REVIEW OF QUALITY CONTROL & EQUIPMENT MAINTENANCE RECORDS

Sheryl Stuckey, MLS (ASCP)^{CM}
Manager, Microbiology Laboratory
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Why and How Is Record Review Performed

- The timely and accurate documentation of quality control testing, equipment maintenance and function checks is necessary to ensure the quality and accuracy of patient diagnostic testing to promote positive patient outcomes.
- The review of this documentation at least monthly is necessary to ensure that follow-up for outliers, trends and omissions have been completed.
- **Primary review of the record** is performed by the person that initially recorded the results. *This is the first opportunity to ensure completion of the record or initial follow-up for any issues (i.e., results outside of stated limits).*
- **Secondary review of the record** is performed by each person who subsequently accesses the record (**ONGOING REVIEW**). *This is the next opportunity to resolve any issues with testing, equipment function, or the record.*

Why and How Is Record Review Performed

Monthly review by the laboratory director or designee is performed to ensure follow-up for outliers, trends and omissions that were not previously addressed. The process for review is as follows:

a. Compile all records needing review for the month and sort according to type (i.e., equipment, reagent, media, etc.).
b. Review the record for omissions, trends, results outside of stated limits, and documentation of corrective action, as needed.
c. Any omissions, failures to document corrective action, unacceptable or incomplete corrective action is considered a variance and must be reviewed with the technologist responsible.
d. Evaluate and investigate the root cause for any issues and complete corrective action if necessary.
e. Document the review by recording the review date and your initials on **each page** of the record.

EXAMPLES OF RECORD VARIANCES

1. Incorrect correction of the record (i.e., overwriting or no date/initials recorded).
2. Incomplete documentation (i.e., quality control results not recorded).
3. Expired reagents used for testing.
4. Equipment maintenance not performed.
5. Quality control testing or equipment maintenance not performed according to schedule.
6. No documentation of corrective action.

MONTHLY REVIEW BEST PRACTICES

- #1 BEST PRACTICE – ALL TEAM MEMBERS CREATE LEGIBLE AND COMPLETE RECORDS.
- Organize the records according to type (i.e., Incubators) so that missing records can be easily detected.
- Do not highlight outliers on the record; flag the page with a Post It note stating the problem and segregate the page in a separate folder designated for record issues.
- Document the corrective action on the record or permanently affix (i.e., staple) documentation of the correction to the original record.
- Immediately file the record in the appropriate storage location once corrective action is completed.

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