From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Monday, April 18, 2005 3:12 PM
To: [redacted]
Subject: RE: Question on CSUCT Reference

Hi [redacted],

This reference was mentioned in the original (1999) guidance. It's the "Technical Report, Software Development Activities, July 1987" that is maintained by the Division of Field Investigations, Office of Regional Operations, Office of Regulatory Affairs, Food and Drug Administration. I'm trying to find an electronic version of this technical report and will let you know when I hear back from DFI.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs (HF-34)
Office of Science and Health Coordination
Office of the Commissioner

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [redacted]
Sent: Wednesday, April 13, 2005 7:53 AM
To: patricia.beersblock@fda.hhs.gov
Subject: Question on CSUCT Reference

Pat,
I got a question yesterday, and realized that I probably hadn't ever figured it out either. The September 2004 Guidance on "Computerized Systems Used in Clinical Trials" has a reference at the end (line 598) - "FDA, Software Development Activities, 1987." Do you have a link to what this is? I always find references to be helpful in understanding the whole point, and sometimes the historical ones demonstrate a progression (or even no change in thinking - these items are still important).
Thank you very much.

[redacted]