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| **Agenda item:** | **11** |
| **Attachment:** | **G** |

**HRA BOARD COVER SHEET**

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| **Date of Meeting:** | 21 September 2016 |

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| **Title of Paper:** | Embedding Quality Management System Principles across the HRA |
| **Purpose of Paper:** | This paper provides an options appraisal of the level that QMS principles are embedded across the organisation and the involvement of the QA team in providing assurance more broadly. The benefits of embedding QMS principles in all HRA functions will be detailed, including the option of extending the scope of the ISO 9001 certification as a possible option whilst recognising the other forms of assurance the HRA receives. |
| **Reason for Submission:** | For Board approval |
| **Details:** | The Board is asked to support the proposal to embed QMS principles in the HRA as a minimum.  Further, the Board is asked to consider the additional investment to proceed with ISO 9001 certification for all functions of the HRA on the understanding that a more proportionate approach is undertaken.  The Board is asked to note that SEMT reviewed this proposal at its meeting on 12th September 2016 and supported the recommendation to embed QMS principles and proceed with ISO9001 certification for all functions of the HRA on the understanding that a more proportionate approach is undertaken.  In summary:   * The detailed work undertaken thus far was in order to create a baseline and the majority of the work required of directorates has been completed. The level of assurance will be more proportionate going forward with greater opportunity for Directors to consider the scope and discuss findings and action plans and opportunities taken to apply corporate learning to avoid repeat or corporate wide findings through early identification and resolution. * Greater collaboration with HGIAS will take place with joined up planning regarding the HGIAS and QMS audit planning cycles and for the HRA QA Manager to attend Audit and Risk Committee meetings * The Assurance Map will be reviewed and utilised by QA and agreed by EMT to identify those areas of functions which appear to be the greatest risk and help inform future audits for both HGIAS and QMS. * QMS findings and reviews will be considered at EMT to allow identification of risk and trends and greater management oversight. * The proposals will support the wider organisational objectives to consider all HRA functions and the contribution of them, not least CAG and Approval and REC as a component part within an overall service. |
| **Suitable for wider circulation?** | Yes |
| **Time required for item:** | 15 minutes |

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| **Recommendation / Proposed Actions:** | **To approve** | | **x** |
| **For information / to note** | |  |
| **For discussion** | |  |
| **Comments** |  | |

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| **Name:** | Stephen Tebbutt |
| **Job Title:** | Head of Corporate Governance |
| **Date:** | 14/09/2016 |

**Embedding Quality Management System Principles across the HRA**

**Introduction**

On the 15th March 2016 the Board agreed with the Executive Management Team’s (EMT) recommendation to pause the work to expand the HRA’s ISO certification to all functions / services provided by the HRA and beyond the REC accreditation activity.

This decision to pause was taken due to competing priorities faced by the organisation and the opportunity to further consider the approach and how it sits across other internal and external audit activity. This pause has been helpful in allowing further consideration of the appropriateness of the approach and the various options available to the organisation.

Prior to the decision to pause, significant progress had been made in working towards extending the scope with the majority of the HRA’s functions reviewed by QA. These reviews were particularly detailed and thorough to prepare the HRA for the initial aspects of ISO 9001 certification and in hindsight a pause to consider alternatives and repeat findings could have been introduced sooner to be more proportionate, reflecting the competing challenges faced by staff in addition to the certification requirements. For example, repeat findings regarding the annual review standards set for policies and failure to meet them largely due to them being applied as a default and no corporate wide system in place to manage them.

However, this initial work can be considered as essential baseline work which was necessary to be completed in order to embed Quality Management System (QMS) principles within HRA functions and colleagues can be assured this initial concentration of work will not be required going forward. This level of review would not be anticipated for the future review cycle e.g. QMS audits would consist of a review of a sample of policies/procedures rather than a review of all documentation.

Following the decision to pause the work the Board should note there are a number of action plans which remain outstanding however it is recognised the remaining findings in general did not signify any material risk to the organisation. The outstanding action plans are currently being completed based on business priorities and capacity. Of the findings which Directors agreed involved material risks to the organisation (e.g. CAT findings), separate steps have been put in place to resolve the issues. There is full recognition of the need to separate out the material risks of findings to the organisation as separate to any risks that are limited to the delivery of the QA assurances (with or without a commitment to certification).

As an organisation with regulatory functions it is essential the services we deliver to support the UK research environment are of a high quality, compliant with statutory/regulatory requirements and fit for purpose. Therefore embedding a strong quality assurance approach across the organisation is crucial in providing assurance to participants, researchers and other stakeholders that the services we provide are of a high standard with continual improvement promoted. Certification of that approach can be a key part of our credibility, equally QA and certification of it must be proportionate.

This paper provides an options appraisal of the level that QMS principles are embedded across the organisation and the involvement of the QA team in providing assurance more broadly. The benefits of embedding QMS principles in all HRA functions will be detailed, including the option of extending the scope of the ISO 9001 certification as a possible option whilst recognising the other levels of assurance the HRA receives, such as the Health Group Internal Audit Service (HGIAS).

**Benefits of embedding QMS principles across the organisation**

In making a decision to support the embedding of QMS principles across the organisation by extending the scope to all HRA functions (based on the seven ISO 9001:2015 principles; customer focus, leadership, engagement of people, process approach, improvement, evidence based decision making and relationship management), it is important for SEMT to note the potential benefits in comparison with the associated costs and potential savings.

The QA team is small and is made up of only two members of staff; the HRA Quality Assurance Manager and the HRA Quality Assurance Business Support Manager. Prior to the change in directorate in April 2016 the QA team had a third member of staff who has now moved to focus on standards as part of the Systems and Development Directorate. Costs are therefore relatively low at approximately £107K (pay and non-pay).

The main role of the team, prior to the decision to embed QMS principles across the organisation, had been quality assurance of the REC service as required under the Governance Framework for Research Ethics Committees (GAfREC); a role which has been undertaken professionally and the principles of which are now firmly embedded in the REC accreditation and REC quality control processes. The QA function is ISO 9001 certified with the service provided to Devolved Administration (DA) RECs and one which provides an important assurance to researchers and participants alike.

Whilst this has been the main focus of the QA team they are involved in other areas of work for the HRA, such as joint administration of the Shared Ethical Debate Scheme and the management of the collection of user satisfaction from users of the HRA, plus other project work including leading the implementation of the HRA Hub Central Library.

It is important to flag any additional work to embed QMS principles would be undertaken from within the current QA team resourcing. A decision to step back from the broader application of QA could result in potential savings but given there are only two posts and the REC accreditation is a statutory requirement the decision making might be better positioned as a consideration of appropriate investment of the resource rather than a consideration of whether it is required. Given the nature of our work two full time equivalents would not be a high investment in QA.

Benefits in embedding QMS principles include:

* In adopting common policy/procedure/instruction templates, developed by the QA team working to ISO 9001 principles, and adopting QA procedures such as QC and user satisfaction, the HRA has minimised the unnecessary variance when implementing procedures over the five HRA sites. An example of this was the roll out of the HRA Minute taking and letter writing guidance by the HRA Operations team; the guidance was developed, with QA input, disseminated, training provided and then members of the QA team working with the Operational team to complete QC on the minutes and collect feedback from users of the REC system.
* New functions, and where applicable existing functions, have considered the inclusion of proportionate QC and the possible benefits of collecting user feedback as part of the QMS roll out. When used appropriately both of these QA tools can help manage potential risks for the organisation, ensure that any lessons are learnt and ultimately improve procedures/ functions. An effective QMS will lead, in time, to less issues and problems within the organisation being identified.
* Whilst it is important to note that embedding QMS principles will not provide full protection against all issues, having appropriate assurance of our services and firm policies and procedures in place may reduce the possibility of future problems arising e.g. aspects of the change including the judicial review. Embedding QMS principles and in particular being compliant with ISO 9001 will help ensure all regulation requirements are met for all services which will help protect our reputation. The rigour of our policies have helped in previous instances such as an appeal to the Information Commissioners Office, and subsequently the HM Court & Tribunals Service, were the robustness of our policies were sufficient to reject an appeal. Having this level of rigour across the organisation may help prevent any further instances occurring with clear version control and QC in place.
* Good working practices and common systems have been identified by the audit team and allowed for the sharing of knowledge across all teams, this can be demonstrated through the publication of stakeholder registers, which lists user satisfaction surveys completed, and how results can be accessed and the adoption of existing HRA systems by CAG e.g. HARP.
* The streamlining of policies and procedures, ensuring that unnecessary duplication does not occur within a system, thereby increasing efficiency. An example of this is through working with the Operational team in the reworking of the recruitment process for REC members, which resulted in a more effective system which minimised the potential risk of appointing a member using the wrong expert / lay capacity. In-house procedures relating to equality monitoring were streamlined to provide a proportionate approach which satisfies the appropriate legislation.
* Greater awareness of document control, publication and periodic review have led to a tighter control of current documents on the intranet.
* New systems have been developed because of issues highlighted through QMS auditing, e.g. the ‘*Over-arching policy for the management of all internal HRA policies, procedures, instructions, guidelines and forms’* which formalises the process for drafting, approval, dissemination, publication and management of documents which will be supported through the introduction of HRA Hub. Once the HRA Hub has been rolled out and adopted by HRA staff for the development of internal HRA policies and procedures, it is envisaged that less management time will be spent on the review of internal documents (at management meetings); this is because a documented audit trail of development will provide an assurance that the correct HRA staff with the appropriate knowledge have been involved in the development and review.
* Finally, having an internationally recognised standard for the whole of the HRA will strengthen the HRA’s reputation that as an organisation it takes quality seriously and can be relied on in all aspects of business, and support the HRA’s objective to make the UK a great place to do research and build confidence. This international endorsement may be increasingly important in the changing political climate and the potential challenges resulting from the EU referendum outcome.

**Closer working with HGIAS**

In deciding whether to proceed with embedding QMS principles across the HRA it is important to note other assurance received by the organisation, such as via the HGIAS.

It is recognised that the audits undertaken by HGIAS are a mandatory requirement for the HRA however they do focus on different aspects to that which the HRA QA team would consider. QMS audits aim to verify compliances against the seven ISO 9001 standards and have the benefit of internal detailed knowledge of the organisational functions which allows for collaborative working between QA and HRA teams. HGIAS provides an independent, objective assurance to evaluate and improve the effectiveness of risk management, control and governance processes. Following discussions with Zafir Ali (ZA), Head of Internal Audit, HGIAS however it is agreed that closer working between HGIAS and HRA QA team would benefit the organisation with assurances shared between both.

The audits undertaken by HGIAS and QMS are currently independent of one another from the yearly planning conversations through to reporting. Whilst the audits undertaken by each party do focus on different aspects there is some overlap with reviews of certain functions having taking place by both auditors within a short space of time. To ensure there is greater coordination between audits, closer working with HGIAS is required. To this end the Audit and Risk Committee agreed at its meeting on 1st June 2016 for:

* Head of Corporate Governance to be involved in the initial yearly planning setting conversations with HGIAS alongside the Chief Executive and Director of Finance. These conversations will be used to inform the planning work for HRA QMS Audits.
* HRA QA Manager to attend future Audit and Risk Committee meetings to support closer working and allow feedback and consideration of risk from HRA QMS audits.

This closer working will also be of corporate benefit in other ways. It is noted that a number of recent HGIAS audits may have contained areas of complexity with auditors not fully understanding the nature of the HRA’s business e.g. IRAS partnership arrangements, KPIs. By embedding QMS principles this will allow closer working between the two auditing functions, with the HRA QA team, able to provide greater insight into certain aspects and allow greater assurance. Discussions with ZA have acknowledged that HGIAS and HRA QA can have a mutually beneficial relationship with support for audits undertaken by the HRA QA team to be shared with HGIAS. Assurances identified in the QMS audit could be used by HGIAS in considering the overall assurance of the organisation and support the audit planning process for both teams.

**Assurance Mapping**

The Health Group Internal Audit Service (HGIAS) undertook an assurance mapping exercise in March 2016. An assurance map allows an organisation to clearly identify where and how it gains assurance over key risk or functional area and how effective controls are in managing risks. The assurance mapping exercise was carried out to help identify:

* Significant gaps where there is not enough assurance being provided;
* Potential overreliance on sources of internal assurance; and
* Overlaps of duplication in assurance

Assurance mapping uses a ‘three lines of defence model’ as a basis which is what the organisation has in place to manage and respond to risk.

* 1st line – Assurances received via people, systems, processes, procedures and policies
* 2nd line – Assurances received via the organisation’s governance structures and internal compliance functions for Board reporting, risk management processes etc. e.g. QMS
* 3rd line – Assurances received from external sources e.g. HGIAS and BSI

It is important to note that currently not all sources of assurance have been captured or further assessment may be required as this exercise was conducted by PwC with only certain individuals contacted. However this is a useful visual tool and one which, as part of the extension of scope, the QA team would use to support the audit process.

An initial step would be for the QA team to consider the map with each director individually to ensure it is correct, consider the RAG status for each area and consider any particular gaps or high risk areas. It is recognised there are competing work pressures and the work to complete and embed the assurance map in the organisation will require buy-in from Directors. The HRA QA team will however take responsibility for the assurance map and will support directorates through the process in ensuring the information is accurate, RAG status, level of risk and assurance considered. To this effect, work to embed the map will be on an ongoing piece of work to take place over the next 6 – 12 months.

The tool will however provide an immediate visual tool for management, the Board, DH Sponsor and HGIAS showing the level of assurance in each function and allow a decision to be taken as to whether there are particular risk areas where greater assurance may be required or where there may be areas with low assurance but a low level of risk associated with that function. This would support the audit planning cycle for both QMS and HGIAS audits. It is envisaged the assurance map would be reviewed at EMT on a quarterly monthly basis alongside KPI and risk register consideration with assurance provided to Audit and Risk Committee and Board on a 6 monthly basis. HGIAS and the HRA QA Team would similarly be able to use the tool to support their audit planning cycle to allow a proportionate based approach to be undertaken.

**Proportionality**

As referenced above the initial detailed baseline work was necessary to embed QMS principles within HRA functions however going forward the requirements for QMS audit would be more proportionate. If particular risks or issues are identified which management subsequently agree warrant more detailed investigation this will still be possible. This initial baseline work can be compared to the ISO 9001 certified accreditation scheme improvements of REC Standard Operating Procedures and guidance. Now the processes are firmly embedded the standard is much higher with many more first-time accreditations being achieved. For the reporting period September 2007-April 2008, 71% of RECs received a provisional accreditation with an average of five issues being listed in the subsequent action plans. This is in comparison with 34% of RECs receiving a provisional accreditation (and many more receiving full accreditation) for the reporting period September 2015 – April 2016 with an average of only 3 action plans issued.

In terms of what a function could expect from an audit going forward as part of the ISO 9001 certification, and how this would be different from the baseline work already conducted, the [*Internal QMS Audit Procedure*](https://intranet.hra.nhs.uk/system/files/Internal%20Audit%20Procedure%20V3%2012%20Final%202016%2005%2010.pdf) sets out how the audits will be planned and conducted. A typical external certification audit for a HRA function (e.g. Corporate Secretary) will last one day and involve key members of staff who have a good working knowledge of the relevant policies and procedures in order to verify compliance against the polies/procedures. It is expected that Directors will be asked to attend a short interview with the external auditor, to discuss the business plan objectives relevant to the function and other strategic issues. In response to particular concerns raised previously, the QMS audit will follow a sample based approach to the review of policy and procedure compliance, as well as compliance against QMS principles. The HRA QA team will be on hand to support Directors and teams through this process.

It is recognised that even greater proportionality may be possible in particular functions which have controlled processes which are standard for their sector e.g. Finance. For assurance of the finance team the QA team would look to rely on HGIAS audits which could then be used as evidence for the certification process with BSI. This would remove any potential duplication and would allow the QA team to focus on other parts of the organisation with assurance provided by auditing from a team with in-depth knowledge of the processes and nuances which may not be visible to HGIAS.

A three year cycle of QMS audits by function would be considered alongside the assurance map and the audit plan for HGIAS. Directors however would continue to have the opportunity to discuss and plan the audit scope and arrangements with EMT to have the opportunity to reprioritise the schedule as business needs of the HRA may change.

**Review**

To enable better management oversight and allow cross organisational learning the findings from each HRA QMS audit review will be brought to EMT to note and also shared with HGIAS. With the creation of SEMT, EMT would now seem the more appropriate place for these reviews to be brought to facilitate a shared understanding of issues and risk faced and allow greater management oversight and challenge.

**Options Appraisal**

The Board is asked to consider the following options:

1. **QA role to focus on current responsibilities and not proceed with embedding QMS principles for the rest of the organisation**

This approach would revert to focusing on the REC service and would include:

* Completing 3 year rolling audit programme for the accreditation of all UK RECs
* Joint administration of the REC Shared Ethical Debate scheme with HRA Operational colleagues
* Monitoring of completion of REC Quality Control checklists
* Management of the collection of user satisfaction from users of the HRA
* Maintaining ISO 9001 certification for the HRA QA function

The costs would remain at approximately £107K for the QA team with the existing QA functions maintained within the current QA staffing (2 full time members of staff). ISO 9001 certification would still be required to be maintained solely for the QA function, certification fees would be approx. £1500.

Issues to consider with the option 1 approach;

* The majority of the existing QA is centred around the REC service which could leave those functions, identified as being higher risk with little structured QA input and minimal assurance.
* The reputational risk that we are seen as an organisation, both by internal users and external stakeholders, as not valuing quality.
* Cost of providing this minimum service, as required by GAfREC and a service provided to DAs, is similar to options 2 and 3 with greater value added in other available options.
* The HRA would miss an opportunity to apply QA to other operational functions – CAG and Approval – within an overall corporately applied policy.

1. **Continue to embed QMS principles across the HRA without ISO 9001 certification**

This approach would see the continuation of the roll out of QMS principles throughout the HRA plus the BAU as listed in option 1. The continuation of embedding and maintaining of QMS principles, across all HRA functions would be through the use of QA tools such as audits (working alongside the Health Group audits), collection of user satisfaction, proportionate quality control and management reporting however ISO 9001 certification would not be sought.

The majority of the QMS work, in preparation for certification, has been completed through gap analyses and QMS audits (to check compliance), so the impact on staff, other than members of the QA team, would be confined to those members of staff yet to complete action plans from completed QMS audits. As certification would not be sought the direct financial cost of certification would remain the same as option 1 (approx. £1500 for maintaining QA certification).

Issues to consider with the option 2 approach;

* The QA team is a relatively low cost for the organisation and the additional work would be delivered within the same resource. The value embedding QMS principles versus the cost to the organisation in comparison with the potential cost of not doing so is far outweighed.
* Closer working with HGIAS will allow greater level of assurance to the organisation and better understanding during audits.
* As the organisation would no longer be seeking certification there is a concern that staff would question the need to complete action plans and therefore the QMS principles would not be fully adopted/embedded within the organisation.
* Concern audits would be prioritised as low importance and the HRA quality agenda would suffer because of conflicting workloads.
* Without the framework/timetable of formal certification the maintenance of QMS principles throughout the organisation would be challenging for the HRA QA department.

1. **Continue to embed QMS principles across the HRA with ISO 9001 certification**

The work involved in option 3 would mirror that detailed in option 2. In seeking certification for all HRA functions (including HRA QA certification) over a 3 year period, the direct financial cost would be approx. £8500 in addition to the existing QA Budget of approx. £107k. The resource impact would be slightly increased from option 2 as QMS audits would need to be completed as per schedule in addition to annual external certification audits (by BSI).

Issues to consider with the option 3 approach;

* The majority of the work has been completed to support the ISO 9001 certification over the last 2 years but noting that a number of plans remain incomplete, which will need to actioned prior to certification audits.
* The momentum of imbedding QMS principles would be maintained, along with a more structured approach to continual improvement due the need to demonstrate compliance to QMS principles at certification audits.
* By obtaining ISO 9001 certification it gives the HRA the best chance to truly embed QMS principles in every day working and it becoming business as usual with management buy in.
* Approx. 7 QMS audits per annum (based on risk) with a possibility to reduce numbers with joint working with HGIAS, in addition to 9 audit days over a three year period with the external certification body (BSI) – to note 2 of these would involve HRA QA only. These would need to be completed in line with the schedule agreed by EMT in order to support certification. N.B. We are looking to introduce remote auditing, which would mirror the REC accreditation audits, in order to minimise impact on staff time for QMS audits.
* Clear message to both internal and external stakeholders that the HRA places a great value on quality in all aspects of its business. Gaining and maintaining ISO 9001 certification, an internationally recognised standard on quality, for the whole of the HRA can only support the HRA’s objective to make the UK a great place to do research and build confidence. This international endorsement may be increasingly important in the changing political climate and the potential challenges resulting from the EU referendum outcome.

**Board Decision**

* The Board is asked to support the proposal to embed QMS principles in the HRA as a minimum.
* Further, the Board is asked to consider and support the additional investment to proceed with ISO 9001 certification for all functions of the HRA on the understanding that a more proportionate approach is undertaken.

**In summary:**

* The detailed work undertaken thus far was in order to create a baseline and the majority of the work required of directorates has been completed. The level of assurance will be more proportionate going forward with greater opportunity for Directors to consider the scope and discuss findings and action plans and opportunities taken to apply corporate learning to avoid repeat or corporate wide findings through early identification and resolution.
* Greater collaboration with HGIAS will take place with joined up planning regarding the HGIAS and QMS audit planning cycles and for the HRA QA Manager to attend Audit and Risk Committee meetings.
* The Assurance Map will be reviewed and utilised by QA and agreed by EMT to identify those areas of functions which appear to be the greatest risk and help inform future audits for both HGIAS and QMS.
* QMS findings and reviews will be considered at EMT to allow identification or risk and trends and greater management oversight.
* The proposals will support the wider organisational objectives to consider all HRA functions and the contribution of them, not least CAG and Approval and REC as a component part within an overall service.

**Next steps**

If the Board is supportive of proceeding with ISO 9001 certification for all functions the QA team proposes the following:

*Short term (from now until November):*

* Meetings to be held with each Director to consider their functions, previous reviews and any outstanding action plans and any future areas which require review. Timetable of completion of any reviews or action plans to be considered.
* Consider workload impact of proceeding with certification with each Director and identify where there are generic (organisational wide) findings that should be considered to ensure proportionality
* Consider where issues have wider applicability or are limited to achievement of certification and make recommendations accordingly
* Assurance map to be introduced to each director and management teams and the RAG status for each area considered.

*Longer term (January onwards):*

* Proceed with the Stage 1 certification by the British Standards Institute (BSI) in January 2017 followed by five more external audits (offices and functions to be confirmed) before the end of March 2017.
* Consider the findings of the external audits and make appropriate changes to the HRA QMS.
* Agree a three year audit plan to cover the period of certification (2017-20). Scheduling will take account of the external certification auditing and HGIAs schedules and the perceived risk associated with the function. It is expected that the majority of functions will be audited once during the 3 year period, but if a HRA function/Service is developing or has been substantially revised, or presents a high risk then HRA Management may consider more frequent auditing. Approximately 20 HRA functions/services/offices will be listed on the Internal QMS schedule, with varying frequency of auditing depending on assurance level required (to be agreed by HRA Management).
* To link the current business planning with the quality statement.
* To continue to embed QMS principles within the day to day working of the HRA and embed the assurance map as a key tool for Directors and senior management.

*Steve Tebbutt and Jane Martin*

*August 2016*