

Overview of Changes in AMD Quality System Chapter (Chapter 5) Clause-by-clause description of changes from the 2006 AMD – June, 2014

| 2006 AMD section | 2006 AMD Clause # | Changes made in 2014 AMD | 2014 AMD Clause # |
|---------------------------------------|-------------------|---|-------------------|
| Guidance for Use | | Repealed and replaced by Chapter 1 (Introduction) and Chapter 5 (Quality System) | |
| Purpose | - | Repealed and replaced by Chapter 1 (Introduction) and Chapter 5 (Quality System) | - |
| About Shall, Must, Should, May | - | Revised and replaced by Chapter 1 (Introduction) | - |
| Overview of the AMD 2006 | - | Repealed | - |
| Data Confidentiality | - | Repealed and replaced by Chapter 1 (Introduction) | - |
| Review Process for the MRD | - | Repealed and replaced by Chapter 1 (Introduction) | - |
| 0.0 Amendments to the AMD 1989 | | No change | |
| | 0.1.1 | No change. Will be repealed by Chapters 1 (Introduction), 5 (Quality System) and 9 (Reporting) | - |
| | 0.1.2 | | - |
| | 0.1.3 | | - |
| | 0.1.4 | | - |
| 1.0 Application | | Repealed and replaced by Chapter 1 (Introduction) | |
| 1.1 General | | | |
| | 1.1.1 | Revised and replaced by Chapter 1 (Introduction) | Int 1-A |
| | 1.1.2 | Revised and replaced with clause to require compliance with the AMD, contained in Chapter 1 (Introduction), and replaced “environmental” with “air” | Int 1-B |
| | 1.1.3 | No change (provides effective date for 2006 AMD) | 1.1.3 |
| 2.0 Quality System | | Entire section is repealed and replaced by Chapter 5 (Sections 1.0 through 9.0), except Calibration section (clauses 2.9.34 to 2.9.48) | |
| 2.1 Application of the Quality System | 2.1.1 | Repealed and replaced as guidance in Purpose section | - |
| 2.2 Implementation | 2.2.1 | Revised and replaced in Chapter 5 Section 2.0 (Quality System) | QS 2-A |
| | 2.2.2 | Revised and replaced (date for compliance) | QS 1-A |
| | 2.2.3 | No change | QS 2-B |
| | 2.2.4 | Revised and replaced in QS 2-A | QS 2-A |
| 2.3 Administrative Requirements | | | |
| | 2.3.1 | Repealed and replaced as guidance in Chapter 5 Section 6.0 (Resources) | - |
| | 2.3.2 | Revised with wording changes | QS 6-A |
| 2.4 Document Control | | Repealed and replaced in Chapter 5 Section 3.0 (Document, Record and Data Management) | |
| | 2.4.1 | Revised and replaced with added requirement for “documented | QS 3-A |

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| | | procedures” and former 2.4.1 (iv) repealed and replaced as clause QS 3-B | QS 3-B |
| | 2.4.2 | Revised with minimal wording change | QS 3-D |
| | 2.4.3 | No change | QS 3-C |
| | 2.4.4 | Revised with added requirements for changes to controlled documents and “documented procedures” | QS 3-B |
| | 2.4.5 | Revised with minimal wording changes and replaced with QS 3-E and QS 3-F | QS 3-E QS 3-F |
| | 2.4.6 | Revised and incorporated into QS 3-F | QS 3-F |
| | 2.4.7 | Revised and incorporated into QS 3-F and QS 4-E; and replaced “internal audits” with “audits” | QS 3-F QS 4-E |
| NEW Requirement for identification, storage, protection, retrieval, retention, and disposition of records | | | QS 3-F |
| | 2.4.8 | No change | QS 3-G |
| | 2.4.9 | No change | QS 3-H |
| NEW Requirement for when corrections are made to records | | | QS 3-J |
| | 2.4.10 | Revised with minimal wording change | QS 3-K |
| | 2.4.11 | Revised with added requirement to implement and maintain documented procedures | QS 3-L |
| | 2.4.12 | No change | QS 3-M |
| | 2.4.13 | Revised Removed bullet (a) from regarding control of records and replaced with modification of equipment or software in QS 6-K | QS 3-I QS 6-K |
| | 2.4.14 | No change | QS 3-N |
| | 2.4.15 | No change | QS 3-O |
| 2.5 Internal Audits | | Now appears in Chapter 5, Section 4.0 (Inspection and Audit) | |
| | 2.5.1 | Revised with added “inspections” | QS 4-A |
| | 2.5.2 | No change | QS 4-B |
| | 2.5.3 | No change and incorporated into QS 4-B | QS 4-B |
| NEW Requirement for internal inspections (to plan/schedule) and added guidance | | | QS 4-C |
| | 2.5.4 | Revised and replaced “internal audits” to “audits” | QS 4-D |
| | 2.5.5 | Revised and replaced “internal audits” to “audits” and added “inspections” | QS 4-E |
| | 2.5.6 | Revised and replaced with wording changes to 2.5.6 (a) and (b) and added “inspections” | QS 4-F |
| | 2.5.7 | Revised and replaced by Chapter 5, Section 5.0 (Corrective Action) clause QS 5-A(v) | QS 5-A |
| | 2.5.8 | Revised and replaced “internal audits” to “audits” | QS 4-G |
| | 2.5.9 | No change | QS 4-H |
| 2.6 Non-compliance, Preventative, and Corrective Action | | Now appears in Chapter 5, Section 5.0 (Non-Compliance, Preventive and Corrective Action) | |
| | 2.6.1 | Revised and replaced to not only specify who will be | QS 5-A |

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| | | responsible, but to require that a documented process be in place for handling, investigating and identifying root cause of non-compliance, as well as commencing corrections. | |
| | 2.6.2 | Repealed clause 2.6.2 (ii). Revised and replaced other clauses with added (QS 5-B (vi)) verification activities to evaluate effectiveness of corrective action. 5-B deals with preventive or corrective action. | QS 5-B |
| 2.7 Subcontracting of Environmental Monitoring and/or Reporting | | Now appears in Chapter 5, Section 6.0 (Resources) | |
| | 2.7.1 | No change | QS 6-G |
| 2.8 Purchasing of Services and Supplies | | Now appears in Chapter 5, Section 6.0 (Resources) | |
| | 2.8.1 | No change | QS 6-H |
| | 2.8.2 | Revised and replaced with “all monitoring conducted” | QS 6-I |
| | 2.8.3 | Repealed and incorporated into QS 3-F (former 2.4.5) – maintaining records for all monitoring and maintenance activities | QS 3-F |
| 2.9 Technical Requirements | | Now appears in Chapter 5, Sections 6.0 (Resources), 7.0 (Air Monitoring Methods), 8.0 Calibration, and 9.0 Sampling | |
| | 2.9.1 | Revised and replaced in QS 6-A (was 2.3.2) and guidance in Section 6.0. | QS 6-A |
| | 2.9.2 | No change | QS 6-B |
| | 2.9.3 | Revised and replaced in bullet (iii) under QS 6-B (former 2.9.2) | QS 6-B |
| | 2.9.4 | Revised and replaced with added requirements for personnel to be aware of both the AMD and the Quality System | QS 6-C |
| | 2.9.5 | Revised and replaced with wording changes in QS 6-D 2.9.5(c) was repealed | QS 6-D |
| | | NEW Requirement for person responsible to retain all responsibility of subcontractors | QS 6-E |
| | | NEW Requirement for person responsible to verify that subcontractor meets AMD and Quality System | QS 6-F |
| | 2.9.6 | Repealed and replaced in QS 3-E | - |
| | 2.9.7 | Revised and with added requirement that procedure be documented within QAP – added to QS 6-J (ii) | QS 6-J |
| | 2.9.8 | Repealed as cannot control environmental conditions. QS 6-J requires that procedures be established, implemented and maintained for the operation and maintenance of all monitoring equipment, according to the specs of the equipment. | - |
| | 2.9.9 | Repealed as these clauses specify how, rather than specifying that, a procedure for a QAP be developed. QS 6-J specifies that | - |
| | 2.9.10 | procedures be established, implemented and maintained for the operation and maintenance of all monitoring equipment. QS 7-A and QS 7-C require that monitoring methods be documented and must use methods specified in the AMD. | - |
| | 2.9.11 | | - |
| | 2.9.12 | | - |
| | 2.9.13 | Revised and replaced with added requirement of identification and calibration of relevant monitoring equipment | QS 6-J (i,ii) |
| | 2.9.14 | Revised and replaced in 2.9.13 (QS 6-J (iii)) and refers to QS 9- | QS 6-J |

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| | | B | (iii) |
| | 2.9.15 | Repealed as is required in QS 3-A and QS 3-B (former 2.4.1 and 2.4.2) for documents to be maintained and available. | - |
| | 2.9.16 | Revised and replaced (a) into QS 6-J. Repealed (b) through (h) as QS 3-E, 3-F and 3-G require all relevant records be kept, including those pertaining to equipment specs, performance, maintenance, etc. and documents be controlled and available. | QS 6-J - QS 3-E QS 3-F QS 3-G |
| | 2.9.17 | Revised and replaced in QS 6-J (iv) and (v) regarding approach of documenting procedures. | QS 6-J (iv), (v) |
| | 2.9.18 | Repealed and replaced in non-compliance clauses in Chapter 5 section 5.0 (former Section 2.6) | - |
| NEW Requirement for validation of equipment/software that is modified; refers to QS 7-D and 7-E | | | QS 6-K |
| | 2.9.19 | Repealed as the AMD doesn't prescribe many "monitoring methods" | - |
| | 2.9.20 | Revised and replaced with requirement for <u>all</u> monitoring methods to be accurately documented, to reflect intent of Section 7.0 (monitoring methods). "All phases" of activities is required in comprehensive Quality System (QS 2-A and 2-B) | QS 7-A |
| | 2.9.21 | Repealed and replaced by QS 7-C (former 2.9.23) and QS 7-D and F on not deviating from specified methods and associated note moved to under QS 7-C | QS 7-C QS 7-D QS 7-F |
| | 2.9.22 | Repealed and replaced by QS 6-B (former 2.9.2) on ensuring personnel have proper, up to date training, as well as QS 6-A and 6-D regarding personnel competence and documentation | QS 6-A QS 6-B QS 6-D |
| | 2.9.23 | Revised and replaced with reference of validation from clauses QS 7-D and 7-E | QS 7-C |
| | 2.9.24 | Revised and replaced in QS 7-A (former 2.9.20) on documenting procedures for all monitoring activities | QS 7-A |
| | 2.9.25 | Revised and replaced with added requirement of anything else required by Director | QS 7-B |
| | 2.9.26 | Repealed and replaced with clauses QS 7-A,B, E and F (former 2.9.19, 2.9.20, 2.9.23 and 2.9.28) requiring alternate monitoring methods be validated and approval be attained | QS 7-A, B, E and F |
| | 2.9.27 | Repealed and replaced with QS 7-C (former 2.9.23) which requires that justification be provided for change in monitoring method | QS 7-C |
| | 2.9.28 | No change | QS 7-D |
| | 2.9.29 | Repealed as "validation protocols" do not exist and QS 7-D (former 2.9.28) requires methods be validated to confirm suitability | - |
| | 2.9.30 | Repealed as "validation protocols" do not exist and clause QS 7-D (former 2.9.28) covers requirements | - |
| | 2.9.31 | Revised and replaced with requirement to document procedure to record the protocol used to validate monitoring method (will help when deciding whether to approve alternate method) | QS 7-E |
| | 2.9.32 | Repealed uncertainty of measurement requirements. Estimates of monitoring method and equipment uncertainty are available from the manufacturer and should be documented as per records management clauses. Lab analysis uncertainty should be | - |
| | 2.9.33 | | - |

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| | | attained from the lab performing the analysis. Added guidance in section 7.0 recommending that measurement uncertainty be estimated when a new method is used or a method is modified. Example of how to estimate uncertainty added to Appendix. | |
| | 2.9.34 | No change. Will be replaced by revised Calibration Chapter (Chapter 7) | - |
| | 2.9.35 | Revised and replaced to include “all” monitoring equipment | QS 8-A |
| | 2.9.36 | Revised and replaced and linked to QS 7-C (monitoring methods) | QS 8-B |
| | 2.9.37 | No change. Will be replaced by revised Calibration Chapter (Chapter 7) | - |
| | 2.9.38 | No change. Will be replaced by revised Calibration Chapter (Chapter 7) | - |
| | 2.9.39 | Revised and replaced with added requirement for updating data records. | QS 8-C |
| | 2.9.40 | No change. Will be replaced by revised Calibration Chapter (Chapter 7) | - |
| | 2.9.41 | No change. Will be replaced by revised Calibration Chapter (Chapter 7) | - |
| | 2.9.42 | No change. Will be replaced by revised Calibration Chapter (Chapter 7) | - |
| | 2.9.43 | No change. Will be replaced by revised Calibration Chapter (Chapter 7) | - |
| | 2.9.44 | Text modified slightly | QS 8-D |
| | 2.9.45 | No change. Will be replaced by revised Calibration Chapter (Chapter 7) | - |
| | 2.9.46 | No change. Will be replaced by revised Calibration Chapter (Chapter 7) | - |
| | 2.9.47 | No change. Will be replaced by revised Calibration Chapter (Chapter 7) | - |
| | 2.9.48 | Repealed and replaced with QS 6-E and 6-F on subcontractors | QS 6-E QS 6-F |
| | 2.9.49 | Repealed and replaced as guidance at start of Section 9.0 | - |
| | 2.9.50 | Text modified slightly | QS 9-A |
| | 2.9.51 | Repealed the detail on sampling plan and need for obtaining written authorization. | - |
| | 2.9.52 | Sampling for passives and other non-continuous will be described in the Monitoring Chapter (Chapter 4) of the AMD. | - |
| | 2.9.53 | Detailed requirements for non-routine monitoring are being drafted by the Monitoring Agency. | - |
| | 2.9.54 | Repealed and replaced as guidance after QS 9-A | - |
| | 2.9.55 | Repealed as per 2.9.51 | - |
| | 2.9.56 | Revised and replaced to include traceability of the sample | QS 9-B |
| | 2.9.57 | No change | QS 9-C |
| | 2.9.58 | No change | QS 9-D |
| | 2.9.59 | Revised and replaced with added reference to QS 9-C (former 2.9.57) | QS 9-E |

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| NEW Requirement for use of ESRD Lab Data Quality Assurance Policy | | | QS 9-F |
| New Section in QS - 10.0 Evaluation and Improvement | | | |
| NEW Requirement for process for regular evaluation of Quality System | | | QS 10-A |
| NEW Requirement for continually improving effectiveness of Quality System | | | QS 10-B |
| 3.0 Reporting Requirements | | No change. Entire section will be repealed and replaced once revised Reporting Chapter (Chapter 9) is complete. | - |
| Appendix A Definitions | | Repealed and replaced with definitions in AMD Chapter 1 (Introduction) | - |