

Statement of the problem

7.

Evidence of appropriate controls related to responsibility authority for design and development between VST and the subcontractor could not be provided at this assessment (ref contract #13859)

7.

Root Cause Analysis

The contract was not detailed enough and therefore not comprehensive enough.

We have not be as careful as we should have been when copying documents from Viamed to VST.

7.

Immediate Action

We have had the certificate wording changed to reflect that we do not carry out design and development.

7.

Corrective Action

The VST Boundaries document will be updated to reflect the scope changes.