1.0 Purpose of Procedure

This document is intended to describe the definitions and requirements of Device History Records (DHRs).

2.0 Scope of Process

The scope of this procedure is to define the criteria involved in the creation of device history records for explosive atmospheres product and medical devices and how the DHR storage location is used for other type of product.

3.0 Process Owner(s)

3.1 Manufacturing

3.2 QA Manager

3.3 Engineering

4.0 Procedure

4.1 Device History Records for Medical Devices and Ex Product

A device test and/or configuration record shall always be created and present for medical device product and product for potentially explosive atmospheres. This type of record is referred to as a Device History Record, or DHR, for medical devices. These given regulated product examples will be assigned a serial number, and these device test/configuration records will indicate the product's serial number and will be kept and filed by serial number.

For medical devices, the DHR shall include the identity of the manufacturing job that created the device.

This test/configuration record describes the unit's testing and configuration by indicating that steps have been completed, by recording pass/fail results, by recording numerical values, and by indicating the serial or lot number identities of installed critical components. These records, in addition to the serial and lot number records in Product Resources' ERP system as well as incoming inspection records, allow for traceability from final product back to the manufactured and purchased components that make up the final product. In addition, these records demonstrate conformance to test criteria.

In addition for such product, in any case that a product is re-tested and/or components changed (either because of initial nonconformance or in the case of an RMA return or field service) in the future, then this record shall be appended to with the new results or a new record added so that the overall DHR reflects the entire history. New results or records should note the scenario and the specifics surrounding any change. For example, the firmware or software has been updated from Version X to Version Y. Or, some specific critical component of serial number A has been replaced with one with

serial number B or some repair made. Or, the unit has been recalibrated. Or, this record is from an RMA, and what RMA, and so on.

DHRs are stored in the Device History Records share, and the share is further organized by assembly or product part number and then by serial number. For product that ships in larger volume, there can be a further by-year breakdown for easier records retrieval.

4.2 Device History Record Usage for Other Product

In addition to medical device and Ex product usage, the DHR storage space is also the company's central repository for records established from in-process and final tests. All such records should be saved to this space, scanning records that originated as paper forms.

The organization is the same for such usage where test records are stored by the part number of the assembly (in-process test) or product (final test). Whereas medical device and Ex product is always serialized, this general usage may also be by serial number with organization by job/lot number a second possibility, especially for non-final-product assemblies and in-process testing.

5.0 Control of Records

The storage location and retention period for records referenced above is given in 91-6002, Control of Records.