

Bill of Health
For code name: Texas Project
Hardware and Software

Reviewer: William Mandel

Date 11 Jun 2009

The follow is the “Bill of Technical Health” for a given technical due diligence. This Bill of health is covering only the hardware and software of the Texas Project resulting from a visit on 11 of Jun 2009. The questions concerning the Technical viability are left to others. Because of limited time this report does not cover the manufacturing process.

At this visit we did have access to Engineering Manager, and to various members of the outsourced technical staff.

This review only covers the documentation that is located at the main facility.

0 to 10 (0 is poor, 10 is Excellent)	Assessment of Quality
Software Process	
*Software design process	0(None)
*Software development process	0(None)
*Validation and verification process	0(None)
*Development version control process	0(None)
*Software review process	0(None)
*Software updates and revision process	0(None)
Hardware Documentation	
Hardware design specification	3
Change history	7
Test results	2
FMEA results	None
Hardware maintainability	8
Software Documentation	
*System Specification	4
*Software Specification	4
*Design Specification	2
*Risk management Documents	Said they had but did not see (I think they are looking at the 2000 sys)
*Most current Validation report	None at this time
*Software maintainability	6 (no documentations, good tools, well written)
*Traceability matrix	None
Results from outside audits	3
Other questions:	

Anomaly Management	None
Risk Analysis	Said they had but did not see (I think they are looking at the next generation)
Outstanding Anomalies	NA
Software tools Utilized	9
Hardware tools Utilized	9
Data analysis and integrity process	1
Supporting documentation	2
Lifecycle process	4
Technical Training Material	None
Technical Support Tools	9

Summary of Software Process

There are no documents that support the software process. The software itself is written well. It is the plan of the Engineering staff to release version 1.0 to the Texas Project with out any software design history. There have been some preliminary reviews. The reviews are dated and have a list of who attended. The reviews lack, details or supporting data. The references to software process that can be found are minimal, or misinterpreted as to their intent.

There are many documents that are not under version control.

There seems to be no detail to software architecture. There is reference to hardware architecture.

Summary of Hardware Documentation and Reliability

There seems to be a complete history as to the hardware history, but without support documentation as to why the hardware changed. The new generation device seems to have safety in mind when it was designed. Data/Communication integrity seems to be an oversight. There is neither little or no data collection for diagnostics nor any justification as to why this is not being done.

There are 3 micro-processors in the system. The Windows CE driven Micro DOES run the system, but there are two other very small microprocessors that monitor the RF and the Temperature. *This is reassuring and MAY allow for FDA approval.* This is still a risk factor. I have calls into people that may know more about this. Direct contact with the FDA is recommended about this matter.

Summary of Software Documentation and Reliability

Current there is no software documentation except for a loosely put together Software spec. The Software Spec. lacks may details and tolerances. It is much more hardware oriented. It is a major requirement to have Requirements, Design, Architecture, and Traceability. The Tricor design lacks all of these.

I believe that the engineers do have good intentions to build a safe and reliable device but lack the knowledge to meet FDA and industry standards. As a good auditor says "If you don't have the documentation, it might have well never been done!".

Summary of Technical Strengths

The Texas Project has a strong technical team. I believe that for the most part the design will be successful. (But this will be a rocky road without guidance.) Executive staff seems to be committed to using good tools for both physical design and software development.

Summary of Technical Weaknesses

Having a documentation process is a strong weakness. Traceability is a weakness. There is no way to tell if all of the requirements or safety systems are being met. Technical review of either hardware or software is lacking of substance.

Note:

There are over 41000 lines of code without any formal testing. They think they will be complete in 2 or 3 week time frame. In theory, for a Class 3 device there should be 100% code coverage of testing. With an estimate of 5% in condition types of statement there would be over 2000 test that need to occur. No attempt to write a Validation has occurred as yet.

Areas of Concern

No traceability – major concern

Little software revision control – medium concern

New System Design - major concern

Lack of Complete documentation – medium concern

Incomplete testing – major concern

FDA Audit – Can be a major concern

Time to market – major concern

Cost-low to medium concern (They refused to show an itemized list for new system costs)

Overall “Bill of Technical Health” is Poor with hope.

Overall Summary

- Major concerns
 - o Software and hardware documentations is Poor
 - o Supporting documentation is incomplete or non-existent
 - o The Audit on Design process does not show any deficiency
 - o They think the device will be completed in a few weeks. I estimate 6 to 8 months.
- Recommendations
 - o Investigate the Windows issue
 - o Revamp the development process
 - o Add guidance and training to complete the project with the current staff. (Without the current staff the time to completing could double.)