1.0 Purpose of Procedure

This document describes Product Resources' Management Review process. It provides for a procedure and assigns responsibilities. The procedure provides for the scheduling and attendance, objectives, inputs/agenda, conducting, and outputs of the Management Review process.

2.0 Scope of Process

Product Resources' Management Review is the periodic assessment by company management and key QMS roles of the performance, applicability, and readiness of the QMS and other business processes and their effectiveness. The period of review is the prior calendar year, where the calendar year is Product Resources' fiscal year and its normal business cycle.

3.0 Process Owner(s)

3.1 QA Manager

3.2 Management

4.0 Procedure

4.1 Responsibility for Organizing and Conducting

The Quality Assurance Manager shall schedule, organize, and conduct the Management Review meetings on the schedule set forth below, with the attendance and objectives as stated below.

4.2 Scheduling

The meeting shall occur annually. It is to be begun in Q1 and completed by Q2.

One "meeting" as defined by this document is normally spread amongst multiple sessions, i.e., it is not required or even recommended to cover all agenda items in one sitting. However, the timing between sessions shall be close enough to allow the attendees to keep sight of the overall Management Review.

The President or the QA Manager may schedule additional or special-purpose Management Review meetings at his or her discretion. An upcoming change in the company's scope or change in the context of the organization are examples of conditions that might warrant an additional or special-purpose meeting.

4.3 Attendance

The following personnel shall attend the Management Review meeting. If an individual cannot attend*, the meeting can still take place if more than half of the attendees will be present and if, at the discretion of the QA Manager, the meeting's effectiveness will not be compromised:

o President

o Chief Executive Officer

o Chief Quality Officer

o Chief Financial Officer

o Chief Operating Officer

o Engineering Manager

o Sales Manager

o QA Manager

o Manufacturing Manager

o Test and Service Manager

o Lead Internal Auditor

o Management Representative

Note that one individual may hold multiple of the above roles. Others may attend at the discretion of the QA Manager or the President.

*However, the Management Representative must always attend Management Review meetings. It is a regulatory requirement. The Management Representative represents Product Resources for all regulatory matters.

4.4 Objectives

An objective of the Management Review process is for the management to establish and review objectives for the system, to establish and review associated measurements (metrics) of system performance, to set associated goals, and to compare performance against goals. A second objective to update management on system status, requirements, and changes. The final objective is to ensure the maintained effectiveness of the system and to drive to continual improvement.

When the system as-is is not meeting goals or requirements, current or impending, management initiates action to bring about change to maintain effectiveness of the system or to bring about an improvement.

4.5 Conducting the Management Review

The QA Manager shall conduct the Management Review meeting with the input/agenda items as described below. The QA Manager asks for others' assistance in compiling and presenting data for presentation; see also ownership of maintaining data and trending in 43-2829, Objectives, Measures, and Goals.

For the portions of the review based on objectives, measures, and goals, as results and trends are being presented and discussed, they are compared to goals (where applicable); 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 suggests opportunities for improvement and determinations of system suitability and effectiveness and resources sufficiency, and management makes decisions to take action throughout this process.

4.6 Input/Agenda

The agenda of the Management Review meeting and supporting materials (the presentation) shall be prepared or delegated by the QA Manager and distributed to the attendees prior to the meeting.

The effectiveness of the system, opportunities for improvement, and adequacy of resources shall be considered while reviewing all below agenda items.

Management Review normally begins with the agenda items covered via measurements described in Objectives, Measures, and Goals, following the order in the Objectives, Measures, and Goals document. This is followed by the balance of the input/agenda in the below order, with the items that were covered via Objectives, Measures, and Goals having already been satisfied.

The agenda follows:

4.6.1 Review of previous Management Review meeting action items, follow-ups

4.6.2 Internal audit schedule and status (what audits were scheduled, what audits were completed, when, and what processes were covered by the audits); review of outcomes

4.6.3 External QMS audits by QMS registrars and notified bodies (for example to ISO 9001, 13485, and 80079-34), results and trends; review of actions taken

4.6.4 Customer feedback including: customer surveys, summary of annual, trends of; Customer Complaint Reports, trends of; customer “report cards” for Quality and delivery, trends of, via measurements described in 43-2829, Objectives, Measures, and Goals.

4.6.5 Process performance, trends of, via measurements described in 43-2829, Objectives, Measures, and Goals.

4.6.6 Product conformity performance, trends of, via measurements described in 43-2829, Objectives, Measures, and Goals.

4.6.7 Corrective and preventive action status and trends for types not already itemized in this list or pointed to by it, which are corrective actions which stem from customer audits, nonconforming material, process, inspection except for outgoing, and supplier, and preventive actions.

4.6.8 Known or potential business changes, including changing and newly required standards; assessment of system impact and readiness; see also 91-9001 for requirements for significant QMS change

4.6.9 Review status of explosive atmospheres product including any regulatory activity, QMS requirements, 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.) See also 43-2829, Objectives, Measures, and Goals.

4.6.10 Review status of medical devices including any regulatory activity, QMS requirements, 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.) See also 43-2829, Objectives, Measures, and Goals.

4.6.11 Review of Quality Policy and associated objectives and measurements; for objectives and measurements, reference 91-9004 (Objectives and Analysis of Data) for procedural details and 43-2829 (Objectives, Measures, and Goals) for the current breakdown

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

4.6.13 Risks associated with the QMS; actions taken to address and their effectiveness

4.6.14 Safety, legal, and statutory requirements applicable to Product Resources

4.7 Output

Changes to the QMS and other actions shall be taken as required to guarantee the quality of the company's products and services, to meet the needs of the company, to act on opportunities for improvement, to maintain effectiveness of the system, and to address resource needs.

Meeting minutes shall be generated and distributed to the meeting attendees. The meeting minutes shall cover the group's discussions and conclusions regarding the topics detailed in the above agenda. The meeting minutes shall indicate the meeting date and attendance and these things:

Action items shall be included in the meeting minutes. They are distributed to the meeting attendees. Management Review action shall enter the system as Corrective Action Requests of type Management Review so that action may be taken and tracking and follow-up may occur.

Opportunities for improvement and resources considerations will be included with each agenda item covered by the minutes, as these apply to all agenda items.

The QA Manager is responsible for Management Review minutes, their distribution, and the handling of action items including their follow-up.

The QA Manger will, upon conclusion of all sessions, construct a table of contents or matrix, in all cases illustrating how the above agenda requirements have been met / in what minutes to find their coverage. This is both to ensure full coverage and to provide a guide for auditors.

5.0 Control of Records

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