**Purpose**

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

**Planning**

The QA Department is responsible for planning and scheduling the internal audits. Each main activity comprising the quality system is audited at least once a year. In addition to the annually scheduled audits, the QA Department may select certain activities for more frequent auditing, depending on their status, importance and past compliance history. The audit plan lists all the activities corresponding to the sections of the quality manual, identifies locations where these activities are taking place, and assigns an audit date to each activity/location.

**Audit Team**

Personnel assigned to carry out an audit are independent of those having direct responsibility for the audited activity. It is normally a QA representative, assisted by a trained inspector, who conducts the audits. Personnel from other departments are also encouraged to familiarize themselves with auditing techniques and participate in the internal auditing program as assisting auditors.

Activities that are the responsibility of the QA department are audited by the Director of Operations or the Process Engineer.

**Preparation for Audit**

Auditors prepare for an audit by fully familiarizing themselves with the 21 CFR 210 & 211 standards, refreshing their knowledge of the quality manual and relevant operating procedures, reviewing the nonconformity reports and corrective actions files, and preparing questions and checklist.

**Conducting an Audit**

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.

While conducting an 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 on the Noncompliance Report form (QA-21-F01). 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.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Revision  Number | Revision  Date | Effective  Date | Revision  Author | Quality  Approval | Production Approval | Revision Description |
| 00 | 8/24/2012 | 8/24/2012 | Deborah Durbin | Deborah Durbin | Jason Bumgarner | New Document |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |