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## 1. Policy and Procedure: Continual Improvement

Product Resources shall continually improve the effectiveness of its Quality management system. What follows is a roadmap to the tools and processes that Product Resources uses to accomplish this:

- ) Quality Policy (see 90-2000-5.3)
- ) Quality objectives (see 90-2000-5.4.1)
- ) Audit results (see 90-2000-8.2.2)
- ) Analysis of data (see 90-2000-8.4)
- ) Corrective and preventive actions (see 90-2000-8.5.2 and 90-2000-8.5.3)
- ) Management review (see 90-2000-5.6.1, 90-2000-5.6.2, and 90-2000-5.6.3)

One should follow the above Quality Manual procedure references to learn about these processes that permit Product Resources to continually improve the effectiveness of its Quality management system.

## 2. Policy and Procedure: General

2.1. Product Resources shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of its Quality management system through the use of the Quality Policy, Quality objectives, audit results, analysis of data, corrective and preventive actions, and management review.

2.1.1. One should follow the below Quality Manual procedure references to learn about these processes that permit Product Resources to ensure and maintain the continued suitability and effectiveness of its Quality management system:

- ) Quality Policy (see 90-2000-5.3)
- ) Quality objectives (see 90-2000-5.4.1)
- ) Audit results (see 90-2000-8.2.2)
- ) Analysis of data (see 90-2000-8.4)
- ) Corrective and preventive actions (see 90-2000-8.5.2 and 90-2000-8.5.3)
- ) Management review (see 90-2000-5.6.1, 90-2000-5.6.2, and 90-2000-5.6.3)

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2.2. Product resources shall establish documented procedures for the issue and implementation of advisory notices. These procedures shall be capable of being implemented at any time.

2.2.1. Refer to the following Quality Manual procedures to learn about Product Resources' related processes, as they relate to Product Resources' scope of acting as contract manufacturer and not putting product directly into the market – Product Resources' notification is to its customer, and our customer's notification is to end users, distributors, regulatory bodies, all as applicable:

- ) Management Representative (see 90-2000-5.5.2)
- ) Control of Measuring Devices (see 90-2000-7.6; see specifically Out of Tolerance)
- ) Control of Nonconforming Product (see 90-2000-8.3; see specifically Post-Shipping Notification and Action on Nonconforming Product)

2.3. Records of all customer complaint investigations shall be maintained. If investigation determines that activities outside of the organization contributed to the customer complaint, relevant information shall be exchanged between the organizations involved. Refer to 90-2000-8.5.2 for Product Resources corrective action process, specifically CARs of type customer complaint, including how CAR records are kept; see also 90-2000-4.2.4 for records / record retention. Note that in Product Resources' scope of acting as a contract manufacturer and not putting product directly into the market, the outside organizations involved are limited to our customer and our suppliers.

2.3.1. If any customer complaint is not followed by a corrective or preventive action, this shall be authorized and the reason recorded. Refer again to 90-2000-8.5.2 for Product Resources corrective action process, specifically CARs of type customer complaint.

2.4. If national or regional regulations require notification of adverse effects that meet specified reporting criteria, Product Resources shall establish documented procedures for such notification to regulatory authorities.

2.4.1. Refer again to the following Quality Manual procedures to learn about Product Resources' related processes, as they relate to Product Resources' scope of acting as contract manufacturer and not putting product directly into the market – Product Resources' notification is to its customer, and our customer has notification responsibility for the national or regional regulatory body:

- ) Management Representative (see 90-2000-5.5.2)

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- ) Control of Measuring Devices (see 90-2000-7.6; see specifically Out of Tolerance)
- ) Control of Nonconforming Product (see 90-2000-8.3; see specifically Post-Shipping Notification and Action on Nonconforming Product)