Audit Guide

MRO Qualifying Criteria
2018 Update

Date: 14 December 2018
Owner: MedCo Audit Committee
Author: MedCo Audit Team

1. Introduction

MedCo Registration Solutions' ('MedCo') IT portal facilitates the sourcing of medical reports in soft tissue injury claims under the 'Pre-Action Protocol for Low Value Personal Injury Claims in Road Traffic Accidents' in England and Wales. It allows registered medical experts, Medical Reporting Organisations ('MROs') and commissioners of medical reports to provide or commission medico-legal reports for RTA soft tissue injury claims.

The MoJ's policy aims which underpin the creation of MedCo are to drive up operational standards and improve the quality of the initial medical evidence used in support of whiplash claims.

MROs who register on MedCo can be categorised as either:

- High Volume National MROs ('HVNs'), with the capability to service high numbers of clients with reports to agreed minimum standards and timeframes; or
- Regionally based MROs ('RBs') that service one or more local markets.

MedCo is committed to ensuring that MROs are properly constituted businesses with satisfactory systems and resources to operate to the minimum required standards. MedCo has therefore instituted an on-going audit programme against the revised MoJ Qualifying Criteria ('QC') issued on 25 October 2016, accompanying MedCo Guidance ('Guidance') issued on 7 November 2016 and updated on 14 May 2018 and applicable Frequently Asked Questions, applicable to:

- All existing MROs;
- All prospective new RB MROs, prior to being set to "live" status on the MedCo Portal; and
- Applications for proposed re-categorisation from RB to HVN status, to evaluate the extent to which they meet the Additional QC (Table 2), prior to being re-categorised on the Portal.

This Audit Guide is published on the MedCo website and distributed by the MedCo Audit Team to MROs when notice has been given that an audit has been scheduled and prior to the first on-site visit.

The purpose of the Audit Guide is to ensure that the audit process is understood, that the nature of the audit and the documents needed for the audit can all be prepared in advance to ensure that the audits can run as smoothly as possible.

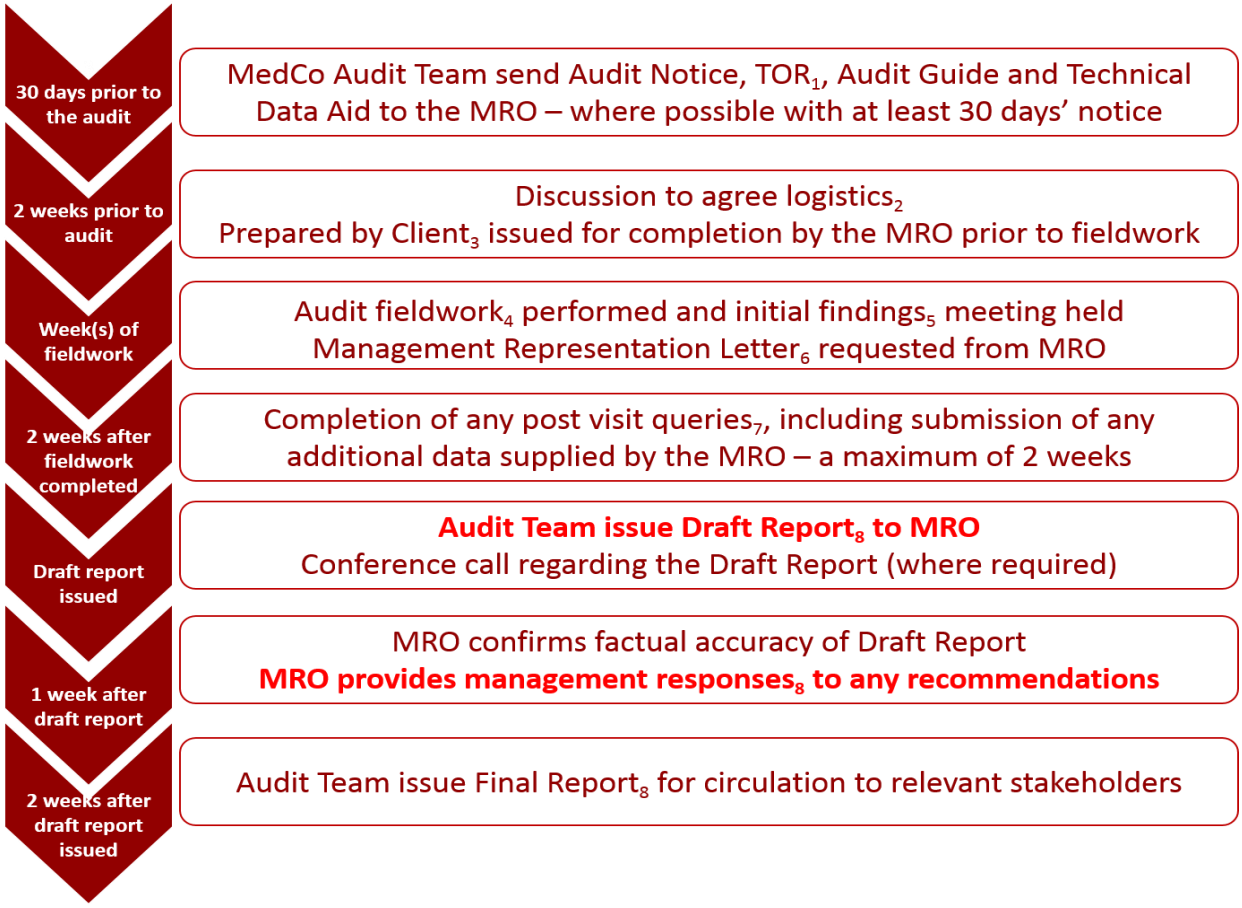
The MRO being audited should review this document and prepare for the audit based on the guidance provided.

MedCo may update the Audit Guide from time to time and whilst this document outlines the process as far as possible, there will inevitably be some circumstances where the process varies slightly or the illustrative timelines vary significantly due to the progress of other audits, changes in the MedCo Audit Team's priorities (at the MedCo Audit Committee's discretion) or unforeseen circumstances. Where any of these is the case the Audit Team will endeavour to keep Auditees informed.

2. Summary of Audit Process & Timelines

2.1. Standard Audit Process

An overview of the key stages in the audit process is shown in the diagram below, with indicative timelines that exclude any time during which the MedCo Audit Team is awaiting information from the MRO and numbered notes that provide further details on certain documents / terms. MROs should note the significance of the stages highlighted in red.



[1] Terms of Reference ('TOR'): This includes the timing and key contacts for the audit. The TOR, Audit Guide and Technical Data Aid are provided to the MRO after issue of the 30 days' audit notice but before the on-site visit.

[2] Discussion to agree logistics: Requests to change the date of our on-site visits to a time outside the range stated in the Audit Notice will only be considered in very limited circumstances. Any unavailability without good reason having been provided is likely to be considered indicative of the MRO's inability to meet the QC and Guidance.

[3] Prepared by Client ('PBC'): A document requesting background details and information about the MRO ahead of the audit, which the MRO should complete and return to the Audit Team prior to the visit.

[4] Audit Fieldwork: We will follow the approach set out at section 3, Audit Approach and conduct at least one on-site visit during our audit fieldwork, the number of visits and duration dependent upon the evidence (see section 4. Audit Evidence) provided by the MRO.

[5] Initial Findings meeting: A findings meeting may be offered at the end of the final on-site visit, if appropriate, e.g. enough information has been gained by the Auditor to make some conclusions, where the Auditor will share details of the audit findings as at that point in time with the Auditee. This meeting will not constitute the sum total of all audit findings, as there may be outstanding queries to be resolved and further queries may arise once the work performed to date has been subjected to management review.

[6] Management Representation Letter: The MRO will be asked to provide a management representation letter i.e. on the MRO's headed notepaper prior to the issue of the draft report. The letter should be addressed to the MedCo Audit Team, dated and signed by at least one MRO Executive Director stating unambiguously:

a) Whether the MRO's Executive Directors and/or senior management:
   i. Are aware of the MoJ's policy intentions in regard to MedCo;
   ii. Have read the applicable QC and the MedCo Guidance;
   iii. Have conducted their own review of the MRO's operations to assess compliance against the QC and Guidance. If so, the conclusions of this review should be clearly authorised; and
   iv. Have fully disclosed and neither withheld from, nor misrepresented to, the MedCo Audit Team any information that could be material to the evaluation of any individual QC criterion.

b) Whether the MRO:
   i. Is independent of any other MRO or non-MRO organisation that services MROs. Any potential connections or relationships that could be seen to compromise the MRO's ability to operate independently, and the nature of them, should be listed; and
   ii. Is part of a common third party ownership model and one or more MROs are within the overall ownership structure. If so, all the MROs in the structure should be disclosed and their role within the structure, in particular the extent to which they operate as standalone entities.
   a) Explanations for specific matters requested by the auditors. This is likely to arise where there is a lack of clarity, consistency or otherwise insufficient evidence on material points.

Failure to provide the management representation letter in whole or part by the time the draft audit report is issued may compromise all evidence provided by the MRO i.e. it will be insufficiently reliable and unsubstantiated, as MRO management do not formally stand behind it. Should any statements in the management representation letter subsequently turn out to be materially incorrect, they will be reported by the MedCo Audit Team to MedCo (see section 7, Post Audit) and, in the opinion of the MedCo Audit Committee, this will constitute evidence of multiple breaches of the Ethics Policy and breach of the MRO User Agreement in terms of co-operation with the audit process.

[7] Post visit queries: The 2-week timescale envisages the MRO properly preparing its evidence so that by the end of the final onsite visit only a small number of queries remain outstanding - see section 4, Audit Evidence, in particular the heading on timescales for providing evidence.

[8] Draft and Final Report: MROs will have one week in which to comment on the factual accuracy of the draft audit report and provide management responses to any recommendations made (see section 5), after which time it can be issued in final form – more details are provided at section 5, Audit Reporting.

2.2. Audit Process for New MRO Registrations

The new registration audit will follow the standard audit process above, except that:

- Pre-Audit checks will be completed by MedCo. These cover (but may not be limited to) company details, certain documentary evidence (e.g. insurances) and confirmations (e.g. accepted MRO User Agreement, declared financial links and read the QC and Guidance);
- Once the audit fee has been paid, the applicant is passed to the MedCo Audit Team:
  - No audit notices are issued, as by applying the applicant accepts than an audit is required;
  - The audit scope will always be all the Minimum QC;
  - If the Pre-Audit checks indicate concerns, in lieu of a full audit, a limited fact-finding telephone call / site visit will be scheduled. The fact-finding call/visit seeks to determine if the applicant has taken any substantive action in relation to the core functions (see Guidance 1.1) and, if not, a full audit will not be performed and the results to date will be set out in a report, as per the standard reporting process;
  - The audit will focus on whether the applicant has all the core functions (see Guidance 1.1) ready to operate from day 1 upon being set to 'live' status on the MedCo Portal;
- Should the Audit Committee approve the applicant's application to be a MRO, upon being set to 'live' status it will immediately be included within the on-going audit programme for existing MROs:
  - The timing for its first 'existing MRO' audit will be after the applicant has been operational for either a set period or has received a set number of instructions, as determined by the MedCo Audit Committee; and
  - The audit focus will be on whether the applicant operates in a manner that is compliant with the QC, as opposed to its intended processes as audited when applying to be a MRO.

2.3. Audit Process for Acquisitions

Audits may also be triggered where a material change takes place affecting an MRO's business such as a change in control through mergers and acquisitions. In that instance the audit will follow the standard process above, except that:

- Where the acquirer entity/group does not own an existing Medco-registered MRO, the acquired MRO will be audited against all the Minimum QC (and Additional QC if a HVN MRO) either at the earliest opportunity once the acquirer has taken control or after a set period as determined by the MedCo Audit Committee; and
- Where the acquirer, as a result of the acquisition of a MedCo-registered MRO, creates a "**common third party (individual and/or corporate) ownership model**" as per the Guidance, all MedCo-registered MROs within this model will be subject to audit as determined by the MedCo Audit Committee.

2.4. Audit Process for Re-Categorisation

The re-categorisation audit will follow the standard audit process above, except that:

- MedCo will perform a pre-qualification check first, to ensure that the MRO is eligible for such an audit. Eligibility refers to the MRO:
  - Meeting the minimum volume of reports and minimum period for sustainability for the SLAs as set out in the Guidance. If these are not met, the request for re-categoriation will be referred to the Audit Committee for determination as to whether any audit work will be undertaken or not.
- No audit notices are issued, as by applying the applicant accepts that some form of audit work is required;

- Where it is accepted by MedCo that the applicant is eligible for a re-categorisation audit, but the MRO's total volume of MedCo and non-MedCo reports in any 12-month period in the last 4 years has not exceeded 10,000 reports, in lieu of a full audit, a limited fact-finding meeting / site visit may be scheduled instead at which:
  - The onus will be on the MRO to demonstrate that it is a credible applicant for HVN status, taking into account the comments in the Guidance for re-categorisation applicants and the evidence requirements set out in the Guidance, this Audit Guide and the Technical Data Aid (see Section 4 Audit Evidence);
  - Applicants that present evidence which does not meet the above standards of evidence are unlikely to be considered credible applicants or to have applied prematurely; and
  - The meeting/visit will seek to determine if the applicant has taken any substantive action in relation to key elements of QC 2.2 and:
    - If so, a full audit will be performed;
    - If not, the results from the fact-finding meeting/visit to date will be set out in a report, as per the standard reporting process, for the MedCo Audit Committee to determine whether it has sufficient information to make a decision on the applicant's re-categoration or whether it requires a full audit to be completed.

2.5. Re-Audit Process

Where a re-audit of the MRO is required, (see Section 7 Post-Audit), it will follow the standard audit process above, except that:

- The Audit Notice is served via the decision letter from the MedCo Audit Committee;
- A "prepared by client" document is optional and at the discretion of the Audit Team dependent on the time since the original audit;
- The scope of the re-audit depends upon the circumstances giving rise to it; and
- The nature of the re-audit will suit the circumstances of each MRO e.g. the status the MRO is seeking to retain / attain, length of time since the original audit and extent of evidence supplied in relation to addressing prior recommendations. It may therefore involve some QC being re-tested in full, some only through recommendations being followed up and others that have not been audited previously.

2.6. 'No Notice' Audits ('NNAs')

NNAs are a mechanism to ensure that MedCo's system of compliance is not undermined by any MROs attempting to game the system or lower their standards in between audits. With the notice provisions of the standard audits it is possible for materially non-compliant MROs to anticipate them and attempt to cover their tracks, which has been encountered on some standard audits to date. However, NNAs can expose such practices and these types of audits act as both a deterrent and an enforcement tool.

NNAs are initiated at the request of the MedCo Audit Committee, based upon one or more known or suspected material breaches of the User Agreement e.g. (not an exhaustive list):

- Material failings in meeting one or more of the core function QC as detailed in the Guidance;
- Failing to disclose material information about its compliance to MedCo or the MedCo Audit Team e.g. operating 'shell' entities or attempting to set up new 'shell' entities;
- Providing evidence to MedCo or the MedCo auditors that is inaccurate, misleading or not authentic;
- Undermining the operation of the MedCo Portal by acting upon another MRO's instructions and/or bypassing or facilitating the bypassing of the MedCo Portal for MedCo-type work; and
- Failing to adhere to the Database Rules.

The information used to initiate NNAs can come from multiple sources including (not an exhaustive list):

- The Audit Team's assessment of the authenticity of the evidence provided by an MRO for its audit;
- Analysis of the cumulative information gained from all the MRO audits to date;
- Analysis of MedCo MI across the system i.e. Users, MROs and experts;
- Specific, credible and verifiable complaints against MROs received by MedCo Enquiries from e.g. Users, MROs, experts, claimants, administrative agencies, regulators and members of the public; and
- The MRO's track record of actions or inactions, as well as those of its owners, directors and any other individual or bofy corporate exerting direct or indirect control over the MRO.

It is for the MedCo Audit Committee to consider the information and to decide based on the information that they have seen whether a NNA should be triggered.

NNAs do not follow the standard audit process or any of the above variations of it, but operate as follows:

- Physical visits will only take place between 10am – 4pm on business days. A visit may be as short as 30 minutes or as long as 6 hours, depending upon the circumstances of the NNA.
- For security purposes, MedCo Audit will send an email to the MRO at the same time as the auditor(s) physically arrive(s) at the MRO's location, confirming that a NNA is being conducted and stating the objective(s) of the NNA and the name(s) of the auditor(s) physically outside:
  - This email will be sent to the MRO's primary and secondary contact details on the MedCo Portal.
  - If in any doubt, the MRO should immediately call the MedCo Audit telephone number (see section 9) and ask to speak to the Audit management team for confirmation.
- The audit approach provisions in section 3 of this guide will apply. However, given the nature of a NNA:
  - The way in which they are deployed may be quite different from that conducted previously.
  - Testing is likely to have a narrower focus but be more in-depth.
- The audit evidence provisions in section 4 of this guide will apply, in particular clause 7.
- A NNA may be conducted in conjunction with a standard audit, should the Audit Team have reasonable suspicions as to the authenticity of the MRO or the evidence provided by it during the audit. In such instances, the MedCo Audit Committee has pre-authorised the MedCo Audit Team to conduct a NNA.
- The Audit Team will report back to the Audit Committee in the format that it considers appropriate for the circumstances of the NNA (e.g. formal report, verbal update, email, memo or as part of a general audit update paper). Where the MedCo Audit Team produce any form of formal report, a draft version will be provided to the MRO for comment in the same manner as for a standard audit report.

As NNAs are designed primarily to investigate suspected breaches of the User Agreement, there is an inherent motivation for a MRO to delay, defer or otherwise obstruct a NNA, which is why the consequences for this are severe, as set out in the User Agreement. Therefore, to prevent any misunderstandings:

- As long as a MRO is trading, it cannot delay or defer a NNA. MROs should ensure that if the owner / director or senior day-to-day manager is on holiday, ill, away on business or otherwise unavailable, that it has a member of staff to operate the MRO in his/her absence capable of hosting any NNA.
- If access to any of the MRO's premises is denied completely or withheld for an unnecessary amount of time to a bona fide (see security check above) member of the MedCo Audit Team, for whatever reason, it will constitute a material lack of co-operation.
- Timing is critical to the MRO's co-operation with the NNA process. Evidence available or not availalble on the day of the NNA has materially more value than any provided subsequent to it.

NNAs may be conducted as isolated audits or as part of a co-ordinated action i.e. multiple NNAs conducted simultaneously in multiple locations on multiple MROs.

2.7. Forensic Audit

Any of the above audit types can be undertaken as a forensic audit. The audit team will undertake an audit on a forensic basis if directed to do so by the Audit Committee. The following situations are examples when the Audit Committee is likely to direct the audit team to undertake a forensic audit:

- Concerns as to the veracity of statements / assertions made to MedCo;
- Reservations as to the authenticity of evidence provided to MedCo by the MRO, including during the audit process;
- Lack of co-operation with MedCo's processes (including actions or lack of actions that interfere with the audit process as set out in this guide); and
- Evidence of seemingly unethical behaviour.

Similar sources of information will be used as for NNAs for assessing whether an audit will be conducted on a forensic basis or not. The decision whether to undertake a forensic audit will be made by the Audit Committee. Where an audit is conducted on a forensic basis, it will follow the applicable audit process for the type of audit being conducted. In addition, the process may involve, but is not limited to, the following more detailed elements:

- The audit may be conducted as an extended on-site visit;
- Official identification documents and other HR records may be requested for all members of staff including members of staff who have left the organisation in the 12 months prior to the audit;
- Details of all related parties (of the MRO's owners, directors and senior managers) that the MRO has a commercial relationship with or which are otherwise involved with its day-to-day operations may be requested;
- All members of staff may be interviewed at least once;
- The audit may use computer assisted audit techniques, for which a complete set of the MRO's MedCo case data, non-MedCo case data (only if provided in support of a HVN application) and expert data for the previous 12 months will be required from all systems utilised in that period, in electronic format, to enable analysis and comparison;
- The system log detailing all system administrator, configuration or equivalent changes to the system and its data may be reviewed for the period under review;
- Full bank statements for all MRO bank accounts and other financial records may be requested; and
- Third party verification may be peformed in relation to instructing parties, experts and suppliers (including software and accountancy suppliers). Permission will be sought from the MRO for the MedCo Audit Team to communicate with third parties.

The onus is on the MRO to provide evidence of its compliance with the QC. If an audit is conducted on a forensic basis and the information requested is not made available to the auditors or is inaccurate, incomplete or misleading it may lead to further action being taken against that MRO including suspension and/or removal from the system.

3. Audit Approach

For clarity, the audit is an assessment of a MRO's compliance against the QC i.e. MedCo must determine whether the MRO is compliant with the QC or not. Whilst MedCo do wish to have co-operative relationships with MROs, the audit itself is not an iterative or collaborative process whereby the MedCo Audit Team assists each MRO to a position of compliance with the QC. It is ultimately for each MRO to demonstrate its compliance to MedCo's satisfaction using its own resources and own advisors; any other interpretation is inconsistent with the function of audit.

The MedCo Audit Team is not authorised to provide advice to assist MROs (existing, new registration or applicants for re-categorisation/re-audit) in meeting the QC in any scenario, prior to the MedCo Audit Committee or Board's audit outcome decision being communicated to them. Thereafter, the MedCo Audit Team may be authorised to provide further, clarification only, information to the MRO, if requested, as to what it still needs to consider to substantiate that it has fully addressed the recommendations raised in the audit report.

MROs are free to operate any business model that suits their business, as long as it complies with the QC. As a result, there may be multiple different ways that MROs can satisfy the same criterion e.g. different processes for managing medical experts (QC 1.13), which is why the MedCo Audit Team does not follow a prescribed approach to the audit. The onus is on each MRO to demonstrate that its way of operating complies with the QC. The MedCo Guidance on the QC sets out what MedCo considers to be best practice. If a MRO follows the Guidance they are likely to receive a GREEN audit rating. If the MRO chooses to demonstrate compliance with the QC in a different way they will need to ensure that they are able to document compliance satisfactorily.

MROs should have relevant resources (systems, data, staff and documents) available during the onsite audit visit(s) and thereafter to promptly address any outstanding queries.

The MedCo Audit Team will:

- Evaluate the evidence provided by the MRO through appropriate audit techniques, including MRO staff interviews, documentation reviews (including contractual arrangements with key suppliers / third parties), system walkthroughs, sample testing, data analysis (including computer assisted audit techniques) and third party verification, from source to the end result;

- Assess the MROs' evidence for consistency with:
  - Its own observations and analysis of the MRO;
  - The MI available to the MedCo Audit Team from the MedCo Portal; and
  - Wider industry approaches to QC compliance based on the MedCo Audit Team's cumulative knowledge gained through its rolling programme of QC audits;

- Apply the standards of evidence set out in the general principles section of the Guidance; further guidance on these are set out in the next section.

- Check with respect to criterion 1.13 that the geographical coverage the MRO states it provides on the MedCo Portal is substantiated by its capabilities, such that it is not undermining the random allocation model by taking up presentation slots that it cannot realistically deliver on if selected; and

- Consider actions such as those below (not exhaustive) as obstructing the audit process, (which may result in the Audit Team conducting a NNA (see section 2) during the standard audit process), and this will be stated in the final audit report and/or any subsequent reports (see section 7. Post-Audit):
  - Withholding access to MRO premises, relevant staff or records, including through arranging for relevant records e.g. bank accounts/payments to be off the premises during a planned audit visit;
  - Providing materially inaccurate, incomplete or misleading information, which may become known either during the audit e.g. conflicting accounts for the same process/activity by different staff in the same MRO or after the audit e.g. statements in the management representation letter about connections with another MRO that only come to light during another MRO's audit;
  - Seeking to influence auditor objectivity e.g. via persistent and inappropriate behaviour or other unprofessional conduct;
  - Attempting to direct the auditors' testing e.g. pre-selecting transactions for auditors to assess;
  - Wasting auditor time e.g. presenting volumes of irrelevant documentation as evidence; and
  - Presenting evidence with material irregularities e.g. documents printed on another MRO's headed notepaper; individual transaction details on the MRO's system (used to calculate MedCo SLAs) that differ from those on the MedCo Portal when they have the same MedCo reference number; and contracts signed on dates when the MRO signatory was not employed by the MRO.

When assessing compliance with the QC, the MedCo Audit Team will look to assess the extent to which control and decision-making ('CDM') in key areas reside within the MRO rather than with a third party, both legally and in practice. CDM in the key areas set out in the QC and detailed in the MedCo Guidance supports the MRO's position as an independent, fully functional entity. For example, if legally CDM resides with the MRO but in practice lies with a third party whose decisions the MRO merely rubber stamps, the MedCo Audit Team will consider CDM for that activity to reside with the third party.

4. Audit Evidence

This section provides guidance to MROs on preparing their evidence to put themselves in the best position they can to demonstrate that they meet the QC.

1) **2 Year Performance History -** Evidence is sought that the MRO meets the QC at the time of the audit and that it can sustain this performance going forward. Evidence for the latter is based on past performance over a maximum of the previous two years. Where revised QC take effect within this timeframe, the revised QC are not applied retrospectively, but the period prior to the revised QC taking effect still provides relevant evidence as to the MRO's ability to meet the revised QC in the future.

2) **Automation -** MROs' records may range from fully manual to fully automated. The nature of the systems has no bearing on the outcome of the audit, as long as the MRO can:
   - Provide the required evidence; and
   - Demonstrate that it understands how its system works (see below) and that they are fit-for-purpose.

   MROs should note that MedCo has requested software demonstrations from the vendors of core MRO systems for the MedCo Audit Team, so that the auditors have an understanding of the extent to which:
   - The system's functionality does or does not support compliance with the QC;
   - MROs need to initiate system actions vs. system taking action automatically; and
   - MROs need to take action separately outside the system.

3) **Information, Supporting Data and Raw Data:**
   - These terms are interpreted as:
     - **Raw data** is transactional data e.g. lists of dates reports were produced by medical experts;
     - **Supporting data** is raw data that has been integrity checked (e.g. duplicate entries removed) analysed and aggregated e.g. number of reports by medical expert by postcode area pa; and
     - **Information** is the output from the interpretation of the supporting data that directly addresses the QC as interpreted in the MedCo Guidance e.g. how many postcode areas have 60% medical consultations in fixed venues.

   - If a MRO provides no data, the wrong data or only **raw data** to the MedCo Audit Team not only will that be considered a failure to provide any audit evidence, but that act itself will be deemed substantive evidence that the MRO does not know whether it meets the relevant QC or not. It would also be considered a breach of the Ethics Policy, should the MRO assert that it has done the appropriate checks to satisfy itself that it is compliant with the QC as it could not have done so if it only had raw data.

   - If a MRO provides relevant **information** it is prima facie evidence, but will only be substantive once the MedCo Audit Team has checked (through sampling of otherwise) its veracity to the original source. MROs must be able to explain and demonstrate how that information was derived via adequate **supporting data**, otherwise the information will be unsubstantiated and will not constitute evidence.

   - MROs are expected to submit complete and accurate information and supporting data to the auditors for each QC, at the first attempt. For the calculation-intensive elements of the QC, where the auditors identify significant flaws they will inform the MRO and the MRO can resubmit its evidence, provided that this is done within a short timescale. If the data is still significantly flawed at the second attempt, then the auditors are not obliged to provide the MRO with further opportunities to submit evidence.

   - In order to facilitate MROs' production of appropriate evidence for all the quantitative metrics, MedCo has produced a separate Technical Data Aid that sets out the key data fields MROs need to obtain from their systems for certain aspects of the QC, in order to ensure that they have the right raw data in the first place, together with the relevant associated supporting data and information. This document is published on the MedCo website.

   Where MROs do not provide appropriate quantification of their performance against the numerical targets in the QC, where straightforward the MedCo Audit Team may attempt to estimate the MRO's performance using the data available in order to give the Audit Committee the best information available to make its decisions.

4) **Data Sets -** Information provided should be based on complete and comparable data sets e.g. a full year – see Technical Data Aid also. Data provided on a selective (e.g. best 6 months), partial (e.g. 25% of instructions) or random basis will be considered to be insufficient and unreliable evidence. Genuine one-off (not recurring) anomalies can arise from time to time and may be excluded where this occurrence and the effect is disclosed. The onus is on the MRO to demonstrate to the MedCo Audit Team's satisfaction that it was fair and appropriate to exclude them.

5) **Information Disclosure -** Disclosure of information that is, or could be, material to the audit should be clearly, explicitly and fairly communicated to the MedCo Audit Team in good time. Where the MRO discloses such information through inappropriate communication methods (e.g. below), it will not be considered to have been disclosed and may also amount to a breach of the Ethics Policy and the MRO User Agreement (in terms of not co-operating with the audit process):
   - Through implication, as a throwaway comment or inappropriate timing e.g. as meetings end;
   - Through inaccurate, misleading or distracting statements;
   - Through partial or total omission;
   - Through illegibility or other communication barriers to understanding the information;
   - In large documents with the key clauses buried in them and no indication of this; and
   - By swamping the auditors with irrelevant documentation that then obscures relevant documents.

6) **Time to provide evidence:**
   - As the onus is on the MRO to provide the evidence, if it fails to produce it within the time periods set out in the standard audit process or not to the appropriate standard (see heading on Information, Supporting Data & Raw Data above), it will be considered as not having provided it;
   - Where new information received suggests that an aspect previously considered compliant might not be, the auditors may extend the timescales of the audit process set out in Section 2. Summary of Audit Process & Timescales, at their discretion, in order to evaluate this as appropriate; and
   - No new evidence on issues raised in the draft audit report will be considered once it has been issued – that is an absolute cut-off. Evidence relating to actions taken by the MRO to close issues highlighted in the draft audit report will however be considered – see Section 5. Audit Reporting.

7) **Resolving Material Inconsistencies / Irregularities**– Where there are concerns about material breaches of the User Agreement e.g. any of the core function QC or links to other MROs, in particular shell entities (see preamble to the QC), the MedCo Audit Team will consider whether these can be resolved during the audit or whether a forensic audit (as set out in Section 2) is required.

   The MedCo Audit Team will try to resolve such concerns during the audit wherever possible e.g. by using unconventional but relevant sources of evidence, but only should a MRO and/or key MRO staff choose to provide it and only if it is provided in an auditable form. Examples (not exhaustive) include:
   - Official identification documents, to dispel doubts as to a person's identity;
   - Corporate social media accounts for Facebook, LinkedIn and Twitter etc. to dispel doubts that the MRO operates in concert with other MedCo-registered MROs or as a subordinate entity; and
   - Professional LinkedIn accounts for the MRO's owners, directors, day-to-day executives and key personnel, to dispel doubts about their employers, business roles and business activities.

   Under no circumstances will evidence derived from personal social media accounts be considered.

5. Audit Reporting

At the end of the audit fieldwork a draft report will be produced that sets out the extent of compliance by exception, with any recommendations outlining what the MRO should do to address any issues raised:

- No new evidence on issues raised in the observations (recommendations section of the draft audit report) will be considered once the draft audit report has been issued – that is an absolute cut-off.

- Individual recommendations are RAG rated based on the level of severity attached to the issues at the time that they were first identified by the MedCo Audit Team. Any actions taken by the MRO to subsequently address these issues will not change these RAG ratings, but the MRO can choose to include these actions in the final audit report by incorporating them into the MRO's management responses for the relevant recommendations.
- Evidence relating to actions taken by the MRO to address issues highlighted in the draft audit report will however be considered and, if sufficient evidence of implementation is provided prior to the audit report being finalised, the recommendation will be marked in the report as "closed–implemented":
  - MROs are not expected or required to have any recommendations with a "closed-implemented" status at the time the final report is issued. In certain cases this may not be possible as onsite visits may be required to assess implementation (see section 7: Post-Audit); and
  - Where a MRO has multiple recommendations raised, the timeframe between draft and final reports does not represent an opportunity for a MRO to effectively attempt to have the audit re-performed.
- If the MRO asserts that it has taken action but no or insufficient evidence has been provided, the recommendation will remain open.

The MRO will be asked to confirm the factual accuracy of the report and provide management responses to each recommendation i.e. whether the recommendation is accepted, and if so, what action the MRO proposes to take / has taken, by when and the person responsible. The MRO will have one week to provide this, with no extensions save in exceptional circumstances. As requested by the MedCo Audit Committee, where any MRO's responses indicate disagreement, the MedCo Audit Team will re-check the evidence provided during the audit against the basis provided for the MRO's disagreement and the MedCo Audit Team may add comments to the final audit report accordingly. The report will then be finalised and issued to the MedCo Audit Committee and the MRO's nominated contacts.

Each report will be RAG rated (see table below), at the MedCo Audit Committee's request, to reflect the MedCo Audit Team's opinion on the MRO's degree of compliance. The MedCo Audit Committee then reaches its own opinion based on the information in the final audit report. MedCo enforces its own rules to ensure that no-one that has a conflict of interests sits on the Audit Committee or has access to any of the individual MRO audit reports or results.

Audit Report RAG Ratings	
Fully compliant:	The available evidence indicates that all relevant criteria are being met.
Substantially compliant:	Most evidence required to indicate compliance is available, with some minor additional actions needed to demonstrate full compliance.
Partially compliant:	Lack of key evidence in several areas indicates that the relevant criteria have not been met.
Substantially non-compliant:	Significant lack of key evidence indicates minimal or non-compliance with most or all relevant criteria.

The MedCo Audit Team will seek open communication with the MRO's nominated contact(s) throughout the audit. However, to avoid undue delay, the MedCo Audit Team reserves the right to issue draft reports as final (with accompanying explanatory notes) where the overall audit rating is RED or AMBER and where:

- Appropriate co-operation from the respective MRO, in the opinion of the MedCo Audit Team, has not been forthcoming or timely; or
- There is disagreement, such that an "agree to disagree" version of the report is issued.

The audit report will not make any comment on what action should or should not be taken by MedCo where a MRO may not be compliant. Such actions are a matter for the MedCo Audit Committee to determine.

6. Audit Outcome

In the context of the objective of each audit (including NNAs), the Audit Committee interprets the RAG ratings produced by the MedCo Audit Team prima facie as follows:

- Overall report ratings: GREEN – pass, RED – fail and AMBER – referred i.e. it is unclear if pass or fail.
- Individual recommendation ratings: GREEN – minor, RED – fundamental and AMBER – significant.

The Audit Committee may decide to RAG rate individual recommendations or the overall report differently to the MedCo Audit Team for the following reasons:

- Based upon the evidence set out in the report, in its opinion an issue may be more or less significant than the MedCo Audit Team considered it to be; and
- It evaluates the RAG ratings at the time it considers the final audit report and therefore the MRO's management responses to each recommendation could influence the Audit 's Committee's view as to whether the original RAG ratings are still applicable at the time it makes its decision.

The Audit Committee considers the following aspects of a MRO's management response to be important (not exhaustive):

- Acceptance by the MRO that breaches of the QC have occurred and that it agrees to address them;
- The MRO has set out clear, credible and achievable actions it will take to address the breaches,
- The MRO has set a realistic timescale by which it expects the outstanding actions to be completed that reflects the importance of compliance with the QC;
- Ownership of the actions has been assigned within the MRO to specific named individuals; and
- Where applicable, the response makes clear which actions (if any) have been completed and whether evidence of completion has been provided to the Audit Team.

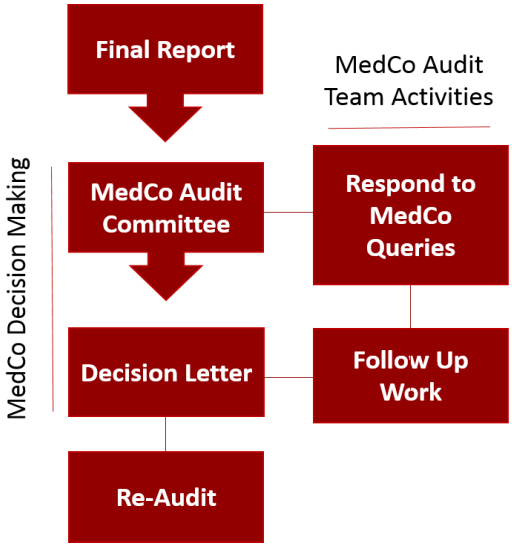
The Audit Committee makes its decision on the MRO's status based on the information contained in the final audit report, which includes the MRO's management responses, and management representation letter. Once the Audit Committee has considered these and reached a decision, that will be communicated by letter to the MRO (the Decision letter – see Section 7: Post-Audit).

There are various decisions that the Audit Committee may make. These include (but are not limited to):

- Concluding that the audit is successful and notifying the MRO;
- Concluding that the audit is successful but that the MRO should be notified of further steps or actions that are required e.g. completion of audit recommendations by specific dates;
- Determining that the audit is unsuccessful and suspending an MRO's access, either entirely or partially (i.e. loss of HVN status) to the MedCo Database for a defined period;
- Requiring that after a defined period of suspension an MRO should undergo re-audit; and
- Determing that the audit is so unsuccessful that they should find that the Agreement between the parties be terminated.

N.B. In order to manage audit resources effectively, the MedCo Board have made a policy decision that when the Audit Committee determine that a MRO should be suspended for a minimum period and require a re-audit, that minimum period should be no shorter than three months. If the MRO is not successful in their re-audit and the suspension remains in place, the second period of suspension should be no shorter than six months.

7. Post-Audit



The following post audit report stages outline the role of the MedCo Audit Team:

1) **Respond to MedCo Queries:** MedCo Audit Team representative(s) attend the MedCo Audit Committee, as required, to present the MRO audit reports to:
   - Clarify any points in the audit reports;
   - Raise relevant matters in the committee discussions to prevent them being overlooked;
   - Highlight comparative issues on other MRO audits;
   - Comment on MRO co-operation with the audit process; and
   - Explain the rationale for the audit ratings.

   The MedCo Audit Team do not:
   - Comment on any matters that are not in the audit reports or management representation letters; or
   - Recommend what course of action MedCo should take.

2) **Decision Letter –** The MedCo Audit Team takes its instructions for each MRO on any follow-up work required (e.g. on open recommendations) and/or rights to re-audit from MedCo's Audit Committee. The Audit Committee's decision and any next steps required will be set out in detail in the Decision Letter sent to the MRO.

3) **Recommendations Follow-Up Work –** Unless a MRO is suspended, the MedCo Audit Team will follow-up with MROs to ascertain the extent to which open recommendations have been implemented. This will be done in line with MROs' specified completion dates and any deadlines set by MedCo, as set out in the Decision Letter. The onus and responsibility is on the MRO to submit evidence of implementation and not for the MedCo Audit Team to chase for it. The level of evidence required to close a recommendation depends upon the RAG rating for each individual recommendation e.g.:
   a. Green rated: A statement from the MRO that it has addressed the point may be sufficient;
   b. Amber rated: Evidence of implementation is required, including the supporting data; and
   c. Red rated: As amber-rated, except that the extent of change might be so significant that an on-site visit is required. This will depend upon the circumstances of each recommendation.

   The MedCo Audit team will inform the MedCo Audit Committee at periodic intervals of the MROs' progress in addressing its recommendations on an exception basis. Unless MROs receive confirmation that specific audit recommendations are closed, they should be considered open.

   Where an MRO has multiple audit recommendations outstanding by their stated due dates, the MedCo Audit Team may request updated management responses from the MRO to accompany the Audit Team's status summary for the MedCo Audit Committee.

4) **All Follow-Up Work (except Recommendations)** – On an exception basis, the MedCo Audit Committee may instruct further work to be completed by the MedCo Audit Team at any point in the audit process once the final report has been issued, including prior to issuing the Decision Letter.

The need for any further work, together with its nature and scope, is at the discretion of the MedCo Audit Committee and is specific to the individual MRO's circumstances. Examples include where:

- A MRO has committed in its final audit report to implementing its recommendations and has subsequently provided evidence of this, which includes sufficient ambiguities that the MedCo Audit Team and/or Audit Committee is uncertain whether the recommendations can be closed or not;
- A MRO asserts repeatedly that the MedCo Audit Team has ignored evidence, used the wrong data or misinterpreted the data. Upon re-assessment of the disputed evidence/data, the implications of any errors that are material to the assessment of one or more of the QC on either side are, if the MRO is proved:
  - Correct, the MedCo Audit Team will revise its final audit report accordingly; or
  - Incorrect, the MRO's assertions will be dismissed by the Audit Committee, which may also query the MRO on its understanding of the QC and ability to meet the evidence requirements for the audit.
- In the opinion of the MedCo Audit Team and/or MedCo Audit Committee, a MRO is believed to have either withheld material information or made materially incomplete, inaccurate or misleading statements in its management representation letter and/or management responses to recommendations. Such facts may only arise after the final audit report has been issued e.g. during the audit of another MRO with which it has more connections than it disclosed.

The MedCo Audit Team will report back to the Audit Committee in the format that it considers appropriate for the query raised (e.g. formal report, verbal update, email, memo or as part of a general audit update paper to the Audit Committee). Where the MedCo Audit Team produce any additional formal reports post the final audit report that introduce any significant new information to that in the final audit report, a draft version will be provided to the MRO for comment in the same manner as the MRO was able to comment on the draft audit report.

5) **Re-Audit –** In circumstances where a MRO accepts MedCo's offer of a re-audit, it must notify Medco Enquiries of this and not the Audit Team. Once received, the MedCo Audit Team will schedule the re-audit for the next available time slot, subject to any minimum waiting periods set out in the Decision Letter. Should the MRO subsequently wish to defer the re-audit, it may do so at any time up until the re-audit commences.

8. Audit Involvement In Escalation Process

The basis for any escalation of an audit decision by a MRO is to disagree with the decision taken by the Audit Committee. That decision will be taken in accordance with the User Agreement. The decision will be taken based on the information in the final audit report and management representation letter. Any progress made by the MRO since the audit is irrelevant to the escalation.

A representative of the MedCo Audit Team may be an attendee at stage 1 or stage 2 escalation meetings at the request of the MedCo representative who will be meeting with the MROs representative.

The role of the audit attendee is to assist in clarifying:

- Any factual matters about the evidence used in the audit, should the MRO query details;
- How the QC were interpreted for the audit report, should the MRO query its application;
- How objectively the audit process was carried out, should the MRO query this;
- Whether evidence provided by the MRO with its management responses to the draft audit report was sufficient for any open recommendations in the final audit report to have been stated as “closed-implemented” instead;
- The validity and significance of any “new” evidence introduced by the MRO at the escalation meetings i.e. that evidence existed at the time of audit but which:
  - Had not previously been provided to the auditors during the audit process;
  - Related to the data and processes in place at the point in time when the audit occurred; and
- The appropriateness of any MRO assertions that have not been substantiated by evidence.

During the escalation process, the MedCo representative may request follow-up work be performed by the MedCo Audit Team. Such requests follow the same process as that set out in section 7. Post-Audit, sub-section (3) and (4).

If, during an escalation meeting on an audit decision, an MRO sets out details of the improvements it has made since the final audit report was issued, then MedCo may take this as evidence that the MRO was not compliant with the QC at the time of audit and therefore the decision made by the Audit Committee was correct at the time that it was made.

9. Contact Us

Please feel free to contact the MedCo Audit Team regarding any questions you may have about this guide, your current audit or whether you have submitted sufficient evidence to close open audit recommendations arising from a previous audit by email at MedcoAudit@mib.org.uk or telephone on 0345 165 2830.

Should you have any queries about your audit, please contact the individual auditors allocated to your audit in the first instance, otherwise the MedCo Audit Team as above. Should any concerns remain unaddressed after this, please contact the Head of MedCo Audit at MedCoAuditManagement@mib.org.uk and if still not resolved, please contract the MedCo Audit Committee.

Any queries about MedCo generally, MedCo Audit Committee / Board decisions about your audit outcome and applying for a re-audit, reor registration on the MedCo Portal should be directed to MedCoEnquiries@mib.org.uk.