1.0 Purpose

The purpose of this procedure is to provide for a system and to assign responsibility for conducting internal Quality audits.

2.0 Policy

A strategic system of planned and periodic audits shall be implemented to verify compliance with all aspects of the installed Quality assurance system.

All Quality related functions shall be internally audited as required by the importance of the activity or the need given the audit history. The default and the minimum is that every aspect is internally audited once per year. No more than 14 months may elapse between the internal audits of any given aspect. Customer or certifying agency (registrar) audits supplement the internal audits but shall not be considered a substitute.

Audits shall be performed based on the company's written procedures and by personnel not directly accountable to the function or area being audited. Follow-up corrective/preventive action shall be taken by management in deficient areas within a specified time frame. See procedures 90-2000-8.5.2 Corrective Action and 90-2000-8.5.3 Preventive Action. Documented objective evidence shall be part of the audit results. Concerns, findings, and corrective/preventive action produced by the internal audits shall be reviewed.

3.0 Responsibility

The Lead Internal Auditor shall be responsible for conducting a portion of the audits and for assigning other assisting auditors to the balance of audits and for maintaining the planned audit schedule. The Lead Internal Auditor shall be responsible for reporting the audit results to the Quality Assurance Manager.

4.0 Audit Team

4.1 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.

4.2 External training or certification of assisting auditors is not required. The Lead Internal Auditor shall receive external ISO 13485 and ISO 19011 training; they may be combined as a single program. In all cases, auditors will be familiar with the ISO 9001 standard and the ISO 19011 standard, which sets forth guidelines and guidance for auditing programs and the conducting of audits. As applicable, auditors will be familiar with other Quality standards being audited, for instance, the ISO 80079-34 extension to our Quality system for the manufacture of products used in explosive atmospheres and the ISO 13485 extension to our Quality system for medical device manufacturing. All auditors will be given an orientation on ISO 19011, ISO 13485, and the forms/templates and procedures currently used for internal audits. In addition, new auditors will receive training by means of internship during at least two internal audits, shadowing or participating with an existing auditor. Department managers who have at least two years of experience with Product Resources' Quality system are exempted from this internship requirement.

5.0 Planning

The Lead Internal Auditor is responsible for planning and scheduling the internal audits and creates an Audit Plan for each calendar year. This Audit Plan is stored on the Quality drive in the Internal Audits folder. Via the Audit Plan, each Quality system process is normally audited once per year (see Policy above) with the Quality Manual being divided into convenient and related sections and each section assigned an audit month. Other Quality standards that are extensions to our Quality system are also normally audited once per year. In addition to the annually scheduled audits, the Lead Internal Auditor working in partnership with the Quality Assurance Manager may select certain processes for more frequent auditing depending on their compliance history. 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 Quality standards. Extra audits may be added 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.

To facilitate internal audit planning, to keep the program on track, to permit for training opportunities, to resolve any auditing problems, and to discuss audit findings and initiate needed actions on observations or non-conformances, the audit team normally meets at the start of each month. The group strives to complete audits within a window of one month early to one month late as compared to the Audit Plan; no more than 14 months may be allowed to elapse between the audits of any given section (see Policy above).

6.0 Preparation for an Audit

Auditors prepare an audit plan by fully familiarizing themselves with the ISO 9001 and other standards and the Product Resources' Quality Manual procedures and other related procedures for the section under review. In addition, the auditor reviews the outcomes of related past audits (including any observations and non-conformances generated and including external audits) and audit non-conformance corrective action files. Past and observations/non-conformances and actions taken shall be included and noted in the audit plan. The goal of this is to assess if non-conformances are still present, if observations have turned into non-conformances, 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 non-conformance.

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 Assurance Manager may review the audit plan prior to an internal auditor conducting an audit.

The Lead Internal Auditor and/or Quality Assurance Manager shall give guidance to the audit team (at a monthly meeting) on how to identify additional ISO 13485 requirements, both from the point of view of the standard as well as from the point of view of Product Resources' implementation. This is repeated for new auditors added to the team.

7.0 Conducting an Audit

7.1 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 can be a few minutes with various persons/departments to track or to verify a process flow or to be shown or pointed to objective evidence of the process. Prolonged preparation time is not to be given for an internal audit. The internal audit is intended to capture how the system is actually running at that point in time.

7.2 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.

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

8.0 Corrective Action and Follow-Up

8.1 If a non-conformance is identified, the Lead Internal Auditor shall request that corrective action be taken. This request is made through QT9 according to procedure 90-2000-8.5.2 Corrective Action. Audit observations do not have the same requirement, but the responsible manager should review observations and address them in expectation that they will be investigated come the next audit. The audit team also reviews observations and/or non-conformances at the monthly internal audit meetings to assist with the process of root cause determination and designing corrective and/or preventive action solutions.

8.2 The type of follow-up to a corrective action is decided by the Quality Assurance Manager and depends on the severity of the problem. Follow-up may consist of a complete re-audit, a partial re-audit, a verbal inquiry to the responsible department manager, a special note for the next scheduled audit of the area, or any other way that obtains evidence of effective corrective action. Follow-up is documented as specified in procedure 90-200-8.5.2 Corrective Action.

9.0 Documentation and Record

9.1 Internal audits are documented by an audit report. 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 consist of the following: copies of the ISO 9001 standard or other applicable QMS standards, copies of procedures, notes, copies of previous audit reports, copies of external audit reports, or objective evidence gathered during the audit. The Lead Internal Auditor is responsible for judging completeness of the audit and is responsible for "Completing" an audit once the Internal Audit Team has discussed. Audit reports will be filed by the Lead Internal Auditor by section number and by calendar year within QT9.

9.2 Copies of the audit reports are available in QT9.

9.3 If the audit detects non-conformance, a Corrective Action Report is done in QT9 according to procedure 90-2000-8.5.2 Corrective Action.

9.4 Implementation of any resulting corrective action and follow-up is documented in QT9.

9.5 The storage location and retention period for audit reports are specified in procedure 90-2000-4.2.4 Control of Records.

9.6 Audit reports are confidential records and shall be treated with due care.