

Report to:	Trust Board (Public)	Agenda item:	SFT4087
Date of Meeting:	2 August 2018		

Report Title:	Revalidation - Annual Board Report			
Status:	Information	Discussion	Assurance	Approval
	X			
Prepared by:	Dr Christine Blanshard, Medical Director & Deputy Chief Executive			
Executive Sponsor (presenting):	Paul Hargreaves, Director of Organisational Development & HR			
Appendices (list if applicable):				

Recommendation:
<p>The Board is asked to</p> <ul style="list-style-type: none"> • Agree that the process of medical appraisal and revalidation is being carried out in accordance with the Regulations • Agree to support the Responsible Officer with the resources she needs to comply with the Regulations • Agree to share this report with the Higher Level Responsible Officer • Approve the 'statement of compliance' confirming that the organisation, as a designated body, is in compliance with the regulations

Executive Summary:
<p>In April 2014 NHS England published a framework for quality assurance for revalidation which requires Responsible Officers (ROs) to produce their annual report on revalidation for the Board of their Designated Body in a prescribed format, and the chairman or chief executive to sign a statement of compliance to be submitted to the level 2 Responsible Officer. This report describes the number of doctors with a prescribed connection to the Trust, the number of completed appraisals within the appraisal year 2017-18, the appraisal quality assurance process, any fitness to practice issues identified and any issues with the appraisal and revalidation process.</p>

Board Assurance Framework – Strategic Priorities	Select as applicable
Local Services - We will meet the needs of the local population by developing new ways of working which always put patients at the centre of all that we do	<input checked="" type="checkbox"/>
Specialist Services - We will provide innovative, high quality specialist care delivering outstanding outcomes for a wider population	<input checked="" type="checkbox"/>
Innovation - We will promote new and better ways of working, always looking to achieve excellence and sustainability in how our services are delivered	<input type="checkbox"/>
Care - We will treat our patients, and their families, with care, kindness and compassion and keep them safe from avoidable harm	<input type="checkbox"/>
People - We will make SFT a place to work where staff feel valued and are able to develop as individuals and as teams	<input checked="" type="checkbox"/>
Resources - We will make best use of our resources to achieve a financially sustainable future, securing the best outcomes within the available resources	<input type="checkbox"/>

Revalidation - Annual Board Report

1. Executive summary

In April 2014 NHS England published a framework for quality assurance for revalidation which requires Responsible Officers (ROs) to produce their annual report on revalidation for the Board of their Designated Body in a prescribed format, and the chairman or chief executive to sign a statement of compliance to be submitted to the level 2 Responsible Officer. This report describes the number of doctors with a prescribed connection to the Trust, the number of completed appraisals within the appraisal year 2017-18, the appraisal quality assurance process, any fitness to practice issues identified and any issues with the appraisal and revalidation process.

2. Purpose of the Paper

This paper serves to give assurance to the Board of the Designated Body that the revalidation process is being carried out in accordance with the regulatory framework.

3. Background

Medical revalidation was launched in 2012 to strengthen the way that doctors are regulated, with the aim of improving the quality of care provided to patients, improving patient safety and increasing public trust and confidence in the medical profession.

Provider organisations have a statutory duty to support their Responsible Officers in discharging their duties under the Responsible Officer Regulations¹ and it is expected that provider boards will oversee compliance by:

- monitoring the frequency and quality of medical appraisals in their organisations;
- checking there are effective systems in place for monitoring the conduct and performance of their doctors;
- confirming that feedback from patients is sought periodically so that their views can inform the appraisal and revalidation process for their doctors; and
- ensuring that appropriate pre-employment background checks (including pre-engagement for Locums) are carried out to ensure that medical practitioners have qualifications and experience appropriate to the work performed.

4. Governance Arrangements

The Medical Director is the Trust's Responsible Officer and has a statutory duty to ensure that doctors participate in an annual appraisal process which meets the requirements for revalidation. Where there is a potential conflict of interest or

¹ The Medical Profession (Responsible Officers) Regulations, 2010 as amended in 2013' and 'The General Medical Council (Licence to Practise and Revalidation) Regulations Order of Council 2012'

appearance of bias in acting as an RO for any of the doctors linked to the designated body, the Trust is required to appoint an alternative RO. This has not been necessary for Salisbury Foundation Trust since the advent of revalidation in 2012.

The Responsible Officer must ensure that appraisals involve obtaining and taking account of all available information relating to the medical practitioner's fitness to practise in the work carried out by the practitioner for the designated body, and for any other body, including other Trusts, independent sector providers and voluntary organisations, during the appraisal period.

She is also required to:

- Maintain records of practitioners' fitness to practise evaluations, including appraisals and any other investigations or assessments.
- Ensure that doctors are appropriately qualified for their proposed duties, including ensuring that appropriate references are obtained and checked and the identity of the doctor is verified. This responsibility is delegated to the Medical Personnel department and since 2017 the Responsible Officer has not been required to "sign off" any references.
- Ensure that medical practitioners have sufficient knowledge of English language necessary for the work to be performed in a safe and competent manner. In practice this means that practitioners from outside the EEA and Switzerland must have passed the PLAB (professional and linguistics assessment board) test and non UK graduates must have passed the IELTS (International English Language Testing system) with a score of at least 7.5 and 7 in all sections. From this year the GMC has also accepted the Occupational English Test at grade B or above as an alternative, and in exceptional circumstances the Responsible Officer can accept a locally administered test of English language skills.
- Review regularly the general performance information held by the designated body, including clinical indicators relating to outcomes for patients. We subscribe to Doctor Foster which gives an overview of a wide range of benchmarked quality and operational data. We also participate in: the GIRFT (getting it right first time) programme which captures benchmarked quality and performance data; all applicable national audits and all applicable national databases and registries. Some services also collect comprehensive local quality data.
- Identify any issues arising from that information relating to medical practitioners, such as variations in individual performance
- Ensure that the designated body takes steps to address any such issues.
- Ensure that appropriate action is taken in response to concerns about medical practitioners' conduct or performance and where appropriate
 - a) take any steps necessary to protect patients;
 - b) recommend to the medical practitioner's employer that the practitioner should be suspended or have conditions or restrictions placed on their practice
 - c) maintain accurate records of all steps taken
- Establish and implement procedures to investigate concerns about a medical practitioner's fitness to practise raised by patients or staff of the designated body or arising from any other source
 - a) initiate investigations with appropriately qualified investigators;

- b) ensure that procedures are in place to address concerns raised by patients or staff of the designated body or arising from any other source;
- c) ensure that any investigation into the conduct or performance of a medical practitioner takes into account any other relevant matters within the designated body;
- d) consider the need for further monitoring of the practitioner's conduct and performance and ensure that this takes place where appropriate;
- e) ensure that a medical practitioner who is subject to procedures under this paragraph is kept informed about the progress of the investigation
- f) ensure that procedures under this paragraph include provision for the medical practitioner's comments to be sought and taken into account where appropriate

The Trust has appropriate policies and procedures for Handling Concerns about the Conduct and Performance of Doctors and Dentists – our policy is currently under review; we also have a comprehensive Remediation policy.

- Where appropriate refer concerns about the medical practitioner to the General Medical Council
- Respond to requests from the GMC for information about a doctors practice
- When requested to do so deal with concerns raised to the GMC at a local level , ensuring only the most serious concerns are investigated by the GMC
- Where a medical practitioner is subject to conditions imposed by, or undertakings agreed with, the General Medical Council, to monitor compliance with those conditions or undertakings
- Make recommendations to the General Medical Council about medical practitioners' fitness to practise

She is line managed in this respect by her “second level responsible officer” who is currently the Medical Director of NHS England South, and appraised with regard not only to her performance as an RO, but on the whole of her practice, by an NHSE appointed appraiser. Her annual appraisal was completed in January 2018 and she was revalidated in March.

The RO has received appropriate training for the role and is engaged in the regional responsible officer network which provides updates and support. She has attended 4/6 of the regional RO network meetings.

The RO is supported by an appraisal lead, Dr Clare Hennebry. The appraisal lead is responsible for ensuring that:

- The trust has enough appraisers
- Appraisers are properly trained and supported in their work
- They carry out sufficient appraisals each year to maintain skills
- Appraisees are helped to identify a suitable appraiser and have a maximum of three consecutive appraisals by the same appraiser
- The appraisal policy for medical staff is kept up-to date and complies with national guidance

- Doctors struggling to engage with the appraisal process are supported and guided through the process

In addition she acts as a source of expert advice for difficulties encountered in the appraisal process, signposting where necessary to further advice and guidance. She works with appraisers and appraisees on continuously improving the value of the appraisal process.

Administrative support to the RO and appraisal lead is by a part time administrator who is responsible for:

- Ensuring that the list of doctors with a prescribed connection to the designated body is up-to-date and correct by cross-referencing it with the electronic staff record (ESR)
- Dealing with queries about the appraisal and revalidation process
- Training and supporting doctors in the use of their e-portfolio
- Reminding doctors when their appraisal is due and supporting them to complete it in a timely manner
- Helping ensure that doctors take relevant clinical governance information to their appraisal
- Supporting the RO in assuring she has access to all the information she needs to make a revalidation recommendation and does so in a timely manner.

After six years in the post Ms Jacqui Cooper has resigned and the post is currently vacant.

Appraisers are responsible for:

- Ensuring they are trained and keep up-to-date with the appraisal requirements for revalidation. This includes completing at least five appraisals per year in order to maintain their skills.
- Ensuring that the doctor's appraisal meets the requirements for revalidation and providing assurance to the RO that this is the case by completing an appraisal output form which confirms compliance.

Appraisees are responsible for ensuring that they have an annual appraisal which meets the requirements for revalidation and feeding back to the appraiser and appraisal lead on the quality and value of the appraisal.

An annual appraisal must be completed on or before the anniversary of the last appraisal. Progress with appraisals is monitored by the RO and administrator at a monthly meeting, and any doctors who have not completed their appraisal by the anniversary of their previous appraisal are sent a reminder. If there is no further progress they are offered a face-to-face appointment with the administrator to support them in completing their portfolio; if this fails the appraisal lead will contact the doctor and offer more intensive support, and the RO will remind the doctor that participation in an annual appraisal process is both a contractual requirement and a requirement to retain a licence to practice medicine. As a last resort the GMC can be informed of non-engagement with the appraisal process.

a. Policy and Guidance

Our appraisal policy for medical staff, remediation policy and handling concerns policy have all been updated within the last year. Our remediation policy has been used as an example of best practice by NHSE, and we have been commended for

the section on non-engagement in the appraisal policy. The handling concerns policy will require further updating in line with national guidance which is currently out to consultation.

5. Medical Appraisal

a. Appraisal and Revalidation Performance Data

For the appraisal year 2017-18:

246 doctors had a prescribed connection to the Trust (a significant rise compared to the previous year) including 181 consultants, 16 SAS doctors and 46 temporary or short-term contract holders (trust locums and junior doctors not in a training post).

Appraisal compliance rates are tabulated below with last years and national figures for comparison. It can be seen that appraisal compliance rates have fallen across the board since 2015/16 and this is thought to be for the following reasons:

1. The vast majority of doctors underwent revalidation between 2012 and 2015. Revalidation was a powerful incentive for doctors to complete their appraisal and doctors at this stage in the five year revalidation cycle are harder to engage.
2. A change in the NSE definition of a timely completed appraisal so that appraisals must be completed on or before the anniversary of the previous appraisal – previously a delay of up to six weeks was acceptable. It has been very difficult to get doctors to understand that a delay of even a few days counts as a delayed appraisal.
3. We have been working to improve alignment of appraisal dates with revalidation dates to ensure all doctors can get five appraisals completed in a five year cycle. This has caused some confusion.
4. Difficulty keeping track of all doctors with a prescribed connection particularly bank doctors, retire-and-returnees and short term contract holders
5. Processes for ensuring that doctors who have a valid reason for missing an appraisal (eg maternity leave or sickness absence) have this recorded require improvement
6. Maternity leave of the revalidation administrator followed by resignation

	Number 2017/18	Number 2016/17	Number 2015/16	Appraisal rate 2017/18	Appraisal rate 2016/17	Appraisal rate 2015/16	Similar Trusts
consultants	181	164	168	83%	81%	94%	91%
SAS	16	18	12	75%	78%	82%	84%
Other	49	19	24	89%	95%	100%	81%
Total	246	201	204	83% (203)	82% (165)	94%	87%

Four doctors were excused due to maternity leave or long-term sickness absence. Thirty-nine doctors had a missed or incomplete appraisal at the time of submission of the national audit. The majority of these were due to the appraisal output form not being signed off or the feedback form not being completed; most of those “missed” were overdue by less than six weeks.

Overall appraisal rates by directorate as at the end of March 2018 were as follows:

	Number of doctors	Not signed off	Out of date
CS&FS	54	2	5
Surgery	75	4	3
MSK	52	3	6
Medicine	65	7	5
	246	13	22
			9%

At the time of writing appraisals more than two months overdue and where approval to delay has not been granted are as follows:

Grade	Directorate	Last appraisal
Locum consultant	surgery	Nov 2016
Middle grade	MSK	Jan 2017
Consultant	MSK	Jan 2017
Consultant	Medicine	Nov 2016
Consultant	Medicine	Jan 2017

All of these doctors are being managed in line with the escalation process in our appraisal and revalidation policy. One consultant's contract has been terminated due to non-engagement with the appraisal and revalidation process. Another consultant was formally managed under our non-engagement process and has since completed his appraisal.

Efforts are underway to recover appraisal performance.

Only nine doctors were due for revalidation during the course of the year as most doctors were revalidated between 2013 and 2015; a positive revalidation recommendation was made in all of them.

No doctors were involved in a remediation process as a result of issues identified at appraisal. However some concerns about the practice of doctors were identified by our governance processes.

Two doctors have been formally investigated for misconduct and one has been referred by the RO to the GMC. One doctor received a six month suspension by the GMC related to issues identified prior to appointment but there have been no concerns about his practice here. One doctor received a two month suspension in relation to misconduct prior to his appointment. We were properly informed of the concerns by the doctors, the GMC and their previous RO.

Two doctors have completed a formal remediation process, one as a result of performance concerns and a period away from clinical practice and one in response to a clinical incident.

The RO meets quarterly with her GMC employer liaison officer to discuss ongoing and potential fitness to practice concerns and regularly consults her National Clinical Assessment Service local adviser for advice.

b. Appraisers

The trust has 42 trained appraisers who have all attended at least one appraiser support group meeting or training session and completed at least one appraisal over

the course of the year. All directorates are represented and the pool of appraisers includes SAS doctors. Around half of our appraisers do fewer than five appraisals per year, so we plan to reduce the number of appraisers over the year to give a ratio of 1:8 or 1:10. We have a small number of “super appraisers” who have advanced skills in appraisal and coaching and are able to undertake a developmental appraisal when there is a performance, health or conduct concern.

We held a number appraiser support group meetings and drop in training sessions, as well as a half day workshop for appraisers, facilitated by the appraisal lead. Topics for discussion were selected by the RO, the appraisal lead and appraisers to ensure they met their needs. As a consequence of feedback on the appraisal process we have included good practice in PDPs and will include examples of good input forms and how to collect supporting information throughout the year.

The appraisal lead attends NHS England (South) appraisal leads network meetings.

The appraisal lead has completed training-the-trainers for appraisal and we are able to offer in-house training to prospective new appraisers.

c. Quality Assurance

Prior to the appraisal meeting the customer care and clinical risk departments supply appraisees and their appraiser information on complaints, concerns and compliments and any incidents they have been named in during the year. However this is reliant on the quality of the indexing on datix and may not always be complete.

We have an appraisal quality assurance board chaired by a non-executive director and including a lay member which last met in June 2018. The board reviews the number, training and engagement of appraisers, the feedback given by doctors to appraisers and independently reviews a random selection of 10% of completed appraisals using a validated quality assurance numerical scoring tool called PROGRESS. The findings can be summarised as follows:

- Most output forms were consistent professional & objective, but tended to be more supportive than challenging. Some forms captured the appraisal discussion better than others
- Some output forms evidenced a process of deep reflection
- Scores ranged from 7-20 (max score 20)
- There was good evidence that the appraisers had prepared well for the appraisal meeting by reviewing the evidence presented and reflecting on it. However gaps in presented evidence were not always identified and there was usually no mention of where the doctor is in the revalidation cycle.
- A minority of forms did not contain sufficient information to show that the doctor was making progress towards revalidation; in these cases the RO needed to refer to the input form to ascertain what evidence had been brought to the appraisal discussion
- Neither the premier IT system nor the MAG 4 form is appropriate for non-training grade junior doctors and something similar to an ARCP (annual review of competencies and progress) form would be more appropriate.
- There was room for improvement in the formulation of personal development plans, some of which focused entirely on CPD rather than a wider range of development needs identified during the appraisal, and most of which were not SMART

Following the appraisal each doctor completes a feedback form which is sent to the appraiser and copied to the appraisal lead. Feedback is used to determine the content of the appraisers support group meetings. Over the last year feedback has been overwhelmingly positive including when the doctor has been appraised from outside their own specialty, with the only negative comments being about the e-portfolio system. The average scores for each domain is given below (maximum score =5)

	2016	2017
Average duration of appraisal meeting (h)	1.76	1.67
Management of the appraisal system	3.96	3.99
Access to the necessary supporting information	3.89	3.83
Appraisers preparation for the meeting	4.55	4.67
Appraisers ability to conduct my appraisal	4.62	4.77
Ability to review progress against last year's PDP	4.59	4.68
Ability to help me review my practice	4.64	4.68
Usefulness for my professional development	4.31	4.53
Usefulness in preparation for revalidation	4.16	4.45
Usefulness of my new PDP	4.26	4.47

In January 2017 we had a peer review visit led by NHS England (South) to review the appraisal and revalidation system. This reported positively with several areas of good practice and substantial assurance on the quality and robustness of our processes. Our action plan in response to the visit has now been completed.

d. Access, security and confidentiality

Access to data in appraisal portfolios is limited to the appraiser, responsible officer and appraisal quality assurance board. Doctors are reminded that no patient-identifiable data should be included in the portfolio.

The data is “owned” by the doctor and can be downloaded to a suitable storage device if the doctor leaves the Trust; the doctor's record on the e-portfolio system is then archived.

e. Clinical Governance

The Quality Directorate and information services support doctors in gathering evidence for their appraisal, including supplying details of audited clinical outcomes, complaints, compliments and significant events.

6. Recruitment and engagement background checks

Prior to recruitment the medical personnel department carries out relevant background checks including confirmation of the doctor's identity, qualifications and professional registration. Out of hours this is the responsibility of the senior clinician on site. On appointment the revalidation administrator asks the doctors previous Responsible Officer to complete a Medical Practice Information Transfer Form disclosing any relevant information to the Trust RO.

7. Risk and Issues

The success of the medical appraisal and revalidation process is dependent upon the expertise of a small number of individuals with limited back-up support.

The trust has only two doctors trained as a Case Investigators and the RO is the only trained and experienced Case Manager. This is mitigated by using non-medical case investigators when the issue is clearly one of misconduct and external case investigators where necessary. An additional case investigator has just been trained and the Clinical Directors are to train as case managers.

A small number of doctors are struggling to engage with the revalidation process and there is a risk that they will lose their licence to practice; however this is unlikely as compliance increases markedly as the revalidation date draws close. The difficulty will be keeping these doctors engaged in appraisal once they have been revalidated, and this is beginning to be apparent as all doctors have now been revalidated once. This is mitigated by support from the appraisal lead and we will also be working more closely with lead clinicians to remind doctors of the importance of regular appraisal and reflective practice.

8. Next Steps

In February the UK Medical Revalidation collaboration published a report evaluating the regulatory impact of medical revalidation. The key findings were:

- The GMCs objective of bringing all doctors into a governed system that evaluates their fitness to practice has been achieved most consistently for those doctors who are employees of a single organisation.
- There is variation in the ease with which doctors can obtain supporting information but most are able to do so and find patient and colleague feedback and review of significant events particularly helpful in a reflective appraisal discussion. There is limited evidence that reflective practice is continued outside of the appraisal discussion.
- The adoption of the GMCs good medical practice framework for the basis of appraisal has resulted in some improvements particularly in personal development plans
- Although appraisal successfully identifies some concerns with doctors practice, particularly in relation to health and workplace issues, there is no evidence as yet that the appraisal and revalidation process is identifying and remedying potential concerns before they become safety issues or Fitness to Practice referrals.
- There is considerable variation in the extent to which ROs share or delegate decision making. ROs generally find the support of the GMCs Employer Liaison Officer valuable.
- There is also variation in the extent to which patients and the public are involved in the revalidation process.

Although much progress has been made over recent years we need to further strengthen the appraisal process. In particular we want to broaden the focus of the appraisal from merely complying with the GMC regulations to using appraisal to align individuals' values and objectives with those of the Trust. We need to fully exploit the potential of skilled appraisal to enable medical staff to reach their full potential.

We need to communicate with our patients and public better about appraisal and revalidation to provide them with assurance that our doctors are up-to-date-and fit to practice.

9. Recommendations

The Board is asked to note this report and agree for it to be shared with the Second Level Responsible Officer.

The Board is further requested to approve the 'statement of compliance' confirming that the organisation, as a designated body, is in compliance with the regulations

A Framework of Quality Assurance for Responsible Officers and Revalidation

Annex E - Statement of Compliance

Version 4, April 2014



NHS England INFORMATION READER BOX

Directorate

Medical	Operations	Patients and Information
Nursing	Policy	Commissioning Development
Finance	Human Resources	

Publications Gateway Reference:

01142

Document Purpose	Guidance
Document Name	A Framework of Quality Assurance for Responsible Officers and Revalidation, Annex E - Statement of Compliance
Author	NHS England, Medical Revalidation Programme
Publication Date	4 April 2014
Target Audience	All Responsible Officers in England
Additional Circulation List	Foundation Trust CEs , NHS England Regional Directors, Medical Appraisal Leads, CEs of Designated Bodies in England, NHS England Area Directors, NHS Trust Board Chairs, Directors of HR, NHS Trust CEs, All NHS England Employees
Description	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.
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 (ROCR approval applied for).
Timings / Deadline	From April 2014
Contact Details for further information	england.revalidation-pmo@nhs.net http:// www.england.nhs.net/revalidation/

Document Status

This is a controlled document. Whilst this document may be printed, the electronic version posted on the intranet is the controlled copy. Any printed copies of this document are not controlled. As a controlled document, this document should not be saved onto local or network drives but should always be accessed from the intranet

Annex E – Statement of Compliance

Designated Body Statement of Compliance

The board/executive management team – [delete as applicable] of [Insert official name of designated body] has carried out and submitted an annual organisational audit (AOA) of its compliance with The Medical Profession (Responsible Officers) Regulations 2010 (as amended in 2013) and can confirm that:

1. A licensed medical practitioner with appropriate training and suitable capacity has been nominated or appointed as a responsible officer;

Comments:

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

Comments:

3. There are sufficient numbers of trained appraisers to carry out annual medical appraisals for all licensed medical practitioners;

Comments:

4. Medical appraisers participate in ongoing performance review and training / development activities, to include peer review and calibration of professional judgements (Quality Assurance of Medical Appraisers or equivalent);

Comments:

5. All licensed medical practitioners¹ either have an annual appraisal in keeping with GMC requirements (MAG or equivalent) or, where this does not occur, there is full understanding of the reasons why and suitable action taken;

Comments:

6. There are effective systems in place for monitoring the conduct and performance of all licensed medical practitioners¹, which includes [but is not limited to] monitoring: in-house training, clinical outcomes data, significant events, complaints, and feedback from patients and colleagues, ensuring that information about these is provided for doctors to include at their appraisal;

Comments:

7. There is a process established for responding to concerns about any licensed medical practitioners¹ fitness to practise;

¹ Doctors with a prescribed connection to the designated body on the date of reporting.

Comments:

8. There is a process for obtaining and sharing information of note about any licensed medical practitioners' fitness to practise between this organisation's responsible officer and other responsible officers (or persons with appropriate governance responsibility) in other places where licensed medical practitioners work;

Comments:

9. The appropriate pre-employment background checks (including pre-engagement for Locums) are carried out to ensure that all licenced medical practitioners² have qualifications and experience appropriate to the work performed; and

Comments:

10. A development plan is in place that addresses any identified weaknesses or gaps in compliance to the regulations.

Comments:

Signed on behalf of the designated body

Name: _____ Signed: _____

[chief executive or chairman a board member (or executive if no board exists)]

Date: _____

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