1.0 GENERAL

1.1 The 500 series Quality Procedures identify the documents and data affecting quality, including documents of external origin, and the methods used to ensure their control.

2.0 APPROVAL AND ISSUE

2.1 Control of the Quality Manual, Quality Procedures, Quality Forms, and Work Instructions are addressed in the Document Control Procedure QP-0500. QP-0500 defines how quality systems documents are controlled, including review and approval prior to use, the use of master lists, unique identification, designation of revision status, distribution, change processing, handling of obsolete documents, methods to ensure that invalid or obsolete documents are not unintentionally used and are identifiable if retained, and that documents remain legible and readily identifiable.

2.2 The control of Reference Documents is addressed in the Reference Documents procedure (see QP-0510) and ensures that they are identifiable and controlled.

3.0 DOCUMENT AND DATA CHANGES

3.1 QP-0500 and QP-0510 define the methods used to execute document change control, including the process to request changes, to review background information to evaluate changes, to approve changes, and to communicate and highlight changes in the document.

3.2 Control of data affecting quality is addressed in the Data Control procedure (see QP-0520).

4.0 RECORDS

4.1 Records of Document and Data Control are retained as defined in the 500 series Quality Procedures and QM Section 16.