

EMCBC QA RECORDS IDENTIFICATION MATRIX

(Based on NQA-1-2008 with addenda through 2009)

Approved: _____

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Date: _____

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NQA-1 Requirements and Applicable QA Records

Requirement 1 – Organization

Requirement 2 – Quality Assurance Program

500 Records

Records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records. Records of indoctrination and training shall include one or more of the following:

- (a) attendance sheets
- (b) training logs
- (c) personnel training records

The employer shall establish and maintain records for indoctrination and training; Auditor and Lead Auditor qualification and requalification; and inspection and test personnel qualification and requalification.

- Quality Assurance Program QAP/QIP
- Quality Assurance Program Implementing Documents
- Qualification of Quality Assurance Assessment Personnel

Requirement 3 – Design Control

900 Documentation and Records

Design documentation and records shall include not only final design documents, such as drawings and specifications, and revisions to those documents, but also documentation that identifies the important steps in the design process, including sources of design inputs that support the final design.

- Not Applicable

Requirement 4 – Procurement Document Control

Requirement 5 – Instructions, Procedures, and Drawings

Requirement 6 – Document Control

Requirement 7 – Control of Purchased Items and Services**800 Records**

Records shall be established and maintained to indicate the performance of the following functions:

- (a) supplier evaluation and selection
- (b) acceptance of items or services
- (c) supplier nonconformances to procurement document requirements, including their evaluation and disposition

- Review, Approval, and Assessment of QAPs/QIPs

Requirement 8 – Identification and Control of Items**Requirement 9 – Control of Special Processes****400 Records**

Records shall be maintained as appropriate for the currently qualified personnel, processes, and equipment of each special process.

- Not Applicable

Requirement 10 – Inspection**800 Records**

Appropriate records shall be established, maintained, and, as a minimum, identify the following:

- (a) item inspected
- (b) date of inspection
- (c) inspector
- (d) type of observation
- (e) results or acceptability
- (f) reference to information on action taken in connection with nonconformances

- Not Applicable

Requirement 11 – Test Control**600 Test Records**

Test records shall be established and maintained to indicate the ability of the item or computer program to satisfactorily perform its intended function or to meet its documented requirements.

Test records vary depending on the test type, purpose, and application, but shall contain the following information, as a minimum,

for the specified application identified in paras. 601 and 602.

601 Test Records

- (a) item tested
- (b) date of test
- (c) tester or data recorder
- (d) type of observation
- (e) results and acceptability

- (f) action taken in connection with any deviations
- (g) person evaluating test results

602 Computer Program Test Records

- (a) computer program tested including system software used
- (b) computer hardware used
- (c) test equipment and calibrations, where applicable
- (d) date of test
- (e) tester or data recorder
- (f) simulation models used, where applicable
- (g) test problems
- (h) results and applicability
- (i) action taken in connection with any deviations noted
- (j) person evaluating test results
- (k) acceptability

- Not Applicable

Requirement 12 – Control of Measuring and Test Equipment

400 Records

401 General

Records shall be established and maintained to indicate calibration status and the capability of measuring and test equipment to satisfactorily perform its intended function.

402 Reports and Certificates

Calibration reports and certificates reporting the results of calibrations shall include the information and data necessary for interpretation of the calibration results and verification of conformance to applicable requirements.

- Not Applicable

Requirement 13 – Handling, Storage, and Shipping

Requirement 14 – Inspection, Test, and Operating Status

Requirement 15 – Control of Nonconforming Items

Requirement 16 – Corrective Action

Requirement 17 – Quality Assurance Records

Requirement 18 – Audits**800 Records**

Audit records shall include audit plans, audit reports, written replies, and the record of completion of corrective action.

- Quality Assurance Program Assessment Schedules
- Quality Assurance Program Management Assessments
- Quality Assurance Program Independent Assessments
- Quality Assurance Program Corrective Action