SMG 8076 FDA State Contract Audit Program Appendix A

Instructions for Evaluating Contract Inspections

The purpose for evaluating the quality of inspections purchased through contracts with state agencies is to determine if the inspection is acceptable. The success of the evaluation depends on how well the auditor and auditee understands his/her role and responsibilities.

Responsibilities of the Auditor

1. Recognize that contract inspections may be performed under state procedures and regulations and may differ in approach and format from an inspection done by an FDA investigator. Remember that the state inspector may inspect this facility several times in a year and consequently, may be more familiar with the firm's equipment and procedures than the auditor. During the pre-assessment meeting, the auditor should begin to assess the auditee's experience and familiarity with the facility being inspected.

2. Become familiar with the state's procedures and regulations and be aware of the legal actions used by the state.

3. Understand the contract requirements.

4. Establish and maintain good rapport with the auditee.

5. Be diplomatic and professional when communicating with the auditee.

6. Be objective and non-judgmental in communications and interactions. Learn to offer guidance and suggestions rather than criticisms.

Preparing for the Audit

1. Set a mutually-agreeable date for the audit.

2. Meet at a location prior to the start of the inspection to discuss the audit and inspection processes.

3. Review the firm's inspection file.

4. Assess the auditee's preparedness (e.g., review previous inspection report(s), review applicable guidance, etc.).

Participating in the Audit

1. Identify yourself after you are introduced by the auditee.

2. Shadow the auditee throughout the inspection. Observe inspection techniques and methods and listen to the questions the auditee asks. Do not follow your own leads

into other areas of the facility, rather follow the auditee's lead only. The auditor should not attempt to influence or assist with the course of the inspection. Instead observe the auditee's inspection approach and techniques.

3. If the auditee doesn't volunteer information or it isn't apparent, ask questions for clarification on the auditee's decision-making process. For example, when the auditee is reviewing records the auditor might ask, "What are you looking for in these records?" or "What if this record is missing?" Always ask open-ended questions to help with your assessment.

4. If asked for guidance, reiterate the guidelines of the audit, for example, you (as an auditor) cannot discuss observations and procedures until after the inspection. Encourage the inspector to proceed as if he/she was alone. If the auditee does not proceed in the most appropriate manner, this should be discussed at the conclusion of the audit and documented on the audit form.

5. Make thorough and specific notes throughout the inspection. Be familiar with the questions on the audit form so that you can make a fair and objective assessment of each question. Complete the audit form at the end of the inspection.

6. Immediately prior to the final discussion with the firm's management, ask the auditee to list or verbalize the violations that will be discussed with management. If there is a significant violation affecting product safety that the auditee did not recognize or address, discuss it with the auditee at this time so that he/she can take appropriate steps before the final discussion.

7. If during the inspection an imminent health hazard is identified, or a situation arises that the auditee is unable to manage AND failure to address it will result in a real public health risk, stop the audit and immediately **EXIT** the facility. A joint inspection may be initiated. If a joint inspection is initiated, reenter the facility and issue a Notice of Inspection (FDA-482) if appropriate.

8. Unless mutually agreed by the auditor and auditee that circumstances described in #7 exist, you **should not** switch from an auditor to the role of an inspector during the audit.

9. Discuss your audit observations with the auditee after the inspection and the discussion with management has been completed. This is the time to offer suggestions for improvement and answer the state inspector's questions. Don't forget to point out the things that were done well! You may provide the auditee with a copy of the audit form.

10. Follow FDA agency policies regarding the disposition of reports and other related documents.

Responsibilities of the Auditee

1. Introduce yourself and the auditor then explain the purpose of the visit and the presence of the auditor to the firm managers.

2. Take the lead throughout the inspection. You will determine the pace of the inspection, question firm managers, determine the processes and equipment to be examined, records to be reviewed, and conduct the inspection as usual under state authority.

3. Be familiar with the specific requirements of the contract.

4. Verify interstate commerce to establish FDA's jurisdiction over a facility. This will assist FDA and the state agency in maintaining a current establishment inventory. It will also aid in selecting firms under the state agency's jurisdiction.

5. Communicate with the auditor throughout the inspection - explain the state's inspection process and what you are observing in the firm.

6. Conduct the closing interview with the firm's management.

7. Record and document the inspection on the appropriate agency forms and any forms required by the contract.

8. Submit reports within timeframes per contract requirements.