DATA ACCEPTANCE PROGRAM

Requirements for ANSI/AAMI ES 60601-1:2005 and ANSI/AAMI ES 60601-1:2005 & A1:2012

Executive Summary:

ANSI/ AAMI ES 60601-1:2005 and ANSI/AAMI ES 60601-1:2005 & A1:2012 requires a manufacturer to have in place a Risk Management process, and further, to use their Risk Management process to define new tests and modify existing tests, as applicable.

ISO 17025 includes requirements for customer agreement to the use of non-standard methods for testing (Clause 5.4.4) and for validation of non-standard test methods (Clause 5.4.5); these requirements can be applied to non-standard test methods developed under an ISO 14971 Risk Management process to allow the acceptance of non-standard test methods under a Data Acceptance Program.

The Data Acceptance Program (DAP) has developed guidelines for the application of Risk Management for DAP participants with ANSI/AAMI ES 60601-1:2005 and ANSI/AAMI ES 60601-1:2005 & A1:2012 within their scope of participation. See appendices to this document for details.

APPENDIX A

Procedure for Inclusion of ANSI/AAMI ES 60601-1:2005 and ANSI/AAMI ES 60601-1:2005 & A1:2012 Standard Test Methods

For a test laboratory to be able to submit test data under a Data Acceptance Program, the test laboratory must have the applicable ANSI/AAMI ES 60601-1:2005 and ANSI/AMMI ES60601-1:2005 & A1:2012 standard test methods within their scope of participation. This can be accomplished during the annual DAP assessment or with a scope expansion project to validate laboratory knowledge of test requirements and the proper conduct of standard test methods.

Responsibility – DAP Assessment Personnel†

Conduct test method validation for applicable tests of ANSI/AAMI ES 60601-1:2005 and ANSI/AAMI ES 60601-1:2005 & A1:2012 and update the test laboratories scope of participation, as appropriate.

Responsibility – Test Laboratory

Demonstrate knowledge of test requirements and the proper method to conduct standard test methods during the annual DAP assessment or scope expansion project.

Optional – Should non-standard test methods be used to support UL Certification of product, determine how compliance to ISO17025, Clauses 5.4.4 & 5.4.5 can be documented within the test laboratories QMS. To be performed only if the manufacturer/test laboratory (as applicable) is preparing for future acceptability of non-standard test methods.

†DAP Assessment Personnel may include Lead Auditor and Technical Auditor, as applicable.

APPENDIX B

Procedure for Use of ANSI/AAMI ES 60601-1:2005 and ANSI/AAMI ES 60601-1:2005 & A1:2012 Non-Standard Test Methods (typically defined by a Risk Management Process)

Responsibility – DAP Assessment Personnel†

Qualified DAP Personnel is to confirm compliance with the following Clauses of ISO 17025 during the annual DAP assessment of the test laboratory:

- 5.4.4 – Non-standard methods
- 5.4.5 – Validation of test methods

Verification of compliance with these clauses is to be included in the DAP annual assessment records for the test laboratory.

†DAP Assessment Personnel may include Lead Auditor and Technical Auditor, as applicable.

Responsibility – Manufacturer/Test Laboratory

The written documentation providing technical justification and validation of the non-standard test methods and the authorization and acceptance from UL CAS Personnel prior to testing is to be recorded in the Manufacturer's device history file. The test laboratory (if different than the manufacturer) will need to have access to these records for review during the annual DAP assessment.

NOTE (Informative):

Since the technical justification for the use of non-standard test methods would target a specific product, it is encouraged that the Risk Management requirements of ISO 14971 are fully implemented prior to development of the technical justification.

This may be achieved through:

- Training
- ISO 14971 Gap Analysis
- ISO 14971 Registration Audit

Responsibility – CAS Personnel

The manufacturer/test laboratory shall provide *CAS Personnel* written documentation providing technical justification and validation of the non-standard test methods being considered. *CAS Personnel* shall review the documentation and/or witness the conduct of non-standard test methods to determine:

- Compliance with Clause 4.2 of ISO 14971 following the technical discussion process documented in the Guidance Document 00-HS-G0400.

- Test laboratory's staff must demonstrate (see ISO 17025 Cl. 4.1.5, 5.2 and 5.4.5):
  - knowledge of the test requirements, and
  - the ability to properly conduct the non-standard test method

- The test laboratory has the appropriate (see ISO 17025 Cl. 5.3, 5.4 and 5.5):
  - environmental accommodations,
  - power capability, and
  - calibrated test equipment for the non-standard test

If the justification is found acceptable, *CAS Personnel* shall provide written authorization and acceptance to the manufacturer/test laboratory prior to testing and update the client laboratory's scope of participation accordingly.

The non-standard test a method technical justification shall be documented in the 60601-1 TRF as Objective Evidence (records) for the applicable ISO 14971 and ISO 17025 clauses. Datasheet packages submitted for UL certification shall document the non-standard test method and other applicable requirements to comply with UL's Data Recording & Reporting Requirements.

APPENDIX C

Procedure for Use of ANSI/AAMI ES 60601-1:2005 and ANSI/AAMI ES 60601-1:2005 & A1:2012 Non-Standard Test Methods for Additional Products

Responsibility – CAS Personnel

The manufacturer/test laboratory shall provide *CAS Personnel* written documentation providing technical justification for application of the previously reviewed non-standard test method(s) to the device in question. *CAS Personnel* shall review the documentation to determine:

- Compliance with Clause 4.2 of ISO 14971 following the technical discussion process documented in the Guidance Document 00-HS-G0400.

That is, an assessment shall be made to determine, through review of the Risk Management File, the appropriate application of the non-standard test method to insure safety and essential performance of the device in question. If application of the non-standard test method to the device in question is found acceptable, *CAS Personnel* shall provide written authorization and acceptance to the manufacturer/test laboratory prior to testing.

The non-standard test method technical justification and validation shall be documented in the 60601-1 TRF as Objective Evidence (records) for the applicable ISO 14971 and ISO 17025 clauses. Datasheet packages submitted for UL certification shall document the non-standard test method and other applicable requirements to comply with UL's Data Recording & Reporting Requirements.

Responsibility – Manufacturer/Test Laboratory

The manufacturer/test laboratory is to apply the non-standard test method to the device in question in support of their certification project, following all applicable DAP procedures and policies as typically applied to a standard test method, as well as any additional or supplementary procedures and policies previously agreed to as being necessary to support application of the non-standard test method.

The written documentation providing technical justification for application of the test method(s) and the authorization and acceptance from the CAS Personnel prior to testing is to be recorded in the manufacturer's device history file. The test laboratory (if different than the manufacturer) will need to have access to these records for review during the annual DAP assessment

END OF DOCUMENT