

DRAWING NUMBER 90-2000-5.6.1	REVISION F	TITLE Management Review - General	PAGE 1 of 3
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1.0 Policy

Product Resources' management shall periodically review the Quality System, receive and make recommendations for changes to the system, and implement the changes.

At scheduled intervals, the Management Representative shall organize a meeting of Product Resources' management to review the Quality System's performance and applicability to the current methodology and international standards to which Product Resources complies, including ISO 9001, ISO 80079-34, and ISO 13485.

2.0 Purpose

The purpose of this procedure is to provide for a system and instructions and to assign responsibilities for evaluating the applicability and effectiveness of the Quality System. This procedure provides for the scheduling, attendance, and objectives of the Management Review meetings.

3.0 Procedure

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

4.0 Schedule

-) The meeting(s) shall occur annually, and are to be completed during Q1
-) One "meeting" as defined by this document may actually be spread amongst multiple sessions, i.e., it is not required or even recommended to cover all agenda items in one sitting. However, the days shall be close enough so as to allow the attendees to keep sight of the overall Management Review. It is recommended that not more than two months elapse between the first and final session.
-) The President or the QA Manager may schedule additional Quality System Review meetings at his or her discretion.

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5.0 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:

- President
- Chief Executive Officer
- Chief Quality Officer
- Chief Financial Officer
- Chief Operating Officer
- Engineering Manager
- Sales Manager
- QA Manager
- Manufacturing Manager
- Test and Service Manager
- Lead Internal Quality Auditor
- 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 Quality System Review meetings. It is a regulatory requirement. The Management Representative represents Product Resources for all regulatory matters.

6.0 Objectives

The objectives of the Management Review process are for the management to establish and review objectives for the system, to establish and review measurements of system performance, to set goals and to compare performance against goals, and to otherwise be updated on system status, requirements, and changes. When the system as-is is not meeting goals or requirements, current or impending, management initiates action to bring about change.

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7.0 Records

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