



SUBJECT: QUALITY MANAGEMENT SYSTEMS

[QMS S1(l)/ Process Review S2, QMS S1(m)/Reporting S1-S3]

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TITLE: RESULT VERIFICATION AND REPORTING

PURPOSE

To ensure that physicians receive useful, timely and accurate reports of patient results.

POLICY

- 1. The Department of Pathology shall issue an original report to the physician or other authorized person submitting a specimen for analysis in a format which is usable, correct and informative.
- 2. The department of Pathology shall perform regular review activities to monitor the accuracy and verify the reporting integrity of patient results entered into the laboratory information system, either manually or through an interface.

PROCEDURES

I. Result Verification

A. Result Verification of Interfaced Results

1. Results which are generated by instrumentation which is interfaced into the laboratory information system (LIS) are checked for integrity by comparison to parameters which are programmed in the LIS including:

- a. Electronic requisition processing
- b. Host query to identify test requests
- c. Positive patient identification by direct bar code scanning and identification
- d. Test specific flags
 - 1. Delta checks
 - 2. Instrument sensitivity and linearity ranges
 - 3. Alert values
 - 4. Review flags
 - 5. Data format requirements including decimal place, text vs. numeric inputs, significant digits
 - 6. Absurd values or inconsistent results
- e. Historical patient data review

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B. <u>Result Verification of Manual Inputs</u>

1. Patient results which are not received by an interface with the laboratory information system (LIS) must be entered manually by the technical staff after being recorded on a worksheet at the time of test performance.

- 2. Manually entered patient result inputs will be reviewed regularly for transcription and data entry errors.
- 3. Each section of the laboratory utilizes review processes to ensure that manual entries are correctly inputted and to timely identify and correct transcription errors when they do occur.
 - a. Double key entry verification test result fields in the LIS are built so as to require a double entry of manual results. The two step, confirmatory data entry response for result reporting reduces the likelihood of a data entry error being repeated in both fields and alerts the user if the two data inputs do not match.
 - b. A supervisor or designee of the laboratory will randomly review and compare the results which are recorded on the worksheet with those entered into the LIS by checking one of the following:
 - 1. A copy of the results printed by the data entry person before result verification, reviewed by the data entry person and compared to the worksheet record. The printed results will be attached to the worksheet for supervisory review;
 - 2. The supervisor will review the data entries electronically through the LIS record (Review Queue);
 - 3. The supervisor will review the workload activity report retrieved through the LIS, either electronically or by paper printout.
- 4. Supervisory review of the manual data entry inputs for clerical or transcription errors will be documented by the initialing of the manual worksheets, chart reports or activity reports by the supervisory staff or their designee.

II. Laboratory Reports

- 1. The laboratory issues a result report for all completed testing, available to authorized persons with the objective to provide useful clinical data in a legible, prompt and accurate manner.
- 2. A result report is issued for each and every specimen submitted to the laboratory for testing. The reports contain the following information:
 - a. The patient name or other identifier;
 - b. The name of the person or institution ordering the test;

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- c. The name of the laboratory and its address;
- d. The name of the laboratory Director;
- e. The date and time, if necessary when the specimen was collected;
- f. The date the specimen was received in the laboratory;
- g. The specimen source, if appropriate;
- h. The test results accompanied by units of measure and reference intervals

sufficient to allow the identification of abnormal values;

- i. Signatures of the persons who reviewed, approved and/or diagnosed the case, where required;
- j. information concerning the condition and disposition of specimens which are unacceptable;
- k. The name and address and date of testing and result reporting if a specimen was forwarded to another laboratory for testing;
- 1. Interpretative statements or pertinent updates of testing information are provided on patient reports whenever necessary to assist the physician in interpreting the results.
- 3. Review of reports
 - a. Reports are reviewed and approved by the director for content and format at the time of implementation of new report formats, new tests or new reporting mechanisms and when major system changes occur.
 - b. At periodic intervals, not to exceed a year the director or designee reviews and approves the content and format of reports.
 - 1. All formats (paper & electronic) are reviewed so as to verify the continued effective communication of patient test results sufficient to meet the needs of the medical staff.
 - 2. A sampling of test results/reports will be chosen for review.
 - 3. Reports from each different system (LIS/HIS, etc) will be reviewed, i.e. wherever patient data can be assessed by clinicians.
 - 4. The date of review and the signature of the reviewer will be placed on the first page of a batch listing the accession numbers reviewed within the batch to serve as documentation of the review process.
- 4. Referral laboratory results
 - a. Results received from referral laboratories are transmitted electronically directly to the laboratory information system in its entirety, so as not to alter or revise the results, information or interpretative statements provided by the testing laboratory.
 - b. When referral laboratory results are unable to be directly transmitted to the laboratory information system or it is not feasible to do so because of the reporting format or content an exact duplicate of the testing laboratory's report is provided to the physician or authorized person ordering the test.
 - c. Results from reference laboratories are reported in a format consistent with other

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laboratory issued reports.

5. Changes in analytical methodology or systems which cause significant changes in interpretations and/or test results are explained with a comment on the report, mass announcement to system users, newsletter or bulletins.

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REFERENCES

- 1. Former Departmental Policy and Procedure entitled System for Detection of Data Transferring/Transcription Errors in Laboratory Information System (LIS), LAB-8
- 2. Pacific Northwest Laboratory Medicine Sentinel Monitoring Network Final Report of the Findings of Corrected Patient Reports; LaBeau, Simon and Steindel; February 1997

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