Statement of the problem
2. Evidence of consideration of Risk for the Tom Thumb design change in 2005 could not be provided at this assessment.

Root Cause Analysis
2.
We did not have the documentation in the Digital System and so we were unable to provided it at the time of the audit.

When the technical files were originally scanned and brought into the system in August 2006. Not all the old records were added. Many of the records were in Intrastats but require specific searches to find and should be specifcally tagged to their correct locations in the technical files.

We have extensive paper archives and we do not always know what we need until it is required.

2.
Immediate Action
The missing documentation will be added to the system, including the communications with MHRA regarding the customers device modification request in 2005. Many communications have been located, including those with the MHRA

We will carry out a further review of the archives to locate other relevant documentation.

We have located a number of documents that relate to this design change, including evidence that the risk was considered, although we have not yet located a formal risk assessment.

2.
Corrective Action
We will make sure that we have the correct relevant information in the system and available for viewing.

We will combine the Design Inputs and Design output files to summarise and simplify the document. So making information accessible, primarily to 3rd parties.

We will combine the Design and Development Compliance and Project Validation so that references to archived documentation can be sign posted.

We will add a Design changes review to the Design Changes document and process. Which will include EN ISO 13485 section 7.3.9.

We will consult qualified third party organisation, that have been recommended highly by our Trade Organisation, on our current interpretation and implementation of

our EN13485, MDD and future MDR with particular reference to historic products.