QAP AUDIT PROCESS

Revision History:

Revision	Date	Author	Purpose of Revision
A	25-Sep-13	Chuck Hardy	Initial Release
B	09-Jan-14	Chuck Hardy	Removed "8D" from text, added member responsibilities
C	18-Aug-15	Chuck Hardy Kristen Clevidence	Revised international shipping to assure proof of delivery for Canada/International members, Updated text for AMS corrective action system, added Class designations to audit findings.

1.0 Purpose

1.1 The purpose of this document is to define the Quality Assurance Program (QAP) audit process.

2.0 Scope

2.1 This document applies to auditing of QAP dealer members in good standing as defined by NMEDA bylaws and as listed in the AMS.

3.0 Definitions and Acronyms

3.1 AMS – Administration Management System, the system or database used by NMEDA to keep track and record of member's information.

3.2 Audit Coordinator – the representative at the audit firm that is responsible for handling and processing the communications coming from the NMEDA QAP Coordinator (QAPC).

3.3 AF (or Audit Firm) – an independent (third-party) contractor that provides Auditing for the QAP program.

3.4 Audit Finding – see "Findings".

3.5 CAR – Corrective Action Request

3.6 Dealer Member – a mobility equipment dealer that pays dues to and abides by NMEDA bylaws, QAP Rules, and Guidelines.

3.7 Findings – a comment or result that occurred during an audit. This can be a nonconformance that was identified by the auditor or the QAPC during audit review. This may or may not lead to a corrective action or out-of-sequence audit depending on the nature and/or severity of the finding.

3.8 IAW – in accordance with.

3.9 Major – this is a Class 1 finding and requires a formal Corrective Action Request (CAR), but does not require and out-of-sequence audit.

3.10 Major OSAR – A Major Out-of-Sequence Audit Request (OSAR) is a Class 1 finding and requires a formal CAR and an out-of-sequence audit.

3.11 Member types – there are four (4) member accreditation types based on the work the member performs. These include mobility equipment installer, high-tech installer, structural modifier, and a combination of all three.

3.12 Minor – this is a Class 2 finding and a simple action and evidence the finding was closed is satisfactory.

3.13 NMEDA – National Mobility Equipment Dealers Association.

3.14 OFI – Opportunity For Improvement, this is a Class 3 finding and is an indication that there is an opportunity for improvement. There is no action required, however in some instances continuing findings of similar nature can turn an OFI into a Minor finding.

3.15 Out-of-Sequence Audit – this is an audit that is required under certain circumstances such as defined by a corrective action or as the result of a noncompliance/Major finding during a QAP audit.

3.16 OSAR – Out-of-sequence Audit Required (also see Major OSAR).

3.17 QAP – Quality Assurance Program, the program that Dealer members are accredited.

3.18 QAP contact – A requirement of the QAP, this is the single point of contact for QAP related communications for the dealer member.

3.19 QAPC (or QAP Coordinator) – is the person assigned at NMEDA to handle and process all member information related to audits or the audit firm.

3.20 QCM – Quality Control Manual developed by the dealer member and approved by NMEDA.

3.21 UPS – United Parcel Service.

3.22 USPS – United States Postal Service.

4.0 Responsibilities

4.1 NMEDA Quality Control Director - is responsible to oversee the QAP audit program and its execution. This includes creating process documents, hiring the independent audit firm, being the main point of contact with the audit firm when issues need to be resolved, and making recommendations when necessary to QAP standing committee.

4.2 NMEDA QAP Coordinator (QAPC) – is responsible to work with the membership coordinator on collection and archival of membership documents. Reviewing audit reports as they are received. Assigning corrective actions as warranted. Interface with the AF on audit scheduling and any issues that arise from the audit program. Assure that the member information in AMS is up to date. Create reports as requested for audit or audit firm performance. Notify the AF if an out-of-sequence audit is required. Send letters to members when adverse action is being taken.

4.3 Dealer Member (QAP Contact) –is responsible to complete any CARs or actions requested from the NMEDA QAPC, as well as maintain communications throughout the process.

4.4 Audit Firm (AF) – the third party audit firm is responsible to initiate and approve a contract with each QAP dealer member that defines the responsibilities of both the audit firm and the dealer member. Interface with, and schedule all of the audits with the dealer members. This includes maintaining an audit calendar. Hiring qualified auditors. Execute all audits in a timely manner in accordance with the audit schedule and as defined by the audit/inspection process section of the QAP rules. The audit firm shall designate a "audit coordinator" that is the primary interface with the QAPC.

4.5 QAP Standing Committee – is responsible for defining the QAP Rules that are audited.

4.6 NMEDA Board of Directors – is responsible to approve the QAP audit firm, establish audit pricing, and review audit firm performance for the membership.

5.0 Associated Documents

5.1 QAP-101 – NMEDA Quality Assurance Program (QAP) Rules

5.2 QAP-102 – New Dealer Member Accreditation process

5.3 QAP-103 – NMEDA Guidelines

5.4 QAP-F05 – NMEDA QAP Label Order form

5.5 QAP-F06 – Audit Report form

5.6 QAP-F07 – Dealer QAP Feedback form

5.7 QAP-F13 – QAP Accreditation Certificate form

5.8 OPS-002 – NMEDA By-Laws

6.0 Procedure

6.1 Audit Firm Selection and Audit Pricing

6.1.1 The NMEDA Quality Control Director will identify and present to the Board of Directors audit firms independent from NMEDA and capable of performing the duties of the QAP audit program.

6.1.2 The NMEDA Board of Directors will select the audit firm based on capability, experience, performance, and price.

6.1.3 The NMEDA Board of Directors will approve the negotiated price to be paid by the dealer members for each audit including annual and out-of-sequence audits.

6.1.4 The audit firm's performance will be reviewed as described in the contract or statement of work agreed to between NMEDA and the audit firm.

6.2 Audit Frequency

6.2.1 The audit frequency for all dealer member types is annual. Member types are defined in the QAP Rules under Section III "Categories of Accreditation".

6.2.2 Out-of-sequence audits may be assigned as described in section 6.8.

6.3 Audit Scheduling

6.3.1 New Member (Initial) Audit:

Note: this process is completed one time. Skip to section 6.3.2 if the member has already completed the initial audit and is listed as a member in "Good Standing".

6.3.1.1 During the initial membership application and accreditation process, the initial audit will be carried out within six (6) weeks of the NMEDA acceptance of all required paperwork including an approved Quality Control Manual (QCM).

6.3.1.2 The QAPC will notify the audit firm's audit coordinator that it is time to schedule the initial audit.

6.3.1.3 In addition to notifying the AF audit coordinator, the QAPC will send copies of all necessary member information and documents as well as update the AMS database with the planned Audit date.

6.3.2 The audit schedule shall be maintained by the audit firm.

6.3.3 Audits should be scheduled, when practical, at least eight (8) weeks in advance. As a minimum a target month shall be established and communicated on the schedule.

6.3.4 The audit schedule shall be shared with NMEDA either electronically (dynamic) or updated weekly with the QAPC by a means acceptable to both parties.

6.3.5 The QAPC shall keep the AMS updated with all audit scheduling information.

6.4 Audit Procedure

6.4.1 The audit shall be carried out in accordance with QAP Rules [QAP-101] Appendix A.

6.5 Reviewing and Processing Audit Reports

6.5.1 The QAPC will receive the completed audit reports [QAP-F06] within twenty-four (24) hours of the audit from the individual auditors and shall complete a review within five (5) business days of receipt.

6.5.2 The QAPC will interface with the dealer member, the individual auditor, the quality director, or the audit firm to resolve any questions or initial concerns found during the review.

6.5.3 If there are no findings that will require action, log the audit as “no findings” and proceed to section 6.8.

6.6 Audit Nonconformance Processing

6.6.1 When the QAPC identifies and/or concurs with a noncompliance (or finding) in an audit report as recorded by the auditor, the QAPC will determine (or agree with) the severity of the finding using the Audit Finding Matrix (Appendix C of the QAP Rules) as a guide.

6.6.2 To determine the class of the finding the QAPC will first use the Audit Findings Matrix found in the QAP Rules [QAP-101] Appendix C.

6.6.2.1 If the determination for what action is necessary is not found in the QAP Appendix C, the QAPC will consult with the Quality Control Director for determining what course of action will be followed.

6.6.2.2 All findings are categorized by Class. Details as to what actions are required on behalf of NMEDA, the Audit Firm, and the Dealer Member is found in the QAP Rules Appendix C [Audit Findings and Actions Matrix].

6.6.2.2.1 Class 1 – Major finding, including out-of-sequence major (OSAR).

6.6.2.2.2 Class 2 – Minor finding.

6.6.2.2.3 Class 3 – Opportunity For Improvement (OFI).

6.6.3 The QAPC may also consult with the dealer member or the audit firm to gain more information about the finding or any question they may have as a result of the review of the completed audit report.

6.6.4 If it was determined that no additional action on the part of the dealer member is required, proceed to section 6.8.

6.6.5 Once the severity class of the finding has been determined/agreed, the QAPC will perform the following activities:

6.6.5.1 Severity Class 1 – Major OSAR

6.6.5.1.1 This level of severity results in suspension and requires the dealer member to complete a formal Corrective Action. This level of severity also requires and out-of-sequence audit (OSAR).

6.6.5.1.2 Initiate a corrective action request (CAR) through AMS.

6.6.5.1.3 Draft and send a USPS certified letter with return receipt to the US dealer member QAP contact. For international members, a letter will be sent using UPS-Standard with Signature Required.

6.6.5.1.4 The letter shall state that the member is having their QAP accreditation suspended until such time that the deficiencies found are resolved and objective evidence provided (action item closed in AMS).

6.6.5.1.5 The letter shall provide a list and details of the finding/noncompliance(s) found that require action. The letter shall also indicate that an out-of-sequence audit is required. Note: all actions are assigned and completed using AMS (member portal).

6.6.5.1.6 The QAPC shall await the return receipt or delivery/signature confirmation showing delivery of the letter has been confirmed before changing the member status in AMS to “Suspended”. This allows the dealer time to present arguments, or ask for clarifications prior to the adverse action.

6.6.5.1.7 Once the return receipt or delivery/signature confirmation is received by the QAPC and all questions or arguments (if there were any) are resolved, the QAPC shall change the member status in AMS to “Suspended” and send a copy of the letter previously sent to the dealer member to the audit firm’s audit coordinator for their reference and to trigger the AF that an out-of-sequence audit will be required (note: the AF must wait for the CAR to close out before scheduling the OSAR).

6.6.5.1.8 Note: The dealer can follow the appeals process if they think the action is not justified, this typically takes place after the suspension is placed.

6.6.5.2 Severity Class 1 – Major (no out-of-sequence audit required)

6.6.5.2.1 This level of severity results in suspension and requires the dealer member to complete a formal Corrective Action.

6.6.5.2.2 Initiate a corrective action request (CAR) through AMS.

6.6.5.2.3 Draft and send a USPS certified letter with return receipt to the US dealer member QAP contact. For international members, a letter will be sent using UPS-Standard with Signature Required..

6.6.5.2.4 The letter shall state that the member is having their QAP accreditation suspended until such time that the deficiencies found are resolved and objective evidence provided.

6.6.5.2.5 The letter shall provide a list and details of the finding/noncompliance(s) found that require action. AMS shall make it clear the due date for the CAR response.

6.6.5.2.6 The QAPC shall await the return receipt or delivery/signature confirmation showing delivery of the letter has been confirmed before changing the member status in AMS to “Suspended”. This allows the dealer time to present arguments, or ask for clarifications prior to the adverse action.

6.6.5.2.7 Once the return receipt or delivery/signature confirmation is received by the QAPC and all questions or arguments (if there were any) are resolved, the QAPC shall change the member status in AMS to “Suspended” and send a copy of the letter previously sent to the dealer member to the audit firm’s audit coordinator for their reference.

6.6.5.2.8 Note: The dealer can follow the appeals process if they think the action is not justified, this typically takes place after the suspension is placed.

6.6.5.3 Severity Class 2 – Minor

6.6.5.3.1 This level of severity does not result in suspension, but does require some action to be taken.

6.6.5.3.2 Action is assigned, completed, and closed out using AMS.

6.6.5.3.3 The objective evidence can be in the dealers’ format and can include supporting documents, photos, or any other details necessary to satisfy the QAPC that the finding has been resolved.

6.6.5.4 Severity Class 3 – Opportunity For Improvement (OFI)

6.6.5.4.1 This level of severity does not result in suspension, and also does not require any formal action on the behalf of the dealer member. An OFI is used when the auditor/initiator see’s something that is not completely correct, but does not rise to the level of a formal nonconformance or finding.

6.6.5.4.2 OFIs can be used to bring a matter to the attention of the dealer member about a process, observation, or circumstance that could be improved.

6.6.5.4.3 OFIs do not always require the dealer to act, respond, or incorporate suggestions; however there are times when an OFI is used in the same manner as a verbal warning, in that if the dealer does not take any action by the time of a subsequent audit, it could turn into a more severe finding.

6.6.5.4.4 OFIs are intended to allow flexibility and discretion to the auditor and the use of OFIs over formal findings such as Major or Minors will be monitored by the

QAPC. If in any instance the QAPC finds the auditor is abusing the use of OFIs, the QAPC will alert the audit firm coordinator of the alleged frivolous activity and there will be an investigation by NMEDA and the AF to determine if further action is warranted.

6.7 Out-of-sequence Audits

6.7.1 If it was determined that an out-of-sequence audit was warranted, proceed to section 6.7.2, otherwise skip to section 6.8.

6.7.2 The out-of-sequence audit shall be scheduled by the audit firm and shall be completed (carried out) within sixty (60) days of the date shown on the QAPC letter to the dealer member.

6.7.3 If there is any reason the out-of-sequence audit cannot be completed in the sixty (60) day timeframe, the AF audit coordinator shall notify the QAPC with the planned date.

6.8 Issuing Accreditation Certificates

6.8.1 Accreditation certificates [QAP-F13] are only issued when the dealer member successfully passes the audit and under the following conditions:

6.8.1.1 No Findings, or only Minors and/or OFIs – Certificate is issued immediately.

6.8.1.2 Major Findings – Certificate is not issued until corrective actions are closed and "Suspension" status is changed to "Good Standing".

6.8.2 The accreditation certificate is valid for one calendar year from the date of the audit, or the date the QAPC sends the letter to the dealer, whichever is later.

6.8.3 The QAPC inserts the dealer name and location on the certificate along with the appropriate date (the date shows Month and Year only) and signature.

6.8.4 For the initial audit only, the QAPC will ship the accreditation certificate with a wood certificate frame such as (or similar to) the one shown in figure 1, otherwise the certificate is sent alone unfolded in a 9" x 12" (or similar) mailer via standard shipping methods.

[figure 1]

6.9 Dealer QAP Feedback Form Processing

Note: Dealer QAP Feedback forms are voluntary submissions by the dealer members and will not be received for all audits completed. The data on the forms may also be incomplete and be received at random intervals.

6.9.1 The Dealer QAP Feedback form [QAP-F07] shall be left by the auditor with the dealers QAP contact or audit point of contact at the conclusion of the audit.

6.9.2 The auditor shall not require, nor shall the auditor witness or handle the completed form as this could induce bias into the dealer member responses.

6.9.3 Any completed Dealer Audit Feedback forms sent to the QAPC directly from the auditor shall be rejected and not used for performance data measurements. The only feedback forms used for data performance measurements are ones that the dealer has independently sent (via web submission, email, fax, or other means).

6.9.4 In addition to leaving a feedback form with the dealer member, the auditor should make the dealer aware that the feedback can be provided electronically via the NMEDA member web page as an alternate means to faxing it in.

6.9.5 If no feedback form is received within two weeks of the audit completion, the QAPC will send a reminder email or other communication to the dealer member's QAP Contact or designee requesting that the feedback form be completed.

6.10 Updating Audit Information in AMS

6.10.1 The QAPC is responsible for all relevant audit related information in the AMS. This includes but is not limited to:

6.10.1.1 First Audit (Initial Accreditation) Date.

6.10.1.2 Last Audit Date.

6.10.1.3 Next Audit Date (Planned).

6.10.1.4 Next Audit Date (Scheduled).

6.10.1.5 Initiation of any Corrective Actions, including updates.

6.10.1.6 Electronic (paperless) archival of all audit related documents in appropriate dealer member folders.

6.10.1.7 Membership Status updates if suspended and then re-instated.

6.10.1.8 QAP contact validation.

6.10.1.9 24-hour service phone number validation.

6.10.1.10 Adding audits to Audit History.

6.11 Audit Firm Performance

6.11.1 The audit firm's performance is analyzed at a minimum annually at the beginning of the fiscal year by the NMEDA staff and the Executive Director, and reviewed by the QAP committee and/or BOD.

6.11.2 The audit firm contract with NMEDA is used as a basis for any expectations and/or actions.

6.11.3 The NMEDA Executive Director and/or Quality Control Director will provide the results of the analysis to the audit firm, including any actions required.

6.11.4 The BOD has the final decision on any extensions to the AF contract.

7.0 Records

7.1 Records are maintained in accordance with the Records and Retention Policy as stated in the Policies and Procedures Manual (Latest Revision)

8.0 Flowsheet