2013 QCMD EQA Regulatory Range

Regulatory EQA Manual
REGM002-01
Introduction to the QCMD EQA Regulatory Range

The frequency of challenge within an annual EQA survey varies considerably between different EQA providers and the types of EQA schemes they offer. In general the number of EQA distributions or challenges within a calendar year is driven by professional opinion, both scientific and clinical. Key factors include the number of tests the laboratory performs per year; pathogen prevalence; and the range & complexity of tests used. In addition, the EQA provider also has to consider the different needs of the national regulatory agencies and accreditation bodies which sometimes set the minimum number of challenges per year. In response to these requirements QCMD has established the regulatory EQA programmes for HIV, HBV and HCV viral load in order to further support individual laboratory’s local regulatory requirements.

The regulatory programme format will comprise of four challenges per year. Two full EQA panels (8-10 panel members) and two core EQA panels consisting of 4 panel members. The focus of the programmes is on quantitative detection and following each EQA challenge ‘on-line’ reporting will enable participating laboratories to monitor their cumulative performance over time. On completion of the four challenges, laboratories will be provided with an annual summary report. The report will provide an overview of laboratories’ annual performance and where appropriate, feedback aimed at supporting quality improvement in line with the laboratories regulatory requirements.

How will the new format work?

There will be two distributions per year. Each distribution will consist of one full EQA panel and one core EQA panel for each regulatory EQA you have registered for. This means that you participate in two full EQA challenges per year and also two core EQA challenges. An example of the proposed schedule of distributions is provided in table 1.

Table 1: Schedule of distribution for the regulatory EQA programmes in 2013

<table>
<thead>
<tr>
<th>Distribution</th>
<th>Panel</th>
<th>Distribution date</th>
<th>Reporting period</th>
<th>Reporting time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Full EQA – A</td>
<td>Quarter 1 2013</td>
<td>Quarter 1 2013</td>
<td>4 weeks</td>
</tr>
<tr>
<td>1</td>
<td>Core EQA – 1</td>
<td>Quarter 1 2013</td>
<td>Quarter 2 2013</td>
<td>2 weeks</td>
</tr>
<tr>
<td>2</td>
<td>Full EQA – B</td>
<td>Quarter 3 2013</td>
<td>Quarter 3 2013</td>
<td>4 weeks</td>
</tr>
<tr>
<td>2</td>
<td>Core EQA – 2</td>
<td>Quarter 3 2013</td>
<td>Quarter 4 2013</td>
<td>2 weeks</td>
</tr>
</tbody>
</table>

Key to Table 1

- **Distribution** – the number of each distribution.
- **Panel** – The name of each panel.
- **Distribution date** – the quarter that the panels will be distributed to your laboratory.
- **Reporting period** – The quarter that you will be expected to analyse the panel and return results. QCMD will notify you when the analysis and reporting time begins.
- **Reporting time** – the number of weeks your laboratory will have to analyse the panels and return results.

You will receive a series of samples that are designed to resemble clinically significant specimens and/or assess specific analytical assay characteristics. You will be required to test these samples using your routine assay and standard procedures as well as complete a technical questionnaire, which includes questions regarding your laboratory set-up, assay method and procedures. The results from your laboratory testing and answers to the technical questionnaire are reported back to QCMD on-line.

What are the key benefits?

- Higher frequency of challenges per year
- ‘On-line’ reporting enables your laboratory to monitor your cumulative performance over time
- Annual summary report provides an overview of your laboratory’s annual performance, a cumulative score for the annual EQA and trend analysis (continued in future participant rounds)
- Inclusion in full EQA programme Final Reports
How do I register for the regulatory EQA programmes?

You can register for the regulatory EQA programmes through your QCMD participant profile by completing the programme registration form. In some regions QCMD collaborates with a local distributor, who should be contacted in the first instance about registering. Please note participants can register for any of the regulatory EQA programmes they wish to participate in (HIV, HBV and/or HCV viral load).

Testing of the panels and reporting of results

How long will I have to test the panel and report results?

This depends on the panel.

- There are two full EQA panels per year and for these you will have four weeks to analyse the panel and return your results.
- There are two regulatory EQA panels per year and for these you will have two weeks to analyse the samples and return your results.

How do I return results?

You will receive a unique username and password. This allows access to the on-line QCMD IT EQA Management system (QCMD-ITEMs). You can use your profile area to monitor your progress, manage your EQA tasks, report your results and complete the technical questionnaire information, as well as provide feedback to QCMD on aspects of the EQA programme.

If you have difficulty accessing the QCMD-ITEMs on-line, please contact the QCMD Neutral Office.

You have a defined period within which to test and report your EQA results. If you do not report your results within the allotted timeframe you will not be included in the data analysis.

What should I do if I have concerns about my performance in the EQA?

EQA results can assist your laboratory in the identification of quality-related issues. However, you should not overreact if you have concerns about your laboratory’s performance but should take time to review your results in line with other quality measures that you undertake. Initial focus should be on determining whether the issue is due to a reporting error during the results return process. You should make maximum use of the EQA report documents and review your results in line with your performance trends from previous EQAs.

If no reporting errors are found, then the focus should turn to your internal quality control (IQC) information. Where both IQC and EQA are found to be in agreement (i.e. both showing a problem), then you should begin a corrective action procedure in line with ISO 15189. The focus of this investigation should include a review of the performance of different aspects of your assay, such as the extraction procedure or internal calibration. Where the IQC results are as expected but the EQA results indicate a possible issue then you should in the first instance contact QCMD to seek advice.

QCMD can generally assist you in a number of ways. You may request additional materials to test and then review the results of this analysis with QCMD. From an educational perspective and where appropriate, additional assistance may include being put in contact with another laboratory using the same assay so that methods and common issues can be discussed.

Participation in these EQA programmes is designed to support and assist your laboratory’s quality requirements. You should ensure regular ‘quality’ meetings with staff in order to review the results of EQAs and to discuss possible issues and actions needed. This helps to ensure that all members of staff are familiar with your laboratory’s quality practices and also fosters a culture that quality is the responsibility of all as well as identifying areas for continuous improvement.