QSE 9: Information Management

Policy	The laboratory controls how patient and laboratory information is received, accessed, transmitted, and stored in both paper-based and electronic information systems.
Purpose	This policy provides direction for the processes and procedures to effectively manage laboratory-generated information.
Responsibility	The Laboratory Medical Director is responsible for turn around time decisions. The Laboratory Supervisor is responsible for adherence to patient confidentiality and review of laboratory results. The Lead Technologists and Quality Manager are responsible for review of laboratory results. Information Technology is responsible for technological processes in the management of electronic information.
Patient Confidentiality	Processes are designed to ensure that patient information is kept private and confidential.
Electronic Information Accessibility and Usage	Electronic data is retrievable only to authorized personnel
Reporting of Results	Results are reported correctly and within established turnaround times.
Results Modification	Any results changed or modified are documented to show both the original and modified results, reason for change, name of person notified, and date and time of notification.
Reporting Delays	Delays in testing or reporting results are relayed to key persons.
Result Reporting Changes	Changes in test methodology or reference ranges are communicated to the ordering staff and/or associated study administrators.
Data Integrity and Storage	Data is stored and used in a manner that maintains the integrity of electronic and paper-based data.
Supporting Documents	The following processes support this policy: • Patient Confidentiality • Accessing and Using Electronic Information • Reporting of Results • Results Modification • Reporting Delays • Result Reporting Changes • Data Storage and Maintaining Data Integrity

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Process for Patient Confidentiality

What Happens	Who's Responsible	Procedures
A policy regarding patient confidentiality and restriction of access to patient information is established	• Laboratory Director • Facility Committee on Patient Confidentiality	• Laboratory Patient Confidentiality Procedure • Facility Patient Confidentiality Procedure
A system is in place to limit access to places where patient information is stored, including paper-based records and electronic data bases	• Laboratory Director • Laboratory Supervisor • Facility Committee on Patient Confidentiality • Medical Records Department • Information Technology (IT) Department	• Laboratory Patient Confidentiality Procedure • Facility Patient Confidentiality Procedure • Medical Records Procedures • IT Confidentiality Procedure
Employees attend required orientation sessions regarding patient confidentiality	• Human Resources • Laboratory Supervisor • Technicians/Technologists	• Patient Confidentiality
Employees sign confidentiality pledge	• Human Resources • Laboratory Supervisor • Technicians/Technologists	• Patient Confidentiality
Requests for patient information are handled in a manner that ensures patient confidentiality and provides information only to approved individuals	• Laboratory Supervisor • Technicians/Technologists	• Laboratory Patient Confidentiality Procedure • Managing Requests for Patient Information

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Process for Accessing and Using Electronic Information

What Happens	Who's Responsible	Procedures
The computer system facilities meet environmental conditions and safeguards for proper system operations	• Information Technology (IT) Department • Facilities Management	• IT Department Procedures • Facilities Management Plans
The computer systems meet laboratory accreditation and regulatory requirements	• IT Department • Laboratory Director • Laboratory Supervisor	• IT Department Procedures • Laboratory Accreditation and Regulatory Requirements
Preventive maintenance is conducted on computer systems	• IT Department	• IT Department Procedures • Preventive Maintenance Records
Disaster recovery plans, including alternative plans for downtime of computer system, are documented and practiced	• IT Department • Laboratory Director • Laboratory Supervisor	• IT Department Procedures • Disaster Recovery Plans • Plan for Computer Downtime
Procedures for backup of information are in place	• IT Department	• IT Department Procedures
Changes to existing programs or validation of new programs is communicated	• IT Department • Laboratory Supervisor	• IT Department Procedures • Staff Notification Policy
Authorized personnel are trained in the use of electronic data management systems	• IT Department • Laboratory Supervisor	• IT Department Procedures • Training Procedures
Security and access are restricted to authorized personnel based on job requirements and functions	• IT Department • Laboratory Director • Laboratory Supervisor • Technicians/Technologists	• IT Department Procedures • Computer Access and Security
An audit trail is available to identify any individual who has accessed, entered, or modified data	• Laboratory Supervisor • Information Technology Department	• IT Policies and Procedures • Computer Access and Security

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Process for Reporting of Results

What Happens	Who's Responsible	Procedures
A procedure for reporting results is written and implemented	• Laboratory Director • Quality Manager • Laboratory Supervisor	• Reporting Results • Laboratory Section-Specific SOPs
Panic levels and population normal ranges are established and methods for reporting them are written and implemented	• Laboratory Director • Quality Manager • Laboratory Supervisor	• Reporting Results • Chart of Analyte Panic Levels • Population Normal Ranges • Test-Specific SOPs
Results reports, including population normal ranges and laboratory information, are generated	• Lead Technologist • Technicians/Technologists	• Reporting Results • Laboratory Section-Specific SOPs
Reported results are compared to the bench worksheet and/or instrument printout to detect discrepancies	• Quality Manager • Lead Technologist • Technicians/Technologists	• Reporting Results • Quality Management
Patient caregivers are notified of panic results	• Lead Technologist • Technicians/Technologists	• Reporting Results • Chart of Analyte Panic Levels • Notification of Results
Results reports are stored according to laboratory and/or facility policy	• Lead Technologist • Technicians/Technologists • Quality Manager	• Reporting Results • Maintaining Laboratory Records

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Process for Result Modification

What Happens	Who's Responsible	Procedures
An incorrectly reported result is identified	• Technicians/Technologists • Quality Manager • Lead Technologist • Patient Caregiver	• Reporting Results • Result Modification
Correct result is entered and a copy of the modified report is initialed by the reporting technician/ technologist and the Laboratory Supervisor	• Technicians/Technologists • Laboratory Supervisor • Lead Technologist • Quality Manager	• Reporting Results • Result Modification
The ordering physician or clinic is notified of the result modification. Notification is documented.	• Lead Technologist • Technicians/Technologists • Patient Caregiver	• Result Modification • Notification of Results
Modified reports, including original results, notification, and reason for change, are maintained	• Quality Manager • Lead Technologist • Technicians/Technologists	• Result Modification • Maintaining Laboratory Records
Modified results are documented under quality assurance monitoring	• Quality Manager	• Result Modification • Quality Management

Process for Reporting Delays

What Happens	Who's Responsible	Procedures
Delays related to result reporting or equipment failures are monitored and documented to help evaluate the overall effectiveness of the laboratory	• Quality Manager • Lead Technologist • Technicians/Technologists	• Reporting Results • Test Turnaround Times • Quality Management
Results of tests that are delayed are relayed to key persons involved in patient care	• Lead Technologist • Technicians/Technologists • Patient Caregivers	• Reporting Results • Notification of Results

Process for Communicating Result Reporting Changes

What Happens	Who's Responsible	Procedures
Changes in test methodology and/or reference ranges are communicated to the ordering staff	• Laboratory Supervisor • Laboratory Director • Patient Caregivers	• Laboratory Section-Specific SOPs • Reporting Results • Laboratory Communication Procedures
Changes in test methodology and/or reference ranges are communicated to the associated study administrators	• Laboratory Supervisor • Laboratory Director • Study Personnel	• Laboratory Section-Specific SOPs • Reporting Results • Laboratory Communication Procedures
Changes in test methodology and/or reference ranges are communicated to laboratory staff	• Laboratory Supervisor • Lead Technologist • Laboratory Staff Members	• Laboratory Section-Specific SOPs • Reporting Results • Laboratory Communication Procedures

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Process for Data Storage and Maintaining Data Integrity

What Happens	Who's Responsible	Procedures
Data is labeled and stored in an area with limited access and appropriate environmental conditions	• Laboratory Supervisor • IT Department	• Data Storage and Accessibility • IT Department Procedures
Procedures for backup of information are in place	• IT Department	• IT Department Procedures
Data integrity is verified after transmission and downtime	• IT Department	• IT Department Procedures
Data integrity is verified by comparing it with the original input at defined intervals to detect errors in data transmission, storage, and processing	• Laboratory Supervisor • Quality Manager • IT Department	• Verifying Data Integrity • IT Department Procedures • Quality Management
Calculations performed on patient data by the computer system are periodically verified/reviewed and documented	• Laboratory Supervisor • Quality Manager • IT Department	• Verifying Data Integrity • IT Department Procedures • Quality Management
Manual reports are periodically reviewed for correctness	• Laboratory Supervisor • Quality Manager • IT Department	• Verifying Data Integrity • IT Department Procedures • Quality Management