

A Framework of Quality Assurance for Responsible Officers and Revalidation

Supporting responsible officers and designated bodies in providing assurance that they are discharging their statutory responsibilities.

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Description	This Framework for Quality Assurance (FQA) provides an overview of the elements defined in the Responsible Officer Regulations, along with a series of processes to support Responsible Officers and their Designated Bodies in providing the required assurance that they are discharging their respective statutory duties.
Cross Reference	The Medical Profession (Responsible Officers) Regulations , 2010 (as amended 2013) and the GMC (Licence to practise and Revalidation) Regulations 2012
Superseded Docs (if applicable)	Replaces the Revalidation Support team (RST) Organisational Readiness Self-Assessment (ORSA) process
Action Required	Designated bodies to receive annual board reports on the implementation of revalidation and submit an annual statement of compliance to their higher level responsible officers. Responsible Officers to submit quarterly and annual returns to their higher level responsible officers in accordance with this guidance.
Timing / Deadlines (if applicable)	
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Document Status

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Foreword

Medical revalidation is a legal requirement which applies to all licensed doctors listed on the General Medical Council (GMC) register in both the public and independent sectors. Its purpose is to improve patient care by bringing all licensed doctors into a governed system that prioritises professional development and strengthens personal accountability.

Medical revalidation is central to how NHS England and the Health System at large are meeting their responsibilities to both patients and staff in improving safety and the quality of care. We are encouraged to see that one year into its implementation, it is delivering value but more needs to be done to maximise benefits in the future.

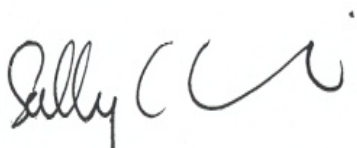
As responsible officers, you have a valuable but demanding role to ensure that the doctors linked to your organisations are up to date and fit to practice. For revalidation to reach its full potential, however you will need to look beyond the process to encourage commitment to professional development and improving patient care.

This Framework of Quality Assurance has been produced to provide assurance and oversight that designated bodies are discharging their statutory duties. It also provides the basis on which you are required to demonstrate that the appropriate resource and systems are in place, that they work effectively and that they meet the agreed national standards.

We hope that this publication is useful to you all as we work towards revalidation being successfully implemented in England.

Dame Sally Davies

Chief Medical Officer
Department of Health



Sir Bruce Keogh

Medical Director
NHS England

15 December 2016

Executive Summary

Organisations designated under the Medical Profession (Responsible Officer) Regulations 2010 and 2013¹ (referred to as the Responsible Officer Regulations) are nominated as 'designated bodies'. These organisations, essentially any body that employs or contracts with doctors, have a duty to appoint or nominate a responsible officer. These senior doctors must ensure that every doctor connected to them, as set out in the legislation:

- i. receives an annual medical appraisal² meeting nationally agreed standards;
- ii. undergoes the appropriate pre-engagement/employment background checks to ensure that they have qualifications and experience appropriate to the work performed;
- iii. works within a managed system in which their conduct and performance are monitored, with any emerging concerns being acted upon appropriately and to nationally agreed standards; and
- iv. has a recommendation made to the GMC regarding their fitness to practise every 5 years, on which their continuing licence to practise is based.

Prior to the launch of revalidation and during the first year of implementation, designated bodies completed regular Organisational Readiness Self-Assessment (ORSA) exercises to determine the level of preparedness for delivering revalidation.

Now that revalidation is well underway, there is a need for designated bodies and responsible officers to be able to provide assurance to patients, the public, the service and the profession, that the appropriate systems and processes are in place, in every designated body in England, to ensure that every licensed medical practitioner (162,000 in England) are safe to practise. This framework pulls together the various approaches to achieving assurance, to assist responsible officers in providing the required confidence that the doctors working in their organisations are up to date and fit to practise. It comprises the following components:

- **Annex A - Core standards:** A comprehensive overview of the requirements of the Responsible Officer Regulations and associated mandatory guidance within a single document. It is set out in a spreadsheet format to enable responsible officers and their organisations to create checklists and other tools to monitor their own compliance with the Responsible Officer Regulations.
- **Annex B - Quarterly Information Template:** This reporting process maintains quarterly communications between responsible officers at the local level and their higher-level responsible officers, to whom they are linked and enables a picture of high-level indicators (including appraisal rates) to be built up over the year, so that any problems can be identified and resolved at an early stage.
- **Annex C - Annual Organisational Audit (AOA):** The prime focus and purpose is to achieve a robust consistent system of revalidation compliant with the Responsible Officer Regulations and with nationally agreed standards. The mandatory audit provides a process by which every responsible officer, on behalf of their designated bodies, provides a standardised return to the higher-level responsible officer. The collated audits will then form the basis of a report to Ministers and ultimately the public, on the overall status of implementation of

¹ <http://www.legislation.gov.uk/ukxi/2010/2841/made> and <http://www.legislation.gov.uk/ukxi/2013/391/made>

² In accordance with GMC guidelines. NHS England Medical Appraisal Policy is published at: <http://www.england.nhs.uk/ourwork/qual-clin-lead/revalidation5/ma-pol/>

revalidation across England. The AOA has been simplified and shortened considerably from its predecessor (ORSA).

- **Annex D - Annual Board Report Template:** The expectation of regulators³ is that the boards of designated bodies (or executive teams for some designated bodies) monitor the organisation's progress in implementing the Responsible Officer Regulations. To assist in this, a board report template has been provided. Mindful of the need for consistency and the need for local flexibility, the template may be modified as required.
- **Annex E - Statement of Compliance:** The Responsible Officer Regulations set out the obligation on the part of designated bodies to provide support to the responsible officer. In demonstrating this support, the chief executive or chairman (or executive if no board exists) is asked to sign a statement of the organisation's compliance to the Responsible Officer Regulations. This is submitted to the higher-level responsible officer, along with the AOA.
- **Annex F – Higher Level Responsible Office Quality Review:** To enhance the level of assurance and provide evidence with which challenges to the system or the decision-making may be handled, all designated bodies will undergo a process to validate the status of their revalidation systems at least once in every 5-year revalidation cycle. The quality review process, formally known as independent verification, is described in this annex.
- **Annex G – Bench-marking, calibration and checking consistency:** The Responsible Officer Regulations make explicit reference to the fundamental requirement for consistency across the country, in terms of approach, decision-making and thresholds for intervention. In addition to the standardised processes, training of key individuals and national policies on key areas, a range of networks and systems of peer review have been set up, working closely with colleagues at the GMC, to calibrate how responsible officers, appraisers and case investigators take decisions, make recommendations, monitor action, learn from each other and share best practice. These are described in this annex.

³ General Medical Council, Care Quality Commission, Monitor and the NHS Trust Development Authority

Contents

1. Introduction	7
1.1. Equality and diversity	9
2. Core Standards	9
3. Monitoring and Reporting	10
3.1. Responsible Officer Monthly Monitoring	10
3.2. Quarterly Information Template (Annex B)	10
3.3. Annual Organisational Audit (AOA) (Annex C)	10
3.4. Annual Board Report Template (Annex D)	11
3.5. Statement of Compliance (Annex E).....	11
3.6. Higher Level Responsible Officer Quality Review (Annex F).....	11
4. Calibration, Consistency, Learning and Best Practice	11
5. ANNEXES	13
5.1. Annex A – Core Standards	13
5.2. Annex B – Quarterly Information Template.....	13
5.3. Annex C – Annual Organisational Audit.....	13
5.4. Annex D – Annual Board Report Template.....	13
5.5. Annex E – Statement of Compliance	13
5.6. Annex F – Higher Level Responsible Officer Quality Review	13
5.7. Annex G – Links to Calibration and Consistency Processes	13

1. Introduction

The Medical Profession (Responsible Officers) Regulations, 2010, as amended in 2013, (commonly referred to as the 'Responsible Officers Regulations') empower responsible officers (senior doctors within each designated body in the UK) to monitor the performance of every doctor holding a licence to practise with the General Medical Council (GMC). This process of regular monitoring culminates in a recommendation from the responsible officer (RO) to the GMC on the doctor's fitness to practise. On the basis of this recommendation, the GMC decides whether or not the doctor's licence to practise should be renewed.

A fundamental principle of medical revalidation is that the systems and processes in place in any given designated body must meet nationally agreed standards of rigour and consistency, for all doctors, regardless of sector, grade or geography. This means that the critical elements of medical revalidation, as defined by the Responsible Officer Regulations and associated guidance, must be subject to an explicit, agreed and consistent process of quality assurance.

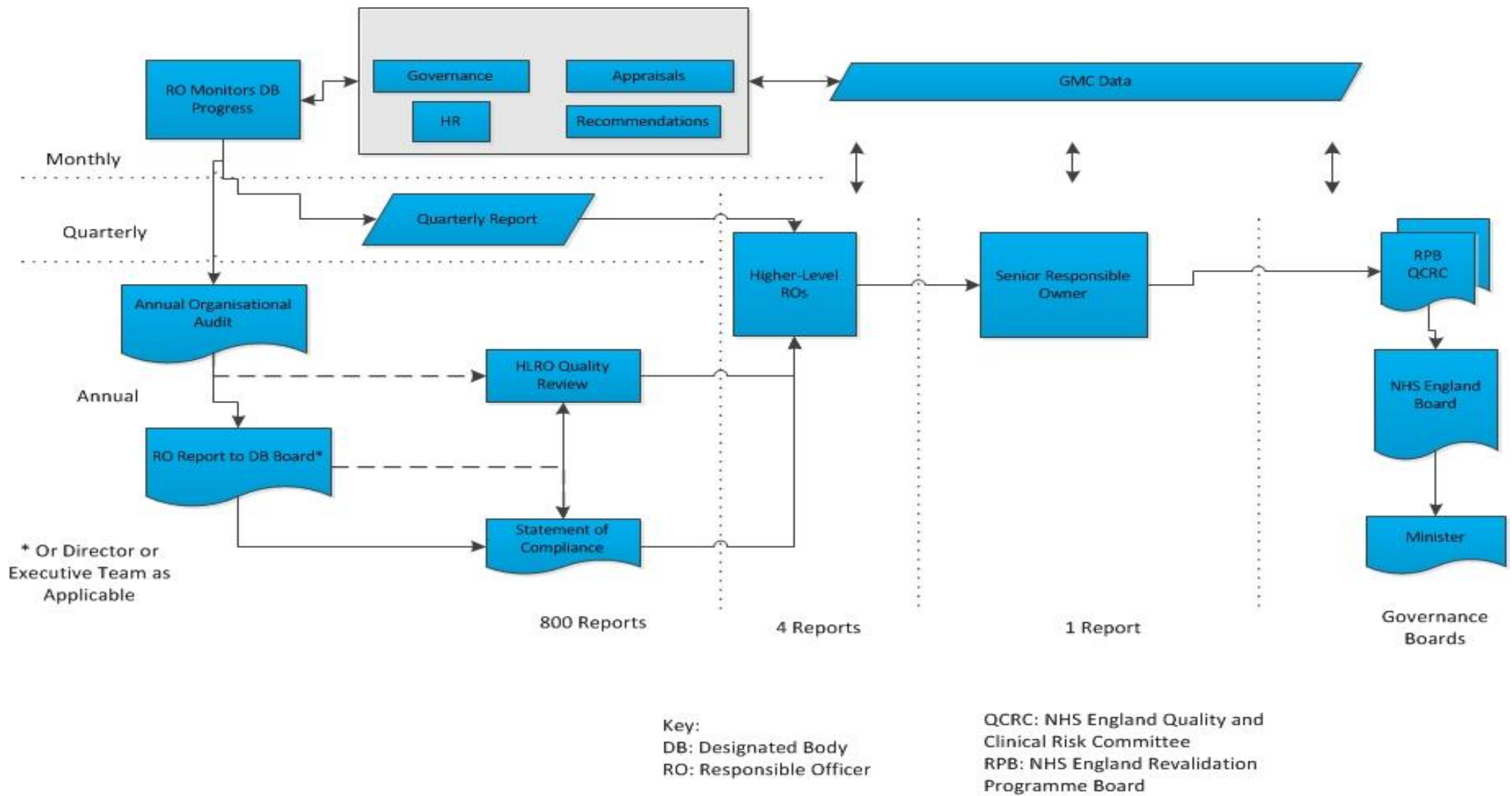
The Framework of Quality Assurance (FQA) provides an overview of the elements defined in the Responsible Officer Regulations, along with a series of processes to support responsible officers and their designated bodies in providing the required assurance that they are discharging their respective statutory responsibilities. In addition to mandatory standards, the FQA will provide standards of good practice in monitoring and taking appropriate action on the performance of doctors. These will be developed further to document best practice, as experience is gained. The FQA provides:

- a tool to help responsible officers assure themselves and their board (or an equivalent governance or executive group) that the systems underpinning the recommendations they make to the GMC on doctors' fitness to practise, including the arrangements for medical appraisal and responding to concerns, are in place, functioning, effective, consistent with those in other designated bodies and compliant with nationally agreed standards;
- a mechanism for assuring higher-level responsible officers and NHS England (as the Senior Responsible Owner for medical revalidation in England) that systems for evaluating doctors' fitness to practise are in place, functioning, effective and consistent;
- an overview of mechanisms available to responsible officers to support them in demonstrating that their practice (as responsible officers) is aligned with other doctors holding the same role; and
- a summary showing the responsible officer's progress towards robust, consistent systems and processes, meeting national standards, as supporting information for their own appraisal.

This FQA is particularly intended to support responsible officers, the boards (or an equivalent governance or executive group) of designated bodies, higher-level responsible officers and the teams supporting the process of revalidation. Its contents will be reviewed regularly as medical revalidation systems, regulations and policies develop.

The FQA is described below in three sections: firstly the standards, secondly how compliance with these standards will be monitored and thirdly the mechanisms in place to deliver calibration and consistency.

The diagram below summarises the overall process.



1.1. Equality and diversity

Equality and diversity are at the heart of the NHS strategy. Due regard to eliminate discrimination, harassment and victimisation, to advance equality of opportunity and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it, has been given throughout the development of the policies and processes cited in this document.

2. Core Standards

The Responsible Officer Regulations make clear that as part of their respective roles as set out in statute, the responsible officer and the designated body must provide assurance that all systems and processes, including those of clinical governance, underpinning the responsible officer's recommendation to the GMC on a doctor's continuing fitness to practise, are functioning effectively. In order to provide this assurance the responsible officer will want to be able to demonstrate that:

- the underpinning systems and processes are in place and functioning effectively, in compliance with nationally agreed standards;
- their own decision-making, and also that of appraisers and case investigators, is robust and consistent, not only at the individual level and internally within the designated body, but also that they are in alignment with the decision-making of peers in other organisations, from all sectors, across the country; and
- the board (or an equivalent governance or executive group) of the designated body is engaged in the process of revalidation, taking active steps to integrate the systems and processes underpinning medical revalidation into the organisation's broader quality and safety agenda.

The elements defined by the Responsible Officer Regulations can be considered in the following categories, as being related to:

- the designated body and the responsible officer;
- appraisal;
- monitoring performance and responding to concerns; and
- recruitment and engagement.

Within each standard, Annex A currently describes 2 levels:

- Essential/core standards, minimum requirements, as set out in legislation and mandated guidance.
- Standards considered as good practice, identified in guidance and other key sources.

The FQA provides a single resource for responsible officers, enabling them to check the extent of their progress towards achieving robust quality assurance of all their systems, from achieving the basic mandatory standard to working at the level of good and, in time, towards excellent practice, whilst also highlighting any areas presenting cause for concern at a stage where effective action may be taken.

Monitoring and Reporting

The FQA and the monitoring processes within it are designed to support all responsible officers in fulfilling their statutory duty, providing a means by which they can demonstrate the effectiveness of the systems they oversee. It has been carefully crafted to ensure that administrative burden is minimised, whilst still driving learning and sharing of best practice. Each element of the FQA process will feed in to a comprehensive report from the national-level responsible officer to Ministers and the public, capturing the state of play in implementing medical revalidation across the country.

The reporting processes are intended to be streamlined, coherent and integrated, ensuring that information is captured to contribute to local processes, whilst simultaneously providing the required assurance. The process will be reviewed and revised on a regular basis.

The monitoring and reporting process comprise the following elements:

2.1. Responsible Officer Monthly Monitoring

It is for responsible officers to determine what information they wish to collate from their own organisations to monitor compliance and progress. The FQA is not prescriptive in this regard, however it is suggested that responsible officers should have the appropriate regular reporting lines in place to assure themselves that appraisals, recommendations, HR processes (pre-engagement checks) and governance processes are in place and functioning effectively.

2.2. Quarterly Information Template (Annex B)

Higher-level ROs will ask all ROs connected to them, to complete a simple quarterly return (Annex B). Not only will this maintain regular communications, but it will also provide oversight of the key indicators (including appraisal rates), allowing any emerging problems to be identified and resolved at an early stage.

The Annual Organisational Audit (AOA) will supersede the need for a quarterly report in the final quarter.

In 2014/15, work will commence to enable ROs to submit quarterly returns via a web-based system.

2.3. Annual Organisational Audit (AOA) (Annex C)

The AOA (Annex C) is a standardised template for all responsible officers to complete and return to their higher-level responsible officer. AOAs from all designated bodies will be collated to provide an overarching status report of implementation across England. This report will be published no later than September each year. Where small designated bodies are concerned, or where types of organisation are small in number, these will be appropriately grouped to ensure that data is not identifiable to the level of the individual.

The AOA has been simplified and shortened considerably from its predecessor, (ORSA), with a focus on what is happening, with what outcome, along with an assessment of the designated body's organisational capacity to ensure a robust consistent system of revalidation. Learning from the experience of ORSA, the AOA has been designed to reduce the administrative burden upon organisations and to be of maximum help to responsible officers in fulfilling their obligations.

In 2014/15, work will commence to enable designated bodies to submit their AOA returns via a web-based system.

2.4. Annual Board Report Template (Annex D)

The General Medical Council (GMC), Care Quality Commission (CQC), Monitor and the NHS Trust Development Authority (NHS TDA) expect that the boards of designated bodies (or executive teams if applicable) should monitor their organisation's progress in implementing the Responsible Officer Regulations.

To assist in this, whilst also promoting the quality of monitoring processes, a board report template has been provided (Annex D). Mindful of the need for consistency and the need for local flexibility, the template may be modified as required.

It is not anticipated that designated bodies will be routinely requested to submit copies of their annual board reports to their higher-level RO. However in some instances this may be necessary, should the designated bodies require support from the regional team with implementation.

2.5. Statement of Compliance (Annex E)

Under the Responsible Officer Regulations, there is an obligation for designated bodies to provide support to their responsible officer.

In demonstrating this support, the chief executive or chairman (or executive if no board exists) is asked to sign a statement of the organisation's compliance (Annex E) to the Responsible Officer Regulations.

This is submitted to the appropriate higher-level responsible officer at the earliest opportunity post submission of the AOA and no later than August 31.

2.6. Higher Level Responsible Officer Quality Review (Annex F)

Ministers, patients and the public, the profession and healthcare providers expect that revalidation will be implemented fairly, consistently and on the basis of honesty. There is an expectation that it will improve the quality of care delivered to patients. Experience has shown that inaccuracies can be introduced when self-reporting mechanisms are the sole source of information^[1]. Higher level responsible officers need to have confidence that every responsible officer is carrying out their statutory duties appropriately, whilst responsible officers need to be able to demonstrate that their own reporting is validated. This level of confidence will be provided through the AOA, strengthened by a quality review process.

The aim of the quality review is to also provide assurance to boards (or equivalent governance or executive group) of designated bodies that the organisation is fulfilling its statutory obligations in ensuring that effective systems are in place to underpin the statutory responsibilities of the responsible officers.

The quality review (Annex F) is carried out by the regional revalidation team once per revalidation cycle for each designated body. Primarily this is based on a desk-top review following submission of the Annual Organisational Audit (AOA). As and when required, the desk-top review may be followed by an email or telephone discussion, or by a face to face quality review meeting with the designated bodies' responsible officer.

The quality review process also helps to identify and disseminate good practice, and is a process for providing support to the designated body to maintain and improve standards of quality and performance.

3. Calibration, Consistency, Learning and Best Practice

In addition to the national policies for medical appraisal and responding to concerns, there are a number of mechanisms in place to drive consistency of decision-making, approach and thresholds for intervention on the part of responsible officers and appraisers. The aim is to ensure that every

doctor, regardless of sector, grade or location in the country, goes through a process, which is demonstrably aligned with agreed national standards.

The mechanisms driving a consistent approach include (see Annex G):

- standardised training and development for responsible officers and appraisers to nationally agreed specifications;
- mandatory engagement with responsible officer networks at which cases are discussed and responses calibrated. These conform to a nationally agreed structure, as set out in the Responsible Officer Network Blueprint;
- a national network for appraisal leads, with local networks for appraisers conforming to a nationally agreed structure; and
- regional and national events for responsible officers and appraisers designed specifically to calibrate decision-making and thresholds for intervention.

The potential for significant learning from the AOA, quality reviews and calibration processes is well recognised. The approach taken is to maximise and streamline the opportunities for triangulation of information throughout the community of responsible officers, appraisers, and all those involved. Learning and models of best practice will be integrated into the FQA through a process of regular review.

4. ANNEXES

4.1. Annex A – Core Standards

4.2. Annex B – Quarterly Information Template

4.3. Annex C – Annual Organisational Audit

4.4. Annex D – Annual Board Report Template

4.5. Annex E – Statement of Compliance

4.6. Annex F – Higher Level Responsible Officer Quality Review

4.7. Annex G – Links to Calibration and Consistency Processes