DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

ASCA Definitions and References

DEFINITIONS

- **ACCREDITATION**
  Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks [ISO/IEC 17000:2004, clause 5.6]
- **ACCREDITATION SCHEME**
  Rules and processes relating to the accreditation of conformity assessment bodies to which the same requirements apply [ISO/IEC 17011:2017, clause 3.8]
- **ATTESTATION**
  Issue of a statement, based on a decision following review, that fulfilment of specified requirements has been demonstrated [ISO/IEC 17000:2004, clause 5.2]
- **CERTIFICATION**
  Third-party attestation related to products, processes, systems or persons [ISO/IEC 17000:2004, clause 5.5]
- **CONFORMITY ASSESSMENT**
  Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled [ISO/IEC 17000:2004, clause 2.1]
- **CONFORMITY ASSESSMENT SCHEME or CONFORMITY ASSESSMENT PROGRAM**
  Conformity assessment system related to specified objects of conformity assessment, to which the same specified requirements, specific rules and procedures apply [ISO/IEC 17000:2004, clause 2.8]
- **CONFORMITY ASSESSMENT SYSTEM**
  Rules, procedures and management for carrying out conformity assessment [ISO/IEC 17000:2004, clause 2.7]
- **CONSULTANCY**
  Participation in any of the activities of a conformity assessment body subject to accreditation [ISO/IEC 17011:2017, clause 3.34]
- **ESSENTIAL PERFORMANCE**
  Performance of a clinical function, other than that related to BASIC SAFETY, where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable RISK
  NOTE ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK.
  [ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, clause 3.27]
- **HARM**
  Physical injury or damage to the health of people or animals, or damage to property or the Environment [ISO 14971:2007, definition 2.2, modified]
- **INTENDED USE or INTENDED PURPOSE**
  Use for which a product, PROCESS or service is intended according to the specifications, instructions and information provided by the MANUFACTURER [ISO 14971:2007, definition 2.5]
- **INTERLABORATORY COMPARISON**
  Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions [ISO/IEC 17025:2017, clause 3.3]
- **LABORATORY**
  Body that performs one or more of the following activities:
  — Testing;
  — Calibration;
  — Sampling, associated with subsequent testing or calibration

[ISO/IEC 17025:2017, clause 3.6]

- **NONCLINICAL LABORATORY STUDY**
  In vivo or *in vitro* experiments in which test articles are studied prospectively in test systems under laboratory conditions to determine their safety. The term does not include studies utilizing human subjects or clinical studies or field trials in animals. The term does not include basic exploratory studies carried out to determine whether a test article has any potential utility or to determine physical or chemical characteristics of a test article [21 CFR 58 Good Laboratory Practice for Nonclinical Laboratory Studies, Sec. 58.3 (d)]
- **PROFICIENCY TESTING**
  Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons [ISO/IEC 17025:2017, clause 3.5]
- **RISK**
  Combination of the probability of occurrence of HARM and the SEVERITY of that HARM [ISO 14971:2007, definition 2.16]
- **RISK ANALYSIS**
  Systematic use of available information to identify HAZARDS and to estimate the RISK [ISO 14971:2007, definition 2.17]
- **RISK ASSESSMENT**
  Overall PROCESS comprising a RISK ANALYSIS and a RISK EVALUATION [ISO 14971:2007, definition 2.18]
- **RISK CONTROL**
  PROCESS in which decisions are made and measures implemented by which RISKS are reduced to, or maintained within, specified levels [ISO 14971:2007, definition 2.19]
- **RISK EVALUATION**
  PROCESS of comparing the estimated RISK against given RISK criteria to determine the acceptability of the RISK [ISO 14971:2007, definition 2.21]
- **RISK MANAGEMENT**
  Systematic application of management policies, PROCEDURES and practices to the tasks of analyzing, evaluating and controlling RISK [ISO 14971:2007, definition 2.22]
- **RISK MANAGEMENT FILE**
  Set of RECORDS and other documents that are produced by RISK MANAGEMENT [ISO 14971:2007, definition 2.23]
- **SEVERITY**
  Measure of the possible consequences of a HAZARD [ISO 14971:2007, definition 2.25]
- **STUDY DIRECTOR**
  The individual responsible for the overall conduct of a nonclinical laboratory study [21 CFR 58 Good Laboratory Practice for Nonclinical Laboratory Studies, Sec. 58.3 (m)]

REFERENCES

- **ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012**, (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- **ISO 14971** Second edition 2007-03-01, Medical devices - Application of risk management to medical devices
- **ISO/IEC 17000** First edition 2004-11-01, Conformity assessment — Vocabulary and general principles
- **ISO/IEC 17011** Second edition 2017-11, Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies
- **ISO/IEC 17025** Third edition 2017-11, General requirements for the competence of testing and calibration laboratories
- **ISO 10993-4** Third edition 2017-04, Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
- **ISO 10993-5** Third edition 2009-06-01, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- **ISO 10993-10** Third edition 2010-08-01, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- **ISO 10993-11** Second edition 2006-08-15, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- **ASTM F756-17** Standard Practice for Assessment of Hemolytic Properties of Materials
- **USP 40-NF35:2017** <151> Pyrogen Test