



Audit Repository Center

3473 '02 FEB -5 P2:24

P.O. Box 1156 • Pottstown, Pennsylvania 19464 • tel: 610-970-1083 • fax: 610-970-4272 • email: ARC@auditcenter.com

February 4, 2002

Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1060
Rockville, MD 20852

Subject: **Docket No. 00D-1538**, Draft Guidance for Industry; Electronic Records; Electronic Signatures, Validation; Federal Register September 24, 2001.

The Audit Repository Center (ARC) is pleased to provide the comments on the Draft Guidance for Industry; Electronic Records; Electronic Signatures, Validation. ARC has been established to serve the FDA regulated industry, providing subscription services that facilitate the sharing of quality audit and organizational assessment information. This service is based in the PDA's Technical Report -32; "Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations" and is prescribed as good engineering practice by the Software Engineering Institute.

ARC supports the agency for offering guidance on the validation of electronic records and electronic signatures and recognizes the amount of effort that went into this draft guidance. We also understand that it is nearly impossible to establish directional guidance that will meet everyone's objectives on an initial draft, especially on such a controversial and dynamically changing subject as e-records and e-signatures. We trust that the Agency will use the constructive input we have provided to make this guidance useful to both the Agency and the Industry.

Specific comments on the guidance are listed by section below:

2. Scope

The term 'System(s)' appears to be used in two contexts: 1.) when describing expectations for work flow process that involve people, actions and tools (technology) and 2.) when describing automation/technology; i.e computer systems.

Recommendation: Define the term 'system' in the glossary and use it with distinguishing attributes in the context of use, e.g. system(s)[workflow], system(s)[technology].

6.0 Special Considerations

6.1.2 Software structural integrity

The second bullet refers to a "reliable" supplier audit. It is unclear what reliable means.

Recommendation: Define reliable audit in terms such as confirmation of conformance to a software quality system & software lifecycle activities.

The words "trusted and competent third party" is used. The words 'trusted and competent' are could possibly be open to a wide range of interpretation. The statement as written does not provide any expectations or criteria for qualification of auditors or methodology used to collect data or that would ensure the reliability of data used. PDA technical report #32 provides all of these criteria and a methodology to ensure reliability of audit data.

Recommendation: Rephrase paragraph 6.1.2 second bullet to indicate "a competent third party using a proven contemporary standard for the technology process"

00D-1538

C 27

Appendix A – References

PDA's Technical Report – No. 32 Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations is not recognized. This work was a 2.5-year effort with the Agency and FDA regulated companies to standardize on supplier auditing activities. The work was predicated on quality systems practices advocated by PDA Technical Report –No. 18 Validation of Computer-Related Systems, ISO, is referenced in GAMP 4 and other contemporary standards organizations, and capability assessments advocated by the Software Engineering Institute (SEI), Carnegie Mellon University. This program directly plugs into COTS Based Systems Engineering evaluation practices and is the subject of a Case Study currently under way with SEI and PDA. We feel the intent of this standard meets, item for item, the needs of both the FDA and Industry, relative to supplier audits, in the light of 21 CFR Part 11 prerequisites for computer system validation..

Recommendation: Add Reference to PDA Technical Report No. 32

The IEEE standards collection includes 1012, ISO 12207, & 1465(which is an adoption of ISO 12119).

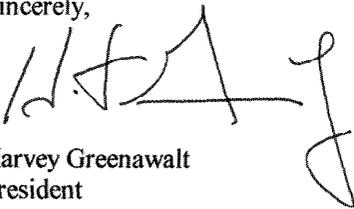
Recommendation: Remove the reference to the generic collection and add the appropriate actual IEEE standard.

ACDM /PSI Computer Systems Validation in Clinical Research – A Practical Guide provides pertinent guidance.

Recommendation: Add reference for ACDM/PSI.

ARC appreciates the opportunity to comment on the guidance. If you have any questions regarding our comments, or how we may assist you with further development of this guidance, please contact me.

Sincerely,

A handwritten signature in black ink, appearing to read 'H. Greenawalt', written over a horizontal line.

Harvey Greenawalt
President