1.0 Purpose of Procedure

This document describes Product Resources' internal audit process. It provides for a procedure and assigns responsibilities for the internal audit team and internal audit committee.

2.0 Scope of Process

Product Resources internal audit process is a strategic system of planned and periodic audits to verify compliance with all aspects of its Quality Management System (QMS).

3.0 Process Owner(s)

3.1 Lead Internal Auditor

3.2 Quality Assurance Manager

4.0 Procedure

Product Resources Internal Audit program is implemented by the internal audit team. All Quality related functions shall be internally audited periodically and as required by the importance of the activity or the need given the audit history. Customer or certifying agency (registrar) audits supplement the internal audits but are not to be considered a substitute.

4.1 Audit Team

Personnel assigned to carry out an audit are independent of those having direct responsibility for the audited activity. Personnel from all departments are encouraged to join the audit team as assisting auditors. Internal auditors come from all functional areas and include a Lead Internal Auditor.

4.2 Audit Planning

The Lead Internal Auditor ("Lead Auditor" hereafter) is responsible for planning and scheduling the internal audits and creates the active audit plan, stored in the QMS system's Auditing module. Via the audit plan, each Quality system process is normally audited once per year and no more than 14 months may elapse between the internal audits of any given aspect. The Tier 2 QMS procedures are grouped into common and/or complementary processes for the most effective auditing. 43-4769, Process Audit Map Tiers 1-2, is the master audit plan in that it groups the Tier 2 procedures as described for internal auditing and shows that all procedures are covered by internal audits; it also maps the procedures back to the external standards ISO 9001 and 13485. Other external standards that are extensions to our Quality system are also normally audited once per year in that their requirements are handling in the same body of Tier 2 procedures.

In addition to the annually scheduled audits, the Lead Auditor working in partnership with the Quality Manager may select certain processes for more frequent auditing depending on their compliance history or based on the size of the process being audited / its prevalence in the company.

Company management via the Management Review may elect to alter the audit plan also based on the history of compliance and in addition the status and importance of certain processes or certain external standards. Extra audits may be requested of the Lead Auditor by company management at any time due to changes such as new or special orders, changing business status, or other circumstances which may warrant a closer look at certain aspects of the Quality system. The Lead Auditor and the internal audit team can make changes to the audit schedule based on results of internal audits and other changes to the QMS or the business that may occur.

4.3 Preparation for an Audit

Auditors prepare an audit plan by fully familiarizing themselves with the related procedures (Tier 2 documents) for the section under review. In addition, the auditor reviews the outcomes of related past audits (including any observations and nonconformances generated and including external audits) and audit nonconformance corrective action files. Past observations/nonconformances and actions taken shall be included and noted in the audit plan. The goal of this is to assess if nonconformances are still present, if observations have turned into nonconformances, and if the area being audited has held the gains in actions taken in response to previous findings. Note the standard that an observation left uncorrected is to be elevated to a nonconformance.

The auditor then prepares the audit plan with its questions and/or checklists and/or aspects of the Quality system to explore. The audit plan is to address both employees' awareness and understanding of the documented procedures (by asking questions) and evidence that the processes are running as described in the documented procedures (by making observations and/or seeing/collecting objective evidence). The Lead Internal Auditor and/or Quality Manager may review the audit plan prior to an internal auditor conducting an audit.

4.4 Conducting an Audit

It is considerate but not required that the auditor contact the persons and/or manager responsible for the area being audited – audits are often process based and as such it is not always possible for any auditor to know where following a process will take them.

While conducting an audit, the auditor seeks whether or not employees are aware of and understand the documented procedures, and equally importantly the auditor also seeks objective evidence demonstrating a pattern of compliance.

If the auditor believes a nonconformance or observation needing specific action is identified, the auditor will note the specifics in the audit report and in the notes section of the audit for discussion at the internal audit committee meeting.

When observations or nonconformances are recorded, they are brought to the attention of the responsible manager. Observations and/or nonconformances are documented in the audit report.

4.5 Internal Audit Committee

The internal audit committee is made up of the Lead Auditor and all assisting internal auditors, as well as the Quality Assurance Manager. The internal audit committee meets typically monthly, reviews audits that have been performed, and reaches an understanding of the outcomes, and makes the decision that an outcome is a nonconformance or an observation needing follow-up action. This committee also gives input to the Lead Auditor for audit planning.

4.6 Results Determination and Follow-Up

The Lead Auditor after review at the internal audit committee meeting will document nonconformances or observation needing follow-up action as Results within the specific audit in the QMS software. A nonconformance will be defined as a departure from a requirement or expectation (intent), where these requirements and expectations come from our own procedures, customer and contractual requirements, the external standards, and/or regulatory requirements. Major nonconformances will be defined as those that represent a total breakdown of process or system as a whole, or failure to have a required documented process or a process implemented. A number of what would otherwise be minor conformances against one process or repeat of minor

nonconformances from audit to audit can be elevated to major if the collective effect represents a breakdown of the process or system. A minor conformance shall be defined as one that is not likely to result in the breakdown of the process or system and wherein there is a not a reduced ability to assure control. Observations are lesser than the above nonconformance definition but if left unaddressed are likely to lead to future nonconformances.

Results that are nonconformances become CARs. Results that are observations needing follow-up action per internal audit committee input become PARs. Other audit observations do not have the same requirement, but the responsible manager should review observations and address them in expectation that they will be followed up on in the next internal audit of that process. The audit team also reviews observations and nonconformances at the internal audit committee meetings to give initial input in the process of root cause determination and what corrective or preventive action solutions may be, and also what containment actions may be needed.

The audit report is emailed by the Lead Auditor to the managers responsible for the processes being audited.

The type of verification on internal audit CARs and PARs is determined in the CAR and PAR handling processes and depends on the severity of the problem and whether or not verification for effectiveness is applicable to the problem and solution. Verification may consist of a complete re-audit, a partial re-audit, a verbal inquiry to the responsible department manager, a review of documents or records, a special note for the next scheduled audit of the area, or any other way that obtains evidence of effective action. If a CAR or PAR has not been issued, follow-up is via the next schedule internal audit of the process.

4.7 Documentation and Record

Internal audits are documented by an audit report (found in the QMS system). An audit report at its minimum consists of the audit plan giving the scope of the audit and updated with the audit findings and may include objective evidence gathered during the audit. The Lead Internal Auditor is responsible for judging completeness of the audit / audit report and is responsible for marking an audit complete in the QMS system once the internal audit committee has discussed it and any needed actions on the audit completed for actions that are not CAR or PAR Results. Actions on the audit, its completion date, and discussion notes from the internal audit committee are maintained in the Notes section of the internal audit in the QMS system.

5.0 Control of Records

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