WRITTEN BY:		APPROVED BY:	DATE:
J. Caruso	Digitally signed by John M. Caruso DN: cn=John M. Caruso gn=John M. Caruso c=United States l=US o=Product Resources ou=Quality Assurance e=jcaruso@prodres.com Reason: I am the author of this document Location: Date: 2013-07-18 16:23-04:00	J. Porter	Digitally signed by Jamie Porter DN: cn=Jamie Porter gn=Jamie Porter c=United States l=US o=Product Resources ou=Quality Assurance e=jporter@prodres.com Reason: I am approving this document Location: Date: 2013-07-18 16:25-04:00

1.0 Purpose

This procedure provides for the agenda of the Management Review meeting as well as explains the process of conducting the Management Review.

2.0 Procedure

The Quality Assurance Manager, Product Resources' Management Representative, shall conduct the Management Review meeting with the agenda items as described below.

As results and trends are being presented and discussed, they are compared to goals; goals can be modified by management in this process. Goals that were not set before (for lack of sufficient data) are set in this process.

The QA Manager and the balance of management make suggestions for improvement and determinations of system suitability, and management makes decisions to take action throughout this process.

3.0 Agenda

The agenda of the Management Review meeting and supporting materials shall be prepared or delegated by the QA Manager and distributed to the attendees prior to the meeting. As a minimum, the agenda shall include the following topics:

- Review of previous Management Review meeting action items, follow-ups
- Internal audit results and trends; review of actions taken
- External Quality system audit results and trends; review of actions taken
- Customer feedback including: customer surveys, summary of annual, trends of; Customer Complaint Reports, trends of; customer "report cards" for Quality and delivery, trends of

- Process performance, trends of, via measurements described in 43-2829

- Product conformity performance, trends of, via measurements described in 43-2829

- Corrective and preventive action (CAPA) status and trends for CAPA types not already itemized in this list (which are general, CAR, and supplier, SCAR)

- Known or potential business changes, assessment of system impact

- Review status of product regulated under the ATEX Directive including any regulatory activity, QMS requirements (ISO 80079-34), and the effective implementation of the QMS requirements (Note: Internal and external audit results as well as required employee training should be considered in judging effective implementation.)

- Review status of product regulated under the Medical Device Directive, medical devices, including any regulatory activity, QMS requirements (ISO 13485), and the effective implementation of the QMS requirements (Note: Internal and external audit results as well as required employee training should be considered in judging effective implementation.)

- Review of Quality Policy and associated objectives and measurements (ref. 90-2000-5.4.1 for procedural details and 43-2829 for the current breakdown)

- Business and system goals (not already discussed) for the current year

4.0 Records

Records of the Management Review meeting shall be kept per 90-2000-4.2.4, Control of Records.