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| **Agenda item:** | **12** |
| **Attachment:** | **G** |

**HRA BOARD COVER SHEET**

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| **Date of Meeting:** | 24 September 2014 |

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| **Title of Paper:** | Quality Assurance Update to HRA Board |
| **Purpose of Paper:** | To the HRA Board of developments within Quality Assurance over the last 12 months or so, to note the achievements of the team and to note the ambition for the coming year. |
| **Reason for Submission:** | To seek that the HRA Board note /confirm developments and support the next steps proposed for the coming year. |
| **Details:** | Paper below |
| **Suitable for wider circulation?** | Yes |

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| **Recommendation / Proposed Actions:** | **To Approve** | | No |
| **To Note** | | Yes |
| **Comments** | Board is asked to note the progress to date and the direction for development | |

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| **Name:** | Tom Smith |
| **Job Title:** | Director of Quality, Standards and Information |
| **Date:** | 17/09/2014 |

**Introduction**

The Quality Assurance (QA) Department, the Board will recall is a small team comprising of, Jane Martin, HRA Quality Assurance Manager, Nicki Watts, QA Business Support Manager, with Carla Denneny joining in July this year, as QA Auditor following a successful HRA Approval Business case and recruitment process.

The QA Department is externally Certified to ISO 9001:2008, by British Standards Institute (BSI) and committed to assisting the HRA in the delivery of high quality services to our users, in sharing good practice between staff teams, promoting innovative ideas and working to secure HRA wide ISO Certification.

**Review of previous year**

Over the 2013/’14 year, QA undertook 32 Accreditation audits of RECs (used to assure the quality of compliance with REC administrative processes), with 100% being undertaken on time and to plan.

The team also manages the Quality Control (QC) procedure (an operationally driven process to check that the REC continues to work to standards between accreditation audits). During the past year QA has revised the QC checklist after receiving informal feedback from the Operational management team and reviewing the outcomes of the accreditation audits. The revisions include a streamlining of the checklist, a more focused approach to the quality of REC work and a move away from a ‘tick box’ checklist. The revised checklist was piloted and refined further before being issued for use.

The Shared Ethical Debate (ShED) procedure, the purpose of which is to review the consistency in decision making between RECs and to encourage ethical debate across committees, has also been updated, with changes being piloted through two exercises and due to report in October 2014. The revision of the procedure aims to make the scheme of greater benefit to REC Members by providing specific feedback through individual REC reports, benchmarking of the RECs review against other participating RECs, providing links to established guidance and providing a quality control of the minutes.

User Satisfaction has been sought for some years and used to assess the quality of the service received by REC applicants and users of HRA services. The recent reports from this data had shown a relatively low response rate and stable profiling for most questions and from April ’14, a revised and shortened question set is being piloted. Results will be known in October from the initial 6 months, however the first three months noted an increase in response rate of 114% on the same period in 2013/’14, which is likely to be due to further highlighting of the feedback route on email signatures and increased targeting for feedback by the QA Department. The interim report April – June‘14 is included at appendix 1.

In addition to the established QA procedures of Accreditation, Quality Control, User Satisfaction and ShED, the QA Department has undertaken gap analysis of TOPs and

CAG, conducted audits on RED Dataset for the London Centre and the use of favourable with conditions decision across the REC service, contributed to the QC of minutes and letters, delivered training on QC and audit standards and ISO 9001 principles.

In order to support the increased scope of ISO 9001 Certification, the QA Department has introduced a Document Control System, which will also manage the HRA’s risk of multiple data sources. The roll out of the Document Control system has started with all HRA Managers being asked to submit their policies, procedures and guidance documents for inputting on the system. The system will then manage the yearly document reviews, version control and ensure that the most current version is released for publication.

The recent BSI QMS external audit of the QA Department, resulted, once again, in no non-conformities/observations being raised, a significant achievement for which Jane and Nicki deserve note. BSI did positively comment on the work of the Department since the last audit and the full report is contained at appendix 2.

**Developments moving forward**

The major development for the department will be the roll out of ISO 9001 across the whole of the HRA and increase in the present certification scope of ISO 9001:2008. The QA team has published a schedule for HRA wide internal audits for the remainder of 2014/’15 and have been working with colleagues to develop policies, procedures and Standard Operation Procedures (SOPs). The internal QMS audits will audit compliance against policies and procedures, as well as the quality management system with a view to improving further the service offered. Indeed, this is a critical part of seeking HRA wide certification.

In order to support the roll out of ISO 9001:2008 a team of 9 internal auditors has been formed from interested members of staff across HRA departments. A QMS Internal Auditing course has been organised for the beginning of October in order to train members of the team in the necessary skills and then it is envisaged, that after a period of ‘shadowing’, members of the team will be able to undertake QMS audits necessary for the widening scope of ISO 9001:2008.

The Department will be undertaking feedback on specific services including the HRA Queries Line, the new NRES decision letters and Research Summaries with a view to further improvements based upon feedback from users, which currently is adhoc and limited.

The role of the Quality Assurance Management Group (QAMG) is likely to develop and include input from internal auditors, wider contributions from HRA staff colleagues and build upon initiatives such as Staff Feedback and Innovation Facility, a pilot being initiated to allow ideas and suggestions to be emailed through to QA to be routed to the most appropriate manager/group to consider, with importantly QA ensuring that feedback is offered within a timely manner.

The QA team will also be continuing to work closely within the Directorate, on the HRA Approval programme, to support the development to our users.

**Summary / Recommendations**

It is proposed, therefore, that the QA team continues the work of the last year, increasing not only the reach of quality within HRA but also continuing to review the service currently provided and suggest improvements where appropriate.

The Board is requested to:

* Note the substantial achievement of the QA team in securing, once again, an external audit, from BSI, in relation to the continuing ISO 9001 Certification without any non-conformities or observations being raised.
* Note that over the last 12 months or so, in addition to continuing to undertaking business-as-usual activities, the QA team have;
* Met with Directors and Managers to assist them in the delivery/drafting of their policies, procedures and SOPs in preparation for internal audits and for external certification next year,
* Completed a gap analysis of CAG and TOPs as these functions moved within the HRA, developing action plans as appropriate, revised and piloted changes to the Quality Control checklist used by operational colleagues and implemented QC checks for letters and minutes of REC meetings,
* Working with Operational and Policy colleagues to improve the ShED process and conduct a pilot of the changes,
* Undertaken with Operational colleagues a revised User Feedback pilot,
* Developed at an early stage Quality Assurance with the HRA Approval programme,
* Introduced an electronic, Document Management System to record, control, archive and version control HRA policies, procedures, SOPs, etc.,
* Formed the Quality Assurance Management Group, as the Management Review Group (required by ISO 9001), and also to be used as a platform to share good practice across the HRA,
* Successfully recruited to the permanent position of QA Auditor and formed a small team of nine internal auditors from within HRA staff.
* Note and support the work of the QA Team over the next 12 months;
* To widen the ISO 9001 Certification scope from the current QA Department to HRA wide, and the input and support that will be required from all Directors /Managers in preparation,
* To undertake a programme of HRA wide internal audits, with accompanying action plans, where appropriate, with a view to external audit next year,
* Provide training and support as appropriate for the newly appointed QA Auditor and the 9 internal auditors as recruited,
* Undertake a review of the pilot work on ShED and the current User Satisfaction pilot (April – September ’14),
* Further the work on User Feedback to encompass feedback from users of the Research Summaries service and Queries Line.
* Make any observations which the Board envisage would assist the delivery of Quality Assurance across the HRA and further embed a quality driven approach into the business of the HRA.

**Tom Smith**

**17 September 2014**

**Appendix 1 – User Satisfaction Report – Interim April - June 2014**

**Appendix 2 - BSI Assessment Report of 21/07/14**