

## Summary of Observations/Comments

### *Vendor Qualification Assessment Visit xxx, 200x*

The following identifies the observations, comments and/or recommendations, if applicable, noted during the xxx visit of xxx, xxx, xxx office on xxx, 200x. Additionally, there is an area for xxx to respond with any plan of action(s) to address these concerns.

**Observation/Comment #1:** There is not a formal HIPAA training in place.

*Response:*

**Observation/Comment #2:** There is not a formal Business Continuity or Disaster Recovery Plan in place.

*Response:*

**Observation/Comment #3:** There is not a process in place if a fire alarm goes off.

*Response:*

**Observation/Comment #4:** The contracted QA personnel reports directly to the VP of xxx.

*Response:*

**Observation/Comment #5:** There are not any IT SOPs that are finalized yet.

*Response:*

**Observation/Comment #6:** There is not an SOP on subcontracted procedures.

*Response:*

**Observation/Comment #7:** There is no SOP describing the handling of regulatory authority inspections.

*Response:*

**Observation/Comment #8:** There is not an SOP to document the procedures, including QC, of transcription or data entry from Source Documents to either the xxx or xxx system.

*Response:*