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I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for conducting internal quality audits.

II APPLICATION

This procedure applies to all activities comprising the quality system.

This procedure directly concerns Quality Assurance and the executive management, and is indirectly relevant to all departments.

III PROCEDURE

1. Internal Quality Audit Plan

1.1 Quality Assurance is responsible for planning and scheduling internal quality audits. Each activity/location unit is audited at least once a year. Activity/Location unit is a single activity of the quality system implemented in a single location (the concept of activity/location unit is further explained in next subsection). In addition to the annually scheduled audits, QA may select certain activity/location units for more frequent auditing, depending on their status, importance, and past compliance history.

1.2 The audit plan is a matrix with the vertical side listing all activities of the quality system and the horizontal side listing locations (areas, functions, departments, product lines, etc.) where the quality system is implemented. Thus, fields in a column represent activities that take place in the location that is identified at the head of the column, and fields in a row represent locations where a given activity may be implemented. Not all fields are relevant. For example, the inspection and testing activities are not relevant in the Human Resources department (location). Fields that are not relevant are crossed out. A field at the intersection of a relevant activity and location represents an auditable

activity/location unit.

1.3 The internal auditing plan schedules dates and assigns audit teams for all auditable activity/location units. Several units may be clustered into one audit.

1.4 The internal auditing plan is synchronized with management reviews of the quality system (refer to Procedure AOP-01-03 Management Review), so that results of an auditing cycle are available for the management review meeting.

1.5 In addition to all elements of the quality system, suitable working environment is also audited. Working environment is audited in all locations.

2. Audit Team

2.1 Personnel assigned to carry out internal audits are independent of those having direct responsibility for the audited activity. If there is no conflict of interest, it is usually Quality Assurance that conducts the audits. Activities that are the responsibility of QA are usually audited by the Production Engineer or other executive managers. Personnel from other departments are encouraged to familiarize themselves with auditing techniques and participate in the internal auditing program as assisting auditors.

2.2 External training and/or certification of auditors is not required. Internal auditors are trained by Quality Assurance. QA maintains a library of publications, articles, and standards instructing in auditing techniques, and auditors-in-training are required to use the library for self-study. Training and/or use of the library are recorded in personnel training records maintained by QA.

3. Preparing for Audit

3.1 Auditors prepare for an audit by fully familiarizing themselves with the QS-9000 standard, refreshing their knowledge of the quality manual and relevant operational procedures, reviewing nonconformance reports and corrective actions files, and preparing questions and checklists.

3.2 At a minimum, checklists include all questions listed in the Quality System Assessment (QSA) Reference Manual. Preparing checklists, auditors also consult Advanced Product Quality Planning (APQP) Manual, Appendix A — Product Quality Planning Checklists.

4. Conducting the Audit

4.1 The manager responsible for the area being audited is contacted at least one week in advance with the proposed audit date. The manager concerned responds with a confirmation or proposes an alternative date.

4.2 While conducting the audit, the auditors seek objective evidence demonstrating whether the audited activities comply with the requirements of the documented quality system. When a noncompliance is noted, it is brought to the attention of, and discussed with, the

responsible manager. Before the end of an audit day, each noncompliance noted during the day is documented using the noncompliance report form (a model of the form is enclosed at the end of this procedure). Auditors fill out only the first part of the form, describing the noted noncompliance. The form is then handed over to the responsible manager who uses its second part to propose a corrective action.

5. Corrective Action and Follow up

5.1 Once a noncompliance is identified and documented, further processing of the noncompliance report follows the same procedure as applies to corrective action requests (QOP-14-01 Corrective and Preventive Action). Upon receiving the report, the responsible manager investigates the cause of the problem noted as a noncompliance, proposes a corrective action to be taken, and indicates the date by which the corrective action will be fully implemented. The auditor reviews and approves the proposed action.

5.2 On, or immediately after, the due date for implementation of corrective action, the auditor follows up with an inquiry or an audit to determine if the corrective action has been implemented and if it is effective. When there is objective evidence that the corrective action is effective, the noncompliance report is closed out. If more work is needed to fully implement the action, a new follow-up date is agreed upon.

6. Documentation and Record

6.1 Internal audits, implementation of resulting corrective actions, and the follow-up audits are documented using the audit noncompliance report form, a model of which is enclosed at the end of this procedure.

6.2 Part 1 of the form contains a description of the nonconforming condition, Part 2 contains the proposal for a corrective action, and Part 3 is reserved for the follow-up audit and closeout of the report.

6.3 Pending noncompliance reports are kept by the auditor who initially issued the report. Storage location and retention period for closed-out noncompliance reports are specified in Procedure QOP-16-01 Quality Records.

6.4 At the end of an auditing cycle, all noncompliance reports established during the cycle are compiled and analyzed, and are presented for the management review meeting.

IV ASSOCIATED DOCUMENTS

- Corrective and Preventive Actions — Oper. Proc. QOP-14-01

Insert **AUDIT NONCOMPLIANCE REPORT FORM** from file FRM1701.DOC