## 1.0 Purpose

The purpose of this document is to define the policies, responsibilities, and procedures for control of design and development changes.

## 2.0 Reference

Online Form: Custom Product Worksheet / Project Worksheet

## 3.0 Design Changes

Design changes may be initiated by a revised product specification from Sales/Marketing or an Engineering Change Notice Request (ECNR), available on the computer system. Any Product Resources department may initiate an ECNR. The customer may effectively initiate an ECNR through the Product Resources Sales Department. The information detailed in the ECNR shall constitute the design input information for the Engineering Department. The Engineering Department shall follow the same procedures for implementing design changes to a product as for designing a new product (i.e., Planning, Design Review, etc., as applicable).

With the noted exception for prototypes, all design changes follow the formal engineering change procedures described in 90-2000-4.2.3 and 43-2627.

### 3.1 Additional Requirements for Regulated Product

Engineers must take note of the Type Certificate field in the manufacturing computer system in an item's record before making a change. If the field is completed, it indicates that the item is for use in a regulated product and is controlled by a certificate or report issued by a regulatory body. Upon considering a change, the Engineer must consult the Certificates database on the company intranet. The Type Certificate field will point to a record or records in the database which in turn will point to the regulatory body involved, the report and/or certificate number, and, when Product Resources is acting as a contract manufacturer, the customer.

When Product Resources is acting as a contract manufacturer, the customer must be contacted if a change is to be pursued on any documentation, schedule or related, and the change must not be carried out until the customer approves of it. It is Product Resources' expectation that the customer will follow the change procedures required for the given

regulatory body and product type. Quality Assurance holds copies of the regulatory reports/certificates, and Engineering should consult them to learn of any applicable guidelines before recommending a change. Quality Assurance also holds a relationship matrix between related and schedule documents, and this matrix may also be consulted to understand the impact of the change. The Management Representative (the QA Manager) is to be copied on any communications requesting such a change, or otherwise the Management Representative is to be the initiator of the change request.

When Product Resources is not acting as a contract manufacturer, changes to regulated product including schedule and related documentation must be approved by the Management Representative (the QA Manager). The Management Representative will follow the change procedures required for the given regulatory body and product type. If the regulatory body is required to be notified on or approve the given change, the Management Representative will communicate the notification or request for change. Only once the Management Representative completes these activities may the Management Representative approve the change and the change be implemented.

## 4.0 Records

The ownership, locations, retention periods, and storage requirements for records described in this procedure are specified in 90-2000-4.2.4.

## 5.0 Definitions

Schedule Document: A schedule document is referenced, revision included, on the regulatory body's certificate and/or report for the product. This is a part of the regulatory body's control, and schedule drawings may not normally be changed without notification and approval.

Related Document: A related document is not referenced on the regulatory body's certificate and/or report for the product. Manufacturers may normally change related documents without notifying the regulatory body. However, the manufacturer must review that the change does not create a disagreement with a schedule document; if it does, the required change to the schedule document must be addressed with the regulatory body.