS, SP and/or IP categories.

GOC-approved qualifications[[5]](#footnote-5) will prepare trainees to meet these outcomes for specialist entry to the GOC register.

The standards are organised under five categories:

1. Public and patient safety

2. Selection and admission of trainees

3. Assessment of outcomes and curriculum design

4. Management, monitoring and review of approved qualifications

5. Leadership, resources and capacity

Each category is supported by criteria which must be met for a qualification to be approved.

**Standards for Approved Qualifications for Specialist Entry to the GOC Register (Additional Supply, Supplementary Prescribing and Independent Prescribing)**

1. Public and patient safety

*Approved qualifications must be delivered in contexts which ensure public and patient safety and support trainees’ development and the demonstration of patient centred professionalism.*

Criteria to meet this standard:

S1.1 There must be policies and systems in place to ensure trainees understand and adhere to the GOC’s [Standards of Practice for Optometrists and Dispensing Opticians](https://standards.optical.org/the-standards/optometrists-and-dispensing-opticians/).

S1.2 Concerns about a trainee’s fitness to train or practise must be reported to the GOC. (The GOC acceptance criteria should be used as a guide as to when a fitness to practise/train matter should be reported.)

S1.3 Trainees must not put patients, service-users, the public or colleagues at risk. This means that anyone who teaches, assesses, supervises or employs trainees must ensure trainees practise safely, only undertake activities within the limits of their competence and are appropriately supervised when with patients and service-users.

S1.4 Upon admission (and at regular intervals thereafter) trainees must be informed it is an offence not to be registered with the GOC at all times whilst studying on a programme leading to an approved qualification for specialist entry to the GOC register (AS, SP and/or IP).

Standard 2 – Admission of Students

2. Selection and admission of trainees

*Recruitment, selection and admission of trainees must be transparent, fair and appropriate.*

Criteria to meet this standard:

S2.1 Selection and admission criteria must be appropriate for entry to an approved qualification for specialist entry to the GOC register (AS, SP and/or IP categories) including relevant health, character and fitness to practise checks. For overseas trainees, this should include evidence of proficiency in the English language of at least level 7 overall (with no individual section lower than 6.5) on the International English Language Testing System (IELTS) scale or equivalent.

S2.2 Recruitment, selection and admission processes must be fair, transparent and comply with relevant legislation (which may differ between England, Scotland, Northern Ireland and Wales), including equality and diversity legislation,andevaluate the suitability and relevance of the applicant’s prior clinical and therapeutic experience.

S2.3 Selectors (who may include a mix of academic and admissions/administrative staff) should be trained to apply selection criteria fairly, including training in equality, diversity and unconscious bias in line with legislation in place in England, Scotland, Northern Ireland and Wales.

S2.4 Information provided to applicants must be accurate, comply with relevant legislation and include:

* the academic, clinical and therapeutic experience required for entry to the approved qualification;
* a description of the selection process and any costs associated with making the application;
* the qualification’s approved status;
* the total costs/fees that will be incurred;
* the curriculum and assessment approach for the qualification; and
* the requirement for trainees to remain registered with the GOC throughout the duration of the programme leading to the award of the approved qualification.

If offers are made to applicants below published academic and professional entry requirements, the rationale for making such decisions must be explicit and recorded.

S2.5 Recognition of prior learning must be supported by effective and robust policies and systems. These must ensure that trainees admitted at a point other than the start of a programme have the potential to meet the outcomes for the award of the approved qualification. Prior learning must be recognised in accordance with guidance issued by The Quality Assurance Agency for Higher Education (QAA) and/or Ofqual / Scottish Qualifications Authority (SQA) / Qualifications Wales / Department for the Economy in Northern Ireland and must not exempt trainees from summative assessments leading to the award of the approved qualification. (If necessary, separate arrangements will be made for the safe transition of trainees who have not yet completed GOC-approved therapeutic prescribing qualifications programmes prior to the introduction of the new outcomes and standards.)

S2.6 Trainees upon application must have identified a suitably experienced and qualified designated prescribing practitioner (DPP) who has agreed to supervise their learning in practice. The trainee’s DPP must be a registered healthcare professional in Great Britain or Northern Ireland with independent prescribing rights. (See standard 4.)

3. Assessment of outcomes and curriculum design

*The approved qualification must be supported by an integrated curriculum and assessment strategy that ensures trainees who are awarded the approved qualification meet all the outcomes at the required level (Miller’s Pyramid: knows; knows how; shows how; and does).*

Criteria to meet this standard:

S3.1 There must be a clear assessment strategy for the award of an approved qualification. The strategy must describe how the outcomes will be assessed, how assessment will measure trainees’ achievement of outcomes at the required level (Miller’s Pyramid) and how this leads to an award of an approved qualification.

S3.2 The approved qualification must be taught and assessed (diagnostically, formatively and summatively) in a progressive and integrated manner. The component parts should be linked into a cohesive programme (for example, Harden’s spiral curriculum[[6]](#footnote-6)), introducing, progressing and assessing knowledge, skills and behaviour until the outcomes are achieved.

S3.3 Curriculum design and the assessment of outcomes must involve and be informed by feedback from a range of stakeholders such as patients, employers, trainees, commissioners, placement providers, members of the eye-care team and other healthcare professionals.

S3.4 The outcomes must be assessed using a range of methods and all final, summative assessments must be passed. This means that compensation, trailing and extended re-sit opportunities within and between modules where outcomes are assessed is not permitted.

S3.5 Assessment (including lowest pass) criteria, choice and design of assessment items (diagnostic, formative and summative) leading to the award of an approved qualification must ensure safe and effective practice and be appropriate for a qualification for specialist entry to the GOC register (AS, SP and/or IP).

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S3.6 Assessment (including lowest pass) criteria must be explicit and set using an appropriate and tested standard-setting process. This includes assessments which occur during learning and experience in practice.

S3.7 Assessments must appropriately balance validity, reliability, robustness, fairness and transparency, ensure equity of treatment for trainees, reflect best practice and be routinely monitored, developed and quality-controlled. This includes assessments which might occur during learning and experience in practice.

S3.8 Appropriate reasonable adjustments must be put in place to ensure that trainees with a disability are not disadvantaged in engaging with the learning and teaching process and in demonstrating their achievement of the outcomes.

S3.9 There must be policies and systems in place to plan, monitor and record each trainee’s achievement of outcomes leading to award of the approved qualification.

S3.10 The approved qualification must be listed on one of the national frameworks for higher education qualifications for UK degree-awarding bodies[[7]](#footnote-7) (The Framework for Higher Education Qualifications of Degree-Awarding Bodies in England, Wales and Northern Ireland (FHEQ) and the Framework for Qualifications of Higher Education Institutions in Scotland (FQHEIS)), or be a qualification regulated by Qfqual, SQA or Qualifications Wales. Approved qualifications for specialist entry to the GOC register (AS, SP and/or IP) must be at a minimum Regulated Qualification Framework (RQF), FHEQ or Credit and Qualifications Framework Wales (CQFW) level 7 or Scottish Credit and Qualifications Framework (SCQF) / FQHEIS 11.

S3.11 A range of teaching and learning methods must be used to deliver the outcomes.

S3.12 To enable the development of trainees’ clinical, diagnostic and prescribing skills to meet the outcomes, the approved qualification must integrate learning and experience in practice (as a guide, approximately 90 hours). The supervision of a trainee’s learning and experience in practice must be co-ordinated by an appropriately trained and qualified registered healthcare professional (DPP) with independent prescribing rights. (See also S4.4-S4.6.)

S3.13 Outcomes delivered and assessed during learning and experience in practice must be clearly identified, included within the assessment strategy and fully integrated within the programme leading to the award of an approved qualification.

S3.14 The selection of outcomes to be taught and assessed during periods of learning and experience in practice and the choice and design of assessment items must be informed by feedback from a variety of sources, such as patients, employers, trainees, DPPs, members of the eye-care team and other healthcare professionals.

S3.15 Equality and diversity data and its analysis must inform curriculum design, delivery and assessment of the approved qualification. This analysis must include trainees’ progression by protected characteristic. In addition, the principles of equality, diversity and inclusion must be embedded in curriculum design and assessment and used to enhance trainees’ experience of studying on a programme leading to an approved qualification.

S3.16 Trainees must receive regular and timely feedback to improve their performance, including on their performance in assessments and in periods of learning and experience in practice.

S3.17 As part of the approved qualification, trainees must meet regularly with their DPP to discuss and document their progress as learners.

4. Management, monitoring and review of approved qualifications

*Approved qualifications must be managed, monitored, reviewed and evaluated in a systematic and developmental way, through transparent processes that show who is responsible for what at each stage.*

Criteria to meet this standard:

S4.1 There must be a clear management plan in place for the award of the approved qualification and its development, delivery, management, quality control and evaluation.

S4.2 The organisation responsible for the award of the approved qualification must be legally incorporated (i.e. not be an unincorporated association) and have the authority and capability to award the approved qualification.

S4.3 The provider must have a named point of contact for the approved qualification.

S4.4 There must be agreements in place between the trainee, their DPP and the provider that describe their respective roles and responsibilities during periods of learning and experience in practice. These must be regularly reviewed and supported by management plans, systems and policies which prioritise patient safety.

S4.5 A trainee’s DPP must be a registered healthcare professional with independent prescribing rights and be an active prescriber competent in the clinical area(s) they will be supervising the trainee in, have the relevant core competencies[[8]](#footnote-8) and be trained and supported to carry out their role effectively.

S4.6 If more than one registered healthcare professional with independent prescribing rights is involved in supervising a trainee, one independent prescriber must assume primary

responsibility for coordinating their supervision. That person will be the trainee’s DPP.

S4.7 The approved qualification must be systematically monitored and evaluated across learning environments using the best available evidence, including feedback from stakeholders, and action taken to address any concerns identified. Evidence should demonstrate as a minimum:

* feedback systems for trainees and DPPs;
* structured systems for quality review and evaluation;
* trainee consultative mechanisms;
* input and feedback from external stakeholders (patients, employers, DPPs, commissioners, trainees, former trainees, third sector bodies, etc); and
* evaluation of business intelligence including progression and attainment data.

This will ensure that:

* provision is relevant, current and informed by evidence, and changes are made promptly to teaching materials and assessment items to reflect significant changes in practice and/or the results of research;
* the quality of teaching, learning support and assessment is appropriate; and
* the quality of learning and experience in practice, including supervision, is appropriate.

S4.8 There must be policies and systems in place for:

* the selection, appointment, support and training of external examiner(s) and/or internal and external moderator(s)/verifiers; and
* reporting back on actions taken to external examiners and/or internal and external moderators/verifiers.

S4.9 Trainees, and anyone who supervises trainees, must be able to provide feedback on progress and raise concerns. Responses to feedback and concerns raised must be recorded and evidenced.

S4.10 Complaints must be considered in accordance with the good practice advice on handling complaints issued by the Office for the Independent Adjudicator for Higher Education in England and Wales (or equivalent).

S4.11 There must be an effective mechanism to identify risks to the quality of the delivery and assessment of the approved qualification and to identify areas requiring attention or development.

S4.12 There must be systems and policies in place to ensure that the GOC is notified of any major events and/or changes to the approved qualification, assessment and quality control, its organisation, resourcing and constitution, including responses to relevant regulatory body reviews.

5. Leadership, resources and capacity

*Leadership, resources and capacity must be sufficient to ensure the outcomes are delivered and assessed to meet these standards in an academic, professional and clinical context.*

Criteria to meet this standard:

S5.1 There must be robust and transparent mechanisms for identifying, securing and maintaining a sufficient and appropriate level of ongoing resources to deliver the outcomes to meet these standards, including human and physical resources that are fit for purpose and clearly integrated into strategic and business plans. Evaluations of resources and capacity must be evidenced together with evidence of recommendations considered and implemented.

S5.2 There must be a sufficient and appropriately qualified and experienced staff team. This must include:

* an appropriately qualified and experienced programme leader, supported to succeed in their role; and
* sufficient staff responsible for the teaching and assessment of the outcomes[[9]](#footnote-9), including GOC registrants and other suitably qualified healthcare professionals.

S5.3 There must be policies and systems in place to ensure anyone involved in the approved qualification is appropriately qualified and supported to develop in their role. These must include:

* opportunities for CPD, including personal, academic and profession-specific development;
* for registered healthcare professionals and DPPs supervising trainees, opportunity for training and support;
* effective induction, supervision, peer support and mentoring;
* realistic workloads for anyone who teaches, assesses or supervises trainees;
* for teaching staff, the opportunity to gain teaching qualifications; and
* effective appraisal, performance review and career development support.

S5.4 There must be sufficient and appropriate learning facilities to deliver and assess the outcomes. These must include:

* sufficient and appropriate library and other information and IT resources;
* access to specialist resources, including textbooks, journals, internet and web-based materials; and
* specialist teaching, learning and clinical facilities to enable the delivery and assessment of the outcomes.

S5.5 Trainees must have effective support for health, wellbeing, conduct, academic, professional and clinical issues.

**Section 3:** **Quality Assurance and Enhancement Method**  **for Specialist Entry to the GOC Register (Additional Supply, Supplementary Prescribing and Independent Prescribing)**

**Introduction**

Our quality assurance and enhancement method describes how we will gather evidence to decide in accordance with the Act whether a qualification for specialist entry to the GOC register in the AS, SP and/or IP categories meets our outcomes for approved qualifications and standards for approved qualifications. This method statement is common to all qualifications for specialist entry to the GOC register.

We will use the outcomes for approved qualifications, standards for approved qualifications and quality assurance and enhancement method together to decide whether to approve a qualification for specialist entry to the GOC register.

The design of the new quality assurance and enhancement method supports our outcomes-orientated approach. It moves away from seeking assurance that requirements are met by measuring inputs to evidencing outcomes. This reflects approaches taken by other statutory healthcare regulators, professional and chartered bodies.

The method does not attempt to describe every permutation of assurance and enhancement. Instead, it establishes a proportionate framework for gathering and assessing evidence to inform a decision as to whether to approve a qualification or withdraw approval of a qualification. The method sets out arrangements for periodic review, annual return, thematic and sample-based reviews, as well managing serious concerns and the type and range of evidence a provider of an approved qualification might consider providing to support these processes.

Underpinning our approach is a greater emphasis on the views of patients, service-users, the public, NHS, commissioners of training and education, and employers, as well as the views of trainees and previous trainees in the evidence we consider. This is to ensure the qualifications we approve are not only responsive to the needs of patients and service-users but also to the rapidly changing landscape in the delivery of eye-care services across the United Kingdom (UK).

The method is organised in seven sections:

1. Legal basis for quality assurance and enhancement
2. Quality assurance and enhancement – definitions
3. Geographic scope
4. Arrangements for current (pre-2021) providers of approved and provisionally approved qualifications
5. Approval of new qualifications (from December 2021)
6. Periodic review, annual return, thematic and sample-based review
7. Scope of evidence
8. Decision-making

**Quality Assurance and Enhancement Method**

1. Legal basis for quality assurance and enhancement

Our powers to undertake quality assurance and enhancement are set out in sections 12 and 13 of the Act. The Act requires the GOC to approve qualifications ‘granted to candidates following success in an examination or other form or assessment which in the Council’s opinion indicates that the candidate has attained all the outcomes leading to the award of the qualification’.

In part approval will be based on reports of appointed visitors (called ‘Education Visitors’) who report to the GOC on the ‘nature of the instruction given’, the ‘sufficiency of the instruction given’ and ‘the assessments on the results of which approved qualifications are granted’ as well as ‘any other matters’ which the GOC may decide.

The Act also gives powers to the GOC to approve ‘any institution where the instruction given to persons training as opticians appears to the Council to be such as to secure to them adequate knowledge and skill for the practice of their profession’.

**Quality Assurance and Enhancement - definitions**

2. Quality assurance and enhancement – definitions

Quality assurance provides assurance that the qualifications we approve meet requirements in accordance with the Act for *‘adequate knowledge and skill’* (section 12(7)(a) of the Act), as described in our outcomes and standards for approved qualifications.

A quality enhancement process goes further than establishing that minimum requirements are met. Enhancement helps us demonstrate we are meeting our statutory obligation to understand both the *‘nature’* and the *‘sufficiency’* of instruction provided and in the assessment of trainees, and provides an opportunity to foster innovation and enhance the quality and responsiveness of provision to meet the needs of patients, the public and service-users.

**Geographic Scope**

3. Geographic scope

In addition to approving qualifications in the UK we may also approve qualifications outside the UK, provided that these are taught and assessed in either English or Welsh. Assurance and enhancement activity undertaken outside the UK will be charged for on a full cost recovery basis.

4. Arrangements for current (pre-2021) providers of approved and provisionally approved qualifications

From January 2022we will begin working with each provider of GOC-approved and provisionally approved post-registration qualifications to understand at what pace providers will be able to adapt their existing qualifications or develop new qualifications to meet the outcomes and standards.

We anticipate most providers will work towards admitting trainees to approved qualifications that meet the outcomes and standards from July 2022*.*

Separate arrangements will be made with The College of Optometrists to ensure that the route to specialist entry to the GOC register is maintained for trainees who graduate from qualifications approved before 2021.

Providers of currently approved qualifications and provisionally approved qualifications will have three options for adapting their existing qualifications or developing new qualifications to meet the outcomes and standards for approved qualifications:

1. adapt an existing approved or provisionally approved qualification and seek approval (as a course change) to a timescale agreed with us;
2. ‘teach out’ an existing approved qualification or provisionally approved qualification to a timescale agreed with us, alongside developing, seeking approval for and recruiting to a ‘new’ qualification (using the process described in section 5, below); and
3. ‘teach out’ an existing approved qualification or provisionally approved qualification to a timescale agreed by us and partner with another organisation(s) or institution(s) to develop, seek approval for and recruit to a ‘new’ qualification (using the process described in section 5, below).

Providers may, in consultation with the GOC, wish to migrate trainees from an existing approved or provisionally approved qualification to the ‘new’ qualification.

During the transitional phase, ‘A Handbook for Optometry Specialist Registration in Therapeutic Prescribing’ (2008) and the ‘Competency Framework for Independent Prescribing’ (2011) including the list of required core competences, the numerical requirements for trainees’ practical experiences, education policies and guidance contained within the handbooks, and our policies on supervision and recognition of prior learning will apply to all existing (pre-2021) GOC-approved and provisionally approved qualifications during the teach out or migration phase.

5. Approval of new qualifications (from 1 January 2022)

We will consider applications for approval of qualifications not currently approved by us in accordance with the risk-based staged approach described below.

For qualifications already approved by the GOC, please see section 4 above, ‘Arrangements for current (pre-2021) providers of approved and provisionally approved qualifications’.

The number, frequency and specification for each stage for approval of new qualifications will vary depending on the proposed qualification’s risk stratification, which can be summarised broadly as:

1. lower risk: a new qualification developed by an existing provider of approved speciality qualifications or provisionally approved speciality qualifications (option b. in section 4 above);
2. medium risk: a new qualification developed by a provider in a partnership or contractual arrangement with one or more organisations or institutions, one or more of which may have experience of awarding a speciality qualification approved by us; and
3. higher risk: a new qualification developed by a provider with limited or no experience of awarding a speciality qualification approved by us.

All new qualifications not currently approved by us applying for GOC approval on or after 1 January 2022 will be expected to meet the outcomes and standards in accordance with the stages outlined below.

**Staged approach to qualification approval** *(for approval of new qualifications)*

*Stage 1.* Initial proposal for the proposed qualification. This stage will explore the strategic intent for the proposed qualification, the rationale for its design, its proposed approach to integration and resourcing, the provider’s corporate form and management, and how the views of stakeholders, including patients, servicer-users, employers, NHS, commissioners of training and education and the public will inform the development, teaching and assessment of the proposed qualification, the draft business case and an outline of the investment necessary to ensure its success, and identification of key risks. The evidence to support stage 1 will normally be a written submission, based on the evidence framework, and supported by a meeting with us (at our offices or virtually) if necessary. Stage 1 may be repeated, particularly for applications stratified as medium or higher risk, until there is confidence the outcomes and standards are on course to be met and the provider is ready to move on to stage 2. The output of stage 1 will be a report to the provider which may or may not be published.

*Stage 2*. Stage 2 will examine the proposed qualification design and its resourcing in more depth (including, for applications stratified as medium or higher risk, investment in key appointments and infrastructure made between stages 1 and 2). This stage will consider the business case, investment and proposed pedagogic approach, the development of learning, teaching and assessment strategies, the involvement of patients, servicer-users, employers, commissioners and the public in qualification design, delivery and assessment, and preparedness for delivery for the first cohort of trainees. By the end of stage 2 all arrangements with partners (if required) will be in place, as will the investment necessary to ensure the qualification’s successful implementation. The evidence to support stage 2 will normally be a written submission, based on the evidence framework, and supported by a meeting with us (at our offices, on site or virtually) if necessary. Stage 2 may be repeated, particularly for applications stratified as medium or higher risk, until there is confidence the outcomes and standards are on course to be met and the provider is ready to move on to stage 3. The output of stage 2 will be a report to the provider which may or may not be published.

*Stage 3.* The purpose of stage 3 will be to assess the readiness of the provider to begin recruiting trainees. The focus will be on detailed curriculum and assessment design, approach to recruitment and selection of trainees, and preparedness to commence delivery of the approved qualification. Stage 3 will confirm that the resourcing of the qualification, as described in stages 1 and 2, is in place (including, for applications stratified as medium or higher risk, investment in key appointments and infrastructure made between stages 2 and 3). By stage 3 the provider will also be expected to evidence good progress in implementing plans approved at stage 2. As stage 3 represents a higher risk to the GOC in terms of its decision-making, the evidence to support stage 3 will normally be a written submission, based on the evidence framework and an on site (or virtual) visit based on the format of a periodic review. The specification of the periodic review required will be informed by the qualification’s risk profile. Stage 3 may be repeated, particularly for applications stratified as medium or higher risk, until there is confidence the outcomes and standards are likely to be met and the provider is ready to move on to stage 4. The output of stage 3 will be permission to commence recruiting trainees. Providers are reminded that the qualification is not approved until a decision of Council is made at stage 5, and to ensure recruitment and advertising material conforms to our standard conditions of approval.

*Stage 4 (a,b,c, etc.).* Stage 4 is repeated each year until the first cohort of trainees, or trainees migrated across into the programme, reach the final year’s study. The focus of stage 4 is on the delivery and assessment of the integrated qualification, including its staffing, resourcing and infrastructure, risk mitigation and progress in implementing plans approved at earlier stages, alongside preparedness for the delivery for the next, and most importantly, final, academic year. At stage 4 patient, servicer-user, employer, commissioner and public engagement in qualification delivery, assessment and review is expected, along with evidence of an increasing volume of inter-professional learning and patient-facing learning and experience as trainees progress through the qualification. At stage 4 (a, b, c, etc.) the provider’s preparedness for, and implementation of, its plan for the integration of patient-facing learning and experience will be examined, as well as its reflections on implementing plans approved at earlier stages, and any changes it proposes to make to the qualification as a result of trainee and stakeholder feedback. As stage 4 represents a higher risk to us in terms of our decision-making, the evidence to support stage 4 will normally be a written submission, based on the evidence framework and, for applications stratified as lower risk, a meeting with us either on site or at our offices (or virtually if necessary). For applications stratified as medium or higher risk, the meeting will take the form of an on site (or virtual) visit based on the format of a periodic review. As at other stages, stage 4 may result in conditions being imposed, which can include halting recruitment for one or more cohorts, until we are reassured that the outcomes and standards are likely to be met and the provider is ready to move on to stage 5.

If a provider is asked to halt recruitment and/or if the decision is that there is no confidence the provider is ready to move to stage 5, the provider may cease to be considered for GOC approval, and trainees will not be eligible for specialty registration. In these circumstances, the provider must inform us how the interests of trainees currently studying on the qualification will be best served, either by transferring to an alternative provider or by being offered an alternative academic award; any costs incurred will be the responsibility of the provider.

The output of stage 4 will be a report to the provider which may or may not be published. Providers are reminded that the qualification is not approved until a decision of Council is made at stage 5, and to ensure recruitment and advertising material confirms to our standard conditions.

*Stage 5.* Stage 5 considers an approved qualification’s ability to meet the outcomes and standards. It is the final stage of the process and takes place in the academic year in which the first cohort of trainees will graduate. The evidence to support stage 5 will normally be a written submission, based on the evidence framework, alongside a periodic review and our attendance at the provider’s final examination board (or equivalent). The specification for the periodic review will be based on the evidence framework and the risk stratification of the qualification, which includes factors such as, but not limited to the results of stages 1 to 4, discharge of previously applied conditions and/or any serious concerns reviews and a sample-based review of the outcomes. The prime purpose of a stage 5 periodic review is assurance about whether the outcomes and standards are met. Depending on whether the application is stratified as lower, medium or higher risk, the periodic review may be desk-based, involve an on site visit or visits, and/or physical or virtual meetings.

A decision by Council as to whether to approve the qualification will rely upon its consideration of the evidence gathered during stages one to five and will be informed by the advice of the Education Visitors. If the decision of Council is to *approve* the qualification (with or without conditions), the decision will specify the date from which the qualification is approved (normally the date of the examination Board for the first graduating cohort of trainees). The duration of the qualification’s approval may be limited if necessary, according to its risk profile.

A provider’s progress through the staged process for approving a new qualification is advisory only until Council decides whether or not to approve the new qualification. This must be made clear to all trainees and applicants until the qualification is approved by the GOC’s Council.

6. Periodic review, annual return, thematic and sample-based review

Approval of new qualifications (from 1st March 2021)

Four methods of assurance and enhancement will together provide insight as to whether a qualification continues to meet our outcomes and standards:

* periodic review (of approved qualifications);
* annual return (of approved qualifications);
* thematic review (of standards); and
* sample-based review (of outcomes).

*Periodic review*. All approved qualifications and qualifications applying for approval will be subject to periodic review. Periodic review considers an approved qualification’s ability to meet or continue to meet the outcomes and standards. It may be desk-based, involve an on site visit or visits, and/or physical or virtual meetings. The frequency and focus of a periodic review will be informed by the risk profile of the qualification, which includes factors such as, but not limited to the results of annual returns, thematic and sample-based reviews, discharge of previously applied conditions and/or serious concerns reviews. The specification for a periodic review will be based on the risk profile of the qualification. The prime purpose of a periodic review is assurance as to whether or not the standards and outcomes are met.

*Annual return.* All approved qualifications must submit an annual return, which is a key part of our assurance method. We will publish the specification for annual returns from time to time, together with the timeframe for the annual returns. Failure to submit an annual return may contribute to a decision to refuse or withdraw a qualification’s approval. Information submitted as part of a qualification’s annual return will inform our risk stratification, the timing and specification of periodic review and the basis for our thematic and sample-based reviews. We may publish a summary report of annual returns from time to time.

*Thematic and sample-based review.* Thematic and sample-based reviews will be a key part of our enhancement method, providing evidence of the *‘nature’* and *‘sufficiency’* of approved qualifications and their assessment. They are both an assurance and an enhancement activity. Their focus is to draw out key themes, identify and share good practice, and address risk in an approved qualification or a group of approved qualifications. Thematic and sample-based reviews may be on a profession-specific/regional/national and/or UK basis. All providers of approved qualifications must participate in thematic and sample-based reviews if required.

The specification for a thematic review will be based on the criteria contained in the standards and published by us from time to time, together with the timeframe for participation.

The focus of sample-based reviews will be the outcomes, to better understand how an outcome is introduced, developed, assessed and integrated within an approved qualification, how a trainee’s achievement of the outcome at the appropriate level (at Miller’s Pyramid) is measured and the pedagogic approaches underpinning its teaching and assessment. Like thematic reviews, we will publish the specification for a sample-based review along with the timeframe for participation from time to time. Sample-based and thematic reviews may be undertaken as part of a periodic review or undertaken directly by us and/or co-commissioned from an external contractor.

Alongside annual review, thematic and sample-based reviews will inform our risk stratification of approved qualifications and the timing and focus of periodic reviews. We may publish a summary report of thematic and sample-based reviews from time to time.

7. Scope of evidence

Approval of new qualifications (from 1st March 2021)

Demonstrating that the outcomes and standards are met should not be unnecessarily onerous, and guidance is given below on the type of evidence a provider may wish to provide. In many cases, this evidence should be readily available standard, institutional documentation which either provides context, such as published institutional-level policies, or qualification-specific information used at programme level by staff, trainees or stakeholders. Whilst we anticipate that the majority of evidence sources will be generic, some evidence may, of necessity, need to be bespoke for this assurance and enhancement method. However, wherever possible we will limit the requirement for bespoke evidence (e.g. programme mapping), and will continue to do so to ensure our assurance and enhancement method is manageable for providers and is proportionate to the decisions we need to make.

Providers are encouraged to have an early conversation with our Education team to ensure appropriate application of our standards in the light of the context, duration or location (e.g. for qualifications awarded by specialist institutions or higher education providers outside the UK) of the qualification.

Evidence sources providers may wish to consider including or referencing within their evidence framework template may include (but are not limited to) those outlined below.

In relation to the outcomes:

* Programme specifications, module descriptors, unit handbooks, module or unit evaluation reports, curricula, timetables, mapping of outcomes to programme specification, indicative documents / subject benchmarks, examples of teaching and assessment materials.
* Description of assessment strategy and approaches to standard setting, copies of academic regulations, policies for the quality control of assessments, examples of assessment schemes, mark sheets, model answers.
* External examiner reports and evidence of responses to issues raised, reports from internal and external moderators/verifiers, copies of external examiner / internal and external moderator/verifier recruitment, retention and training/support policies, examination board terms of reference, minutes.
* Trainee feedback and evidence of responses to issues raised.
* Evidence of stakeholder engagement and feedback, including from patients and carers, in qualification design, delivery and assessment, and evidence of responses to issues raised.
* Description of facilities and resource utilisation to support the teaching and assessment of the outcomes, supervision policies and safe practice, etc.

In relation to the standards:

* Information about the provider, its ownership, corporate form, organisation, leadership and lines of responsibility, evidence of the contractual relationships underpinning the delivery and assessment of the award of the approved qualification, service/local level agreements, agreements between stakeholders / placement providers, management plans, etc.
* Information about the approved qualification, its credit load, length, form of delivery, type of academic award; evidence of internal or external validation/approval by relevant awarding body, example certificate, programme management plans, diagrams, etc.
* Admission policies, admissions data, recruitment and selection information, application packs, recognition of prior learning (RPL) / accreditation of prior learning (APL) policies, advertising and promotional activity, fee schedules, evidence of selectors’ training in equality, diversity and unconscious bias, fitness to train/practise policies, etc.
* Evidence of engagement with service-users, commissioners, patients and the public, trainees and former trainees, employers and other stakeholders in qualification design, delivery and assessment; copies of relevant policies, stakeholder identification strategies, minutes of stakeholder engagement meetings/events, feedback and evidence of responses/action to issues raised.
* Description of the provider’s quality control procedures at institutional and qualification level, evidence of responses to external examiner / internal and external moderator reports, end of programme evaluations, National Student Survey results, reports from other quality control or assurance bodies, and responses to issues raised, copies of trainee feedback, minutes of staff-trainee committees, and evidence of action in relation to issues raised, copies of examination regulations, examination board minutes, verification reports, evidence of policies and their implementation in areas such as academic misconduct, adjustments, data protection, equality and diversity, complaints, etc.
* Description of strategies for teaching, learning and assessment, including approaches to assessment design, standard setting, assessment tariff and assessment load, approach to integration; copies of placement contracts; supervision policies; evidence of training and feedback from placement providers; progression data, equality and diversity, etc.
* Evidence that there are mechanisms for securing sufficient levels of resource to deliver the outcomes to the required standards, including historic and projected resource allocation and review, evidence of physical and virtual learning resources, accommodation, equipment and facilities and assessment of their utilisation, copies of risk assessment and risk mitigation plans, etc.
* Evidence that the staff profile can support the delivery of the outcomes and the trainee experience, including workload planning, staff CVs and staff deployment/contribution to the teaching and assessment of the outcomes, SSR, copies of policies describing the training, induction and support for those supervising trainees, external examiners, expert patients and other stakeholders and evidence of their efficacy, etc.
* Any other evidence the provider may wish to include to demonstrate its qualification meets the outcomes and standards.

A decision as to whether to approve a qualification or withdraw approval of a qualification will depend upon the evidence provided. For that reason, we rely on providers’ responsiveness to provide the information we need to support our decision-making processes.

Our decisions will be based upon a fair and balanced consideration of the evidence provided, using an approach based on the stratification of risk to decide which criteria within our standards and outcomes we will require providers to evidence, how we will gather that evidence (the frequency and type of assurance and enhancement activity), how we will consult our Education Visitors in the consideration of the evidence provided, and how this informs our decision-making.

8. Decision-making

Scope of Evidence

Approval of new qualifications (from 1st March 2021)

All decisions regarding qualification approval or withdrawal of approval or any other matter regarding approval of qualifications are the responsibility of Council. Council may delegate some or all of these decisions according to our scheme of delegation.

Decisions will be informed by the advice of our Education Visitors. In making its decision, Council, and those to whom Council has delegated authority, may choose to accept, reject or modify advice from our Education Visitors in relation to the qualification under consideration.

Council, and those to whom Council has delegated authority, may defer a decision in order to request further information/evidence from the provider, or to consult the statutory advisory committee and/ or Education Visitors, or seek other such advice as is considered necessary.

**Date of approval**

A decision to approve a qualification will include the date from which the qualification is approved, which shall normally be the date of the final examination board for the first graduating cohort of trainees.

**Standard conditions**

Standard conditions will be applied to approved qualifications and qualifications applying for approval, and adherence to standard conditions will be monitored through periodic review, annual return, thematic and sample-based review.

**Conditions, recommendations and requests for information**

As part of the assurance and enhancement process, conditions may be imposed, recommendations may be made and/or further information may be requested.

Conditions specified must be fulfilled within the stated timeframe to ensure the outcomes and standards continue to be met by the approved qualification.

Recommendations must be considered by the provider and action reported at the next annual review.

Information requested must be supplied within the stated timeframe. Failure to meet a condition or supply information within the specified timescale without good reason is a serious matter and may lead to the GOC conducting a serious concerns review and/or withdrawing approval of the qualification.

**Notifications of changes and events**

An important standing condition of approval is the expectation that providers notify us of any significant changes to approved qualifications, their title or other events that may impact upon the ability of a provider to meet our outcomes and standards. Failure to notify us of any significant changes or events in a timely manner may lead to the GOC conducting a serious concerns review and/or withdrawing approval of the qualification.

If we receive complaints, concerns and/or other unsolicited information about an approved qualification, or qualification applying for approval, we will consider this information as part of our risk stratification of qualifications and in the timing and focus of our future assurance and enhancement activity.

**Serious concerns review**

We reserve the right to investigate any matter brought to our attention which may have a bearing on the approval of a qualification. When making the decision to progress to a serious concerns review, we will consider factors such as, but not limited to:

* results of any assurance and enhancement activity;
* concerns regarding patient safety;
* evidence of significant shortfall in meeting one or more of the outcomes or standards;
* evidence of significant shortfalls in staffing and/or resources; and
* failure to meet a condition or provide information within the specified timescale.

A serious concerns review is a detailed investigation into the concerns raised about an approved qualification. Failure to co-operate with a serious concerns review or take action required as a result may mean that Council decides to withdraw its approval of the qualification.

**Withdrawal**

A provider may, by giving notice, withdraw its qualification from our assurance and enhancement process and GOC-approval. In these circumstances, the provider must inform us how the interests of trainees currently studying on the approved qualification will be best served. Withdrawal from our assurance and enhancement process does not preclude the provider from making a fresh application for qualification approval at some point in the future.

If, through assurance and enhancement (annual return, thematic and sample-based review and/or periodic review) a provider fails to demonstrate that their qualification meets our outcomes and/or standards for approved qualifications, and/or does not co-operate with us in the discharge of our regulatory duties, we may decide to withdraw our approval from the qualification. Should we decide to withdraw approval, we will follow the statutory process as outlined in the Act. In these circumstances, we will work closely with the provider, who retains responsibility for, and must act at all times in the best interests of, trainees studying for the approved qualification.

**Appeal**

Providers have the right to appeal a decision to withdraw our approval of its qualification, in accordance with the provisions of section 13 of the Act. In the event that Council decides to withdraw or refuse approval of a qualification (whether entirely or to a limited extent), an appeal may be made to the Privy Council within one month of the decision of Council being confirmed in writing.

ENDS

1. The Act gives GOC powers to approve’ ‘qualifications’ [↑](#footnote-ref-1)
2. Miller, G.E. (1990) The assessment of clinical skills/competence/performance. Acad Med 65: 563–7. [↑](#footnote-ref-2)
3. https://www.rpharms.com/resources/frameworks/prescribing-competency-framework/consultation [↑](#footnote-ref-3)
4. Miller, G.E. (1990) The assessment of clinical skills/competence/performance. Acad Med 65: 56 [↑](#footnote-ref-4)
5. The Act gives the GOC powers to ‘approve’ ‘qualifications’ [↑](#footnote-ref-5)
6. R.M. Harden (1999) What is a spiral curriculum? Medical Teacher, 21:2, 141-143 [↑](#footnote-ref-6)
7. [↑](#footnote-ref-7)
8. See <https://www.rpharms.com/resources/frameworks/designated-prescribing-practitioner-competency-framework> [↑](#footnote-ref-8)
9. As part of the rationale for their choice of student:staff ratios (SSR) providers must regularly benchmark their SSR to comparable providers (alongside seeking student and stakeholder feedback) to determine if their SSR provides an appropriate level of resource for the teaching and assessment of the outcomes leading to the award of an approved qualification. [↑](#footnote-ref-9)