

From: Dr. Tom Shakespeare  
Director Area Cancer Services  
Northern NSW & Mid North Coast Local Health Districts

To Whom It May Concern:

**Re: Mosaiq™ 21 CFR Part 11 Compliance at  
Northern NSW & Mid North Coast Local Health Districts**

In order to comply with the US FDA Section 21 of the United States Code of Federal Regulations, Part 11 the following documents are supplied:

- Completed and Signed 21 CFR 11 Worksheet Assessments (Appendix 1)
  - Some examples of the compliance worksheet includes:
    - Regular back-up of data;
    - Storage of back-up media in a secure location;
    - A contingency plan exists in case Mosaiq™ is unavailable;
    - A full audit trail can be established, allowing the tracking of entries/deletions into/from Mosaiq™ by date, time, identity of person making entry/deletion, reason for entry/deletion and other standard parameters;
    - A reasonable level of security, including specifically that Mosaiq™ access is restricted, that all users have a unique user identification and password, and that the use of Mosaiq™ can be monitored through a full audit trail; and
    - Appropriate training is given to Mosaiq™ users on a documented basis.
- Declaration by the Manager of the Cancer Clinical Trials Unit for the procedure of external parties access to the Oncology eMR (Mosaiq™) system for the purposes of source data verification (Appendix 2)

Sincerely,



Dr. Tom Shakespeare