



A Framework of Quality Assurance for Responsible Officers and Revalidation

Annex D – Annual Board Report and Statement of Compliance.

NHS England and NHS Improvement



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Annex D – Annual Board Report and Statement of Compliance.

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Prepared by: Lynda Norton, Claire Brown, Maurice Conlon

This information can be made available in alternative formats, such as easy read or large print, and may be available in alternative languages, upon request. Please contact Lynda Norton on England.revalidation-pmo@nhs.net.

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Introduction:

The Framework of Quality Assurance (FQA) for Responsible Officers and Revalidation was first published in April 2014 and comprised of the main FQA document and annexes A – G. Included in the seven annexes is the Annual Organisational Audit (annex C), Board Report (annex D) and Statement of Compliance (annex E), which although are listed separately, are linked together through the annual audit process. To ensure the FQA continues to support future progress in organisations and provides the required level of assurance both within designated bodies and to the higher-level responsible officer, a review of the main document and its underpinning annexes has been undertaken with the priority redesign of the three annexes below:

- **Annual Organisational Audit (AOA):**

The AOA has been simplified, with the removal of most non-numerical items. The intention is for the AOA to be the exercise that captures relevant numerical data necessary for regional and national assurance. The numerical data on appraisal rates is included as before, with minor simplification in response to feedback from designated bodies.

- **Board Report template:**

The Board Report template now includes the qualitative questions previously contained in the AOA. There were set out as simple Yes/No responses in the AOA but in the revised Board Report template they are presented to support the designated body in reviewing their progress in these areas over time.

Whereas the previous version of the Board Report template addressed the designated body's compliance with the responsible officer regulations, the revised version now contains items to help designated bodies assess their effectiveness in supporting medical governance in keeping with the General Medical Council (GMC) handbook on medical governance¹. This publication describes a four-point checklist for organisations in respect of good medical governance, signed up to by the national UK systems regulators including the Care Quality Commission (CQC). Some of these points are already addressed by the existing questions in the Board Report template but with the aim of ensuring the checklist is fully covered, additional questions have been included. The intention is to help designated bodies meet the requirements of the system regulator as well as those of the professional regulator. In this way the two regulatory processes become complementary, with the practical benefit of avoiding duplication of recording.

¹ Effective clinical governance for the medical profession: a handbook for organisations employing, contracting or overseeing the practice of doctors GMC (2018) [https://www.gmc-uk.org/-/media/documents/governance-handbook-2018_pdf-76395284.pdf]

The over-riding intention is to create a Board Report template that guides organisations by setting out the key requirements for compliance with regulations and key national guidance, and provides a format to review these requirements, so that the designated body can demonstrate not only basic compliance but continued improvement over time. Completion of the template will therefore:

- a) help the designated body in its pursuit of quality improvement,
- b) provide the necessary assurance to the higher-level responsible officer, and
- c) act as evidence for CQC inspections.

- **Statement of Compliance:**

The Statement Compliance (in Section 8) has been combined with the Board Report for efficiency and simplicity.

Designated Body Annual Board Report

Section 1 – General:

The Agency Board and Corporate Executive Team of the Medicines and Healthcare Products Regulatory Agency can confirm that:

1. The Annual Organisational Audit (AOA) for this year has been submitted.

Date of AOA submission: 5th June 2019

Action from last year: No specific actions were identified last year – the AOA was submitted within the required timeframes.

Comments: Submitted before deadline.

Action for next year: Continued monitoring of performance.

2. An appropriately trained licensed medical practitioner is nominated or appointed as a responsible officer.

Action from last year: No actions from last year - an appropriately trained licensed medical practitioner is appointed as a responsible officer.

Comments: Dr Ian Hudson has been the appointed Responsible Officer since 2013

Action for next year: Ensure a responsible officer is in place after Dr Ian Hudson retires in September 2019. Deputy/alternative Responsible Officer arrangements are in place.

3. The designated body provides sufficient funds, capacity and other resources for the responsible officer to carry out the responsibilities of the role.

Action from last year: No identified action from last year, the Board was satisfied that sufficient resources and funds were available.

Comments: The Agency continues to provide sufficient funds, capacity and resources for the responsible officer to carry out the responsibilities of the role.

Action for next year: No specific actions identified at this stage and funds and resources will continue to be provided.

4. An accurate record of all licensed medical practitioners with a prescribed connection to the designated body is always maintained.

Action from last year: No actions specified last year – the records of all licensed medical practitioners with a prescribed connection is maintained.

Comments: The GMC list of MHRA doctors is kept up to date, using the HR starters and leavers monthly report as well as management email notifications regarding individuals joining and leaving the Agency.

Action for next year: Continue to ensure accurate record of doctors with a prescribed connection to MHRA is maintained.

5. All policies in place to support medical revalidation are actively monitored and regularly reviewed.

Action from last year: No specific actions identified last year.

Comments: Revalidation and responding to concerns policies in place. Kept under regular review through the SOP Working Group mechanism. Might be updated following the peer review in September 2019.

Action for next year: Consider findings of the peer review and make amendments if required.

6. A peer review has been undertaken of this organisation's appraisal and revalidation processes.

Action from last year: Arrangements have been made for Public Health England to conduct a peer review in September 2019.

Comments: An independent review of the MHRA's revalidation appraisal and revalidation processes was previously carried out in November 2015

Action for next year: Take forward any findings of September 19 peer review

7. A process is in place to ensure locum or short-term placement doctors working in the organisation, including those with a prescribed connection to another organisation, are supported in their continuing professional development, appraisal, revalidation, and governance.

Action from last year: None – the Agency has not employed locum or short-term placement doctors.

Comments: No locum or short-term placement doctors are employed by the Agency, but if they were then they would be supported in their continuing professional development, appraisal, revalidation and governance.

Action for next year: If there are any short-term placement doctors working at MHRA then ensure they have the necessary support

Section 2 – Effective Appraisal

1. All doctors in this organisation have an annual appraisal that covers a doctor's whole practice, which takes account of all relevant information relating to the doctor's fitness to practice (for their work carried out in the organisation and for work carried out for any other body in the appraisal period), including information about complaints, significant events and outlying clinical outcomes.

Action from last year: Continued active monitoring of the annual appraisals

Comments: All doctors with MHRA as their designated body have an annual appraisal that covers their whole practice. Any doctors who do work outside the Agency ensure that this is covered in their appraisals with evidence provided. The line management annual appraisal is used as part of the supporting information and any complaints etc should be highlighted in the appraisal form. Action has been taken by the Responsible Officer in relation to unapproved missed appraisals. Reasons for approved missed appraisals are documented (eg maternity leave, new joiners, sick leave, change in career).

Action for next year: Continue to ensure each doctor has an appraisal that covers their whole practice.

- 2. Where in Question 1 this does not occur, there is full understanding of the reasons why and suitable action is taken.**

Action from last year: Continue to ensure all reasons for missed appraisals are documented

Comments: The doctors employed by the Agency who are undergoing the Pharmaceutical Medicine Specialty Training have the Faculty of Pharmaceutical Medicine Deanery as their designated body and therefore do not have a medical appraisal with MHRA.

The reasons for the missed appraisals (category 2 and 3, ie approved and unapproved) are documented in the AOA. It should be noted that the missed appraisal that had been referred to the GMC is still under active review and has not yet been completed; the Agency will work with the GMC in terms of recommended next steps.

Action for next year: Continue to work with the GMC Employment Liaison Advisor as required in relation to any issues.

- 3. There is a medical appraisal policy in place that is compliant with national policy and has received the Board's approval (or by an equivalent governance or executive group).**

Action from last year: None required, a medical appraisal policy is in place.

Comments: A medical appraisal policy is in place, which had been considered and approved by the Agency's SOP Working Group and the Corporate Executive Team (it had also been reviewed by the company who had conducted the previous independent review). It was reviewed and updated following the last independent review of the Agency's revalidation processes and will be re-visited following the planned peer review in September. As with other Agency SOPs, the SOP Working Group is an additional mechanism to ensure the SOPs are regularly reviewed and updated.

Action for next year: Re-visit the revalidation policy and update as necessary. A peer review is taking place in September, findings from which might impact on the policy document.

4. The designated body has the necessary number of trained appraisers to carry out timely annual medical appraisals for all its licensed medical practitioners.

Action from last year: None, sufficient number of trained appraiser in place

Comments: During the reporting period, MHRA had a total of twelve formally trained medical appraisers who conducted the appraisals. Two of these medical appraisers have now left the Agency, however two new medical appraisers were trained and carried out some appraisals in the 18/19 cycle. These new appraisers will be allocated more appraisees in the 19/20 appraisal cycle.

Action for next year: Continue to ensure there are sufficient medical appraisers trained and available, with succession planning as required.

5. Medical appraisers participate in ongoing performance review and training/development activities, to include attendance at appraisal network/development events, peer review and calibration of professional judgements (Quality Assurance of Medical Appraisers² or equivalent).

Action from last year: Continue medical appraiser network meetings

Comments: The Agency has continued to hold regular appraiser network meetings, which provide an opportunity to discuss any issues, compare approaches, develop guidance and supporting information for doctors, review feedback on the appraisal process. Feedback from the NHS England Responsible Officer and Lead Appraiser meetings and the DHSC Responsible Officer network meetings are provided to the appraisers at the MHRA network meetings, to ensure they are kept informed of any updates etc. Refresher training was provided in 2016 following the last independent review and it is proposed that additional appraiser refresher training is held following the peer review to be held in September 2019.

Action for next year: Arrange appraiser refresher training, as appropriate.

6. The appraisal system in place for the doctors in your organisation is subject to a quality assurance process and the findings are reported to the Board or equivalent governance group.

Action from last year: Revalidation Annual report presented to the Board.

Comments: In terms of quality assurance, the appraisal forms and folders are reviewed by the appraiser to provide assurance that the appraisal inputs (the pre-appraisal declarations and supporting information provided is available and appropriate). Once the appraiser is satisfied that with the information provided, the appraisal can take place. Appraisal forms/folders are reviewed by the appraiser and the Revalidation manager/RO to provide assurance that

² <http://www.england.nhs.uk/revalidation/ro/app-syst/>

² Doctors with a prescribed connection to the designated body on the date of reporting.

the appraisal outputs (PDP, summary and sign offs are complete and to an appropriate standard) before revalidation recommendations are made.

Regular appraiser network meetings are held, and these are used to discuss any issues, help ensure consistency in approach, give feedback from the NHS England Responsible Officer and Appraiser Lead meetings and the DHSC appraiser network meetings and share any learning. Through a feedback survey, each appraisee gives specific feedback after their appraisal, which allows ongoing review of feedback at the appraiser network meeting and enables each appraiser to review the feedback as part of each appraisal cycle. Sections of individuals appraisal forms are sometimes considered by the appraisers at the appraiser network meetings, this gives opportunity to discuss the level of detail expected and approach taken etc, which helps ensure consistency and continued learning.

In line with GMC recommendations, lay input into the revalidation processes is being introduced and this will help with quality assurance.

Action for next year: Introduce lay member involvement, present the Revalidation annual report at public board meetings. Continue to seek feedback on the appraisal process and review appraisal documentation.

Section 3 – Recommendations to the GMC

1. Timely recommendations are made to the GMC about the fitness to practise of all doctors with a prescribed connection to the designated body, in accordance with the GMC requirements and responsible officer protocol.

Action from last year: No specific action

Comments: All recommendations were made on time to the GMC; all 18 were positive revalidation recommendations with none being recommended to be deferred.

Action for next year: Continue to make recommendations to the GMC before the revalidation due date.

2. Revalidation recommendations made to the GMC are confirmed promptly to the doctor and the reasons for the recommendations, particularly if the recommendation is one of deferral or non-engagement, are discussed with the doctor before the recommendation is submitted.

Action from last year: None

Comments: All doctors were notified of their revalidation recommendations. The GMC has been notified of a doctor who is not engaging with revalidation processes and the doctor concerned was kept informed. The deadline for action was extended (following further consultation with the GMC) due to the doctor being on sick leave and the case is still under active review.

Action for next year: Continue to make timely revalidation recommendations and discuss any non-engagement with the GMC Employment Liaison Advisor as necessary.

Section 4 – Medical governance

1. This organisation creates an environment which delivers effective clinical governance for doctors.

Action from last year: None

Comments: The MHRA has used the GMC clinical governance checklist to help ensure the delivery of effective clinical governance. Identified areas for improvement to be taken forward, such as lay involvement, Board training and champion, additional processes to ensure consistency in relation to quality assurance.

Action for next year: Implement actions identified using the clinical governance check list.

2. Effective systems are in place for monitoring the conduct and performance of all doctors working in our organisation and all relevant information is provided for doctors to include at their appraisal.

Action from last year: No specific actions identified.

Comments: Line management appraisals (which cover conduct and performance) are incorporated into the physician's medical appraisals.

Action for next year: Continue to ensure line management appraisal information is included as supporting information in all medical appraisals.

3. There is a process established for responding to concerns about any licensed medical practitioner's¹ fitness to practise, which is supported by an approved responding to concerns policy that includes arrangements for investigation and intervention for capability, conduct, health and fitness to practise concerns.

Action from last year: No specific actions, a responding to concerns policy in place.

Comments: There are a number of MHRA policies for all staff which are related to responding to concerns about any licensed medical practitioner's fitness to practice. There is an overarching responding to concerns policy that sets-out arrangements for investigation and other related procedures, and also sign-posts to related Agency policies (e.g. bullying and harassment).

Action for next year: Update the Responding to concerns policy if required following peer review.

4. The system for responding to concerns about a doctor in our organisation is subject to a quality assurance process and the findings are reported to the Board or equivalent governance group. Analysis includes numbers, type and outcome of concerns, as well as aspects such as consideration of protected characteristics of the doctors³.

Action from last year: No specific actions

The Agency's systems for responding to concerns are in accordance with Government wide CS procedures as well as through reporting to the RO for appropriate action. SOPs are approved through our SOP committee. Concerns are collated through normal HR channels.

Action for next year: Continue to ensure that responding to concerns procedures are reviewed to ensure they are sufficient for the organisation's needs. Consider any recommendations following planned peer-review in September 2019

5. There is a process for transferring information and concerns quickly and effectively between the responsible officer in our organisation and other responsible officers (or persons with appropriate governance responsibility) about a) doctors connected to your organisation and who also work in other places, and b) doctors connected elsewhere but who also work in our organisation⁴.

Action from last year: Information to continue to be shared with other Responsible Officers as required.

Comments: Medical Practice Information Transfer (MPIT) forms are requested and completed and shared with other Responsible Officers when a doctor changes their prescribed connection. The HR leavers and joiners monthly report is used to monitor doctors leaving and joining the organisation and line managers of new doctors also normally contact the revalidation manager and this information is used to see when a MPIT needs to be requested from the persons previous designated body. Requests for MPIT forms to be completed by a person's new designated body after they leave the Agency are handled when they are received. There are a couple of doctors who have undertaken some clinical work and evidence from their other employer is included within their appraisal documentation to ensure the whole of practice is covered.

Action for next year: Continue to prepare and receive MPIT forms for joiners and leavers

6. Safeguards are in place to ensure clinical governance arrangements for doctors including processes for responding to concerns about a doctor's practice, are fair and free from bias and discrimination (Ref GMC governance handbook).

³This question sets out the expectation that an organisation gathers high level data on the management of concerns about doctors. It is envisaged information in this important area may be requested in future AOA exercises so that the results can be reported on at a regional and national level.

⁴ The Medical Profession (Responsible Officers) Regulations 2011, regulation 11:
<http://www.legislation.gov.uk/ukdsi/2010/9780111500286/contents>

Action from last year: No specific actions identified.

Comments: Agency governance arrangements follow civil service rules and are fair and free from bias and discrimination. Involvement of a lay representative may provide an additional safeguard regarding fairness.

Action for next year: See if actions are identified as a result of the peer review in September 19.

Section 5 – Employment Checks

1. A system is in place to ensure the appropriate pre-employment background checks are undertaken to confirm all doctors, including locum and short-term doctors, have qualifications and are suitably skilled and knowledgeable to undertake their professional duties.

Action from last year: No specific actions identified.

Comments: Pre-employment background checks are undertaken for all staff, including doctors to ensure they have qualifications and are suitably skilled and knowledgeable. Locum and short-term doctors have not been employed by the Agency.

Action for next year: Continue to conduct pre-employment checks

Section 6 – Summary of comments, and overall conclusion

Please use the Comments Box to detail the following:

- **General review of last year's actions** As of 31st March 2019, the MHRA had 67 doctors with a 'prescribed connection' (excluding the Responsible Officer). Of these doctors, 57 had a completed appraisal, with 6 approved missed appraisals. Unfortunately, there were also two missed unapproved appraisals, one of which is under review with the GMC and in the other case the doctor is leaving the Agency and relinquishing their licence to practice. Two additional appraisals that had been held within the time period but had not been finalised by the appraiser and therefore also fell into the unapproved missed appraisal category – action was taken and the appraisals have now been completed and agreed. 18 positive revalidation recommendations were made to the GMC within the 2018/19 cycle period. This report excludes doctors employed by MHRA but who are trainees enrolled on the Pharmaceutical Medicine Speciality Training as their Designated Body is the Pharmaceutical Medicine Virtual Deanery rather than the MHRA.
- **Actions still outstanding** Undertake peer review in September 19. Continue to liaise with the GMC regarding the non-engagement case.
- **Current Issues** Ensure a responsible officer is appointed following the retirement of the current responsible officer. In the meantime, ensure the alternative responsible officer (Dr Gillian Leng, NICE) aware of any issues

- **New Actions:** Take forward any resulting actions from the peer review, including review of the revalidation policy if required. Establish lay involvement in our revalidation processes and other areas of improvement identified in the clinical governance self-assessment.

Overall conclusion: The Agency is complying with the responsible officer regulations

Section 7 – Statement of Compliance:

The Board of the Medicines and Healthcare Products Regulatory Agency has reviewed the content of this report and can confirm the organisation is compliant with The Medical Profession (Responsible Officers) Regulations 2010 (as amended in 2013).

Signed on behalf of the designated body

Official name of designated body: Medicines and Healthcare Products Regulatory Agency

Name: Professor Sir Michael Rawlins

Signed: _____

Role: Chair

Date: _____