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Analyzing Data and Reporting Audit Results

DURING THE COURSE of an audit, many documents, records, and data may have been reviewed. Some audits have examined every record, while others have recorded samplings of data. In general, the likelihood that the data from the sample matches the true state increases with the number of records reviewed or observations made.

In addition, there are interviews and direct observations of work practices to evaluate. The auditor should maintain an open mind during this process and evaluate the data against the standard or regulation. Evidence obtained through observation may need verification and records may need clarification. If observational evidence will be cited, the auditor should ensure that it has been corroborated in the working papers.

DATA ANALYSIS

The notes taken during the audit serve as the basis for the report and contain the details of the observations. The description of the nonconformance should be complete enough for the auditee to find the record. The details may be necessary to take corrective actions or be of assistance in identifying specific records. In some cases a photocopy of the record may be helpful.

The next step is to categorize and summarize the data or findings. The records, data, or observations should be compared to the standard or regulation and a decision made whether the information meets the requirement. Figure 1 shows a run chart of average turnaround times for CD34 testing, and identifies three occasions when the length of time was excessive. Sometimes, the auditor may need to revisit the area if something appears to be missing or if clarification is needed.

With a simple audit evaluating compliance with a single standard, it may be sufficient to state the number of records reviewed or work practices observed, the number of failures, and the percentage of failures. The information could also be stated as the number of events that met the criteria.

With a comprehensive audit, there may be several single observations that alone would not be cause for a nonconformance. However, these individual observations may fall under the same category such as record-keeping issues, validation planning, or process control. It is possible that the individual observations, when put together, provide enough evidence to support a nonconformance. If several of the individual observations fall under one of the QSEs, a systems problem has been identified.

In order to be cited as a nonconformance, the evidence should show that there was a failure to meet a requirement and that the failure has a negative, significant impact.

- Does the potential nonconformance pose a threat to staff or patients?
- Is there a failure to meet local, regional, state, or federal regulations?
- Is it a requirement of an accrediting organization?
- Is it an internal requirement?

Requirements of accrediting organizations may be less than, be the same as, or exceed the minimum requirements of regulatory agencies. When the requirements of multiple organizations are evaluated during an audit, it is important to be clear about the source of the requirement as well as the nonconformance itself.

Information obtained during an audit that would present a health or safety risk to staff or patients should be reported immediately. Although

audit results can be reported by risk, this is not the usual format unless a critical risk is identified.

FORMAT OF THE REPORT

Once the data and findings are evaluated and categorized, the next step is to review the information to write the report. It is prepared according to a standard format. The auditor may report positive information as well as negative information and compare previous audit results with the current results when conducting a repeat audit.

The data summary could be contained in the body of the report or be an attachment to the report. For a formal audit with an opening and closing meeting, the report would be presented at the closing meeting, or submitted within a few days following the audit. Whether it is a formal audit report or a report from a routine audit, it is best for as little time as possible to elapse between the audit and the preparation and submission of the final report. With a shorter time span, there is more enthusiasm to take necessary corrective actions and less time for other activities to increase in importance. In most internal audits, the results may be discussed at regularly scheduled meetings, or simply forwarded to management for review and signature. When corrective actions require significant changes in operations, a special meeting may be scheduled. The results should also be made available to those participating in the audit and the staff members working in the affected section.

The report serves to enumerate the nonconformances and creates a record of the audit that guides management in taking corrective actions and make plans for process improvements. The specific format of a report can vary from facility to facility or by the organization performing the audit. Appendices W and Y show two different report templates. Appendix Z gives a sample corrective action plan. When the report is separate from the audit plan, an introduction is needed to refer to the purpose and scope of the audit.

- **Introduction.** This section includes the purpose and scope of the audit, laboratory section being audited, standards used, individuals interviewed, records reviewed, and any sampling methods used.
- **Summary.** This section may contain both positive and negative statements that assess the overall compliance with the standards, the ability of the systems to obtain compliance, and the need for and timing of future audits. If there are best practices identified, they may be described in this section.
- **List of Findings and Nonconformances.** Nonconformances should be listed and may contain a severity rating such as critical, major, minor, or incidental. They may be listed in the order of importance or in the order of the standards document being used as the reference. The nonconformance should define the standard not met and the evidence used to make this conclusion, such as "The person performing ____ task was not identified in 15 of 35 records reviewed." It is not necessary for the auditor to note the cause of a nonconformance because this may not be known. This section may also contain audit history, if there were improvements in compliance, and opportunities for improvement.
- **Recommendations for Corrective Action.** The section contains specific areas for improvement. It does not provide detailed instructions for correcting the nonconformance. That is the responsibility of management.
- **Time Frame for Corrective Action.** In a formal audit there will be a defined period for responding to the audit. It is useful to include a time frame in an internal audit to ensure that action is taken in a timely manner.
- **Attachments.** In addition, reports may contain attachments of evidence, list of individuals attending the meetings, and individuals interviewed if not included in the summary section.

INCIDENTAL FINDINGS

Evidence should be related to the audit topic objectives and scope. However, it is not uncommon for the auditor to come upon an

incomplete record or make observations that would be important to report to management. Corrective actions may be needed. This information should be reported as incidental findings but not be included in the request for corrective actions.

EXIT MEETING

Formal audits include an exit meeting to review the findings and list nonconformances. If post-audit activities are needed (eg, corrective action), the responsibilities and time frame are communicated. Exit meetings are not generally held during informal audits. The report is generated and sent to the management team.