NATIONAL CANCER INSTITUTE | Center for Bioinformatics

MEMORANDUM

Date:	10/01/07
Subject:	21 CFR 11 Policy Compliance Statement Regarding C3D

The senior management of the National Cancer Institute Center for Bioinformatics (NCICB) has made every effort through good technology practices and internal operating procedures to develop and utilize systems, which comply with interpretations of 21 CFR Part 11.

21 CFR Part 11 applies when using a computer system to create, modify, transfer or store an electronic representation of any information or process that is regulated by the Food and Drug Administration (FDA). C3D has recently gone through an extensive Certification and Accreditation (C&A) effort to certify its security posture and its procedures as utilized in the System Development Life Cycle (SDLC).

Currently, there is no 21 CFR Part 11 guidance. Keeping this in mind, C3D is compliant in all ways with 21 CFR 11 as deemed by our own interpretation utilizing all of the regulation guidelines.

The regulation identifies specific controls that should be in place to help ensure "the authenticity, integrity, and, when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine."

C3D operates according to the following regulatory controls criteria:

- The system is developed and tested properly
- Auditable records can be generated in both human readable and electronic form
- Only authorized access to records is permitted
- Appropriate audit trails are generated, retained and auditable
- Proper operational sequences are followed
- Only authorized processing is permitted
- Access is limited to authorized users
- Each identification code/password combination is unique and do not become obsolete
- Adequate measures are employed to prevent unauthorized use of passwords
- Audit trails keep a complete time and date stamped record of all changes
- Appropriate policies have been developed for individual accountability
- Documentation is controlled.

NCICB recognizes that this topic will require ongoing attention in order to maintain a tighter compliance to this details of this regulation in the future, Further, C3D understands that the interpretations of 21 CFR Part 11 may differ from organization to organization and sees this as opportunity to continue to build upon its 21 CFR Part 11 compliance considerations.

FDA References

http://www.21cfrpart11.com/
http://www.21cfrpart11.com/files/library/security/tech_supporting_security.pdf
http://www.fda.gov/cder/guidance/5667fnl.htm

Signatures

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