Moving a Clinical Flow Cytometry Laboratory

A practical, quality-based stepwise guide

Sponsored and reviewed by the ICCS Quality and Standards Committee

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Abbreviations

AED	Automated External Defibrillator
CAP	College of American Pathologists
CLIA	Clinical Laboratory Improvement Amendments
FAQ	Frequently Asked Question
IQ/OQ	Installation Qualification / Operational Qualification
IT	Information Technology
LIS	Laboratory information system
PQ	Performance Qualification
PT	Proficiency Testing
QC	Quality Control
QMS	Quality Management System
QSE	Quality System Essential
SOP	Standard Operating Procedure
TAT	Turnaround time
UPS	Uninterruptible power supply

Purpose and scope

Relocating a clinical flow cytometry laboratory is a complex, high-risk project with direct implications for patient care, regulatory compliance, and staff safety. The authors of this module have all planned and completed laboratory moves and aim to share insights and recommendations gleaned from their experiences. This module presents a practical approach to laboratory relocation using a three-phase model (pre-move planning, move execution, and post-move stabilization) aligned to the Quality System Essentials (QSEs, Appendix 1).

Common laboratory relocation types include:

Intra-room relocation which involves moving equipment or workflow within the same room

Intra-building relocation which involves moving laboratory operations to another room or area within the same building

Inter-building relocation which involves transferring laboratory operations between buildings on the same campus or health system site

Off-site relocation which involves moving laboratory operations to a geographically separate location outside the current campus or institution

The process can be planned as a ***phased relocation***, in which sections of the laboratory are moved in stages while operations are maintained, ***a full laboratory transition***, involving complete shutdown and transfer of all laboratory operations to a new site, ***a temporary swing-space relocation*** during renovation or construction, or an ***instrument-specific relocation***, in which individual analyzers or equipment are moved separately from the main laboratory move.

Regardless of the type of relocation, laboratories should adapt the recommendations to local institutional policies and applicable requirements (e.g., CAP, CLIA, and state regulations), and to the scope of the move (e.g., same versus new CLIA license). The relocation process can be organized into three phases, each including activities that map to multiple QSEs: **1) Pre-move Planning**; **2) Move Execution**; and **3) Post-move Stabilization**.

Outline

Phase 1: Pre-move Planning

The pre-move phase is the primary determinant of success and may begin months to years before the physical move.

Organization and leadership

- Establish clear leadership, reporting structure, and escalation pathways
- Define ownership for each major workstream (e.g., assays, instruments, LIS, facilities)
- Consider dedicated project management support for timeline control and cross-team coordination
- Maintain transparent, frequent communication (town halls, FAQs, shared dashboards)

Personnel

- Assess staffing impact, recognizing added workload from:
    - Planning and documentation
    - Packing/unpacking

    - Training and competency reassessment
    - Validation and reverification
- Request additional laboratory or support staff (e.g., technologists, laboratory assistants, technologist aides) as needed
- Engage staff from the beginning, explain the rationale for the move, and provide opportunities for ownership
- Anticipate that workflow changes may require new training documentation. New CLIA numbers require full retraining and competency documentation

Establishing a "communication plan" (including contacts, cadence, content, format)

- Identify key stakeholders and contacts early (e.g., patients, clinicians, transplant programs, vendors, and referral laboratories)
- Define a communication cadence in advance, including routine updates, move-window huddles, and clear escalation pathways for urgent issues
- Communicate anticipated downtime, delays, temporary workflow changes, and contingency plans (e.g., send-outs or reduced testing volume) in a timely manner
- Standardize message content so each communication states what is changing, when it will occur, who is affected, required actions, and where to obtain updates or assistance
- Use multiple communication formats as appropriate (e.g., email notices, tip sheets, FAQs, dashboards, signage, and brief live huddles) to reach different stakeholder groups effectively
- Define post-move expectations clearly, including specimen requirements, reporting changes, and any temporary turnaround time adjustments
- Set conservative service commitments during relocation and aim to exceed them whenever performance allows

Facilities and safety

- Engage facilities and environment/safety teams along with the vendor from the beginning of planning relocation
- Confirm:
    - Appropriate bench material, quantity and design, vibration tolerance
    - Ceiling height and clearances
    - Adequate power and data outlets (normal, emergency, UPS)
    - Eyewash, showers, spill kits, AEDs
    - Waste, exhaust, vacuum, and compressed gases
    - Temperature control and monitoring
    - Ventilation and other related airflow considerations, especially where biosafety cabinets are placed
    - Storage conditions for specimens and reagents (it should be maintained and monitored throughout the relocation process)
- Plan for emergency scenarios (weather events, sheltering, ride-out staffing)
- For off-site laboratories, ensure access to occupational health, security, housekeeping, and IT

Equipment

- Inventory all instruments and determine:
    - What will be moved vs replaced
    - If vendor involvement is needed for uninstall/reinstall and IQ/OQ
- Engage vendors early (often ≥1 year in advance)
- Consider instrumentation redundancy to allow staggered moves and continuous testing
- Ensure sufficient space, power, data, and bench compatibility

Purchasing and inventory

- Develop strategies to:
    - Draw down inventory at the old site
    - Redirect deliveries to the new site
- Ensure validated storage (refrigerators/freezers) is available prior to beginning phase 2
- Anticipate supply chain delays and validation needs
- Prepare comprehensive reagent and supply lists for each validation

Process improvement

- Map current and future workflows in detail
- Evaluate impacts on:
    - Specimen transport, storage and courier services
    - Interdepartmental specimen sharing
    - Internal laboratory foot traffic and equipment placement
- Redesign workflows to optimize efficiency and reduce error risk
    - Unidirectional workflow (biosecurity): receiving and sorting samples, accessioning, panel decision, preparation, acquisition, analysis

Information technology management

- Identify laboratory information system (LIS) impacts:
    - New builds vs modifications
    - Interfaces, routing, billing, report formatting (new CLIA Certificate number and laboratory address)
- Perform full backups of software, analysis templates, and FCS/LMD files
- Plan staged LIS validation
- Verify decimal places, units, reference ranges, comments, and CLIA identifiers

Documents and records

- Begin documentation on day one
- Maintain:

    - Decision rationales
    - Draft SOPs for new workflows
    - Validation and reverification plans
- Obtain medical director approval of validation acceptance criteria in advance

Occurrence management and risk mitigation

- Anticipate increased risk for errors during transition
- Implement:
    - Go-Live Readiness Assessments (traffic-light status: green/yellow/red)
    - Operational dress rehearsals simulating end-to-end testing
- Assign clear corrective actions for identified risk

Phase 2: Move Execution

This phase translates planning into execution and benefits from frequent communication (reflecting on above noted communication plan approach), and clear decision-making. It begins once the new space becomes available and has passed an initial assessment clearing it for use. The estimated timeframe for completion of this phase will vary depending on the size of the laboratory, complexity of the test menu, personnel availability, and whether testing needs to remain uninterrupted during the process and may range from few weeks to several months.

Organization, communication, and personnel

- Maintain frequent check-ins with leadership, other stakeholders and teams involved in the relocation such as facilities, information technology, LIS, couriers and frontline clinical laboratory staff.
- Escalate issues promptly and request additional resources when bottlenecks arise
- Orient all staff to the new space, including safety procedures and emergency routes

Facilities and safety

- Anticipate unexpected issues (bench fit, utilities, casework)
- Resolve safety concerns immediately; no testing should occur with unresolved hazards
- Coordinate closely with facilities for complex fixes

Equipment qualification and validation

- Track all equipment using standardized tools (asset management systems or spreadsheets)
- Include serial numbers, nicknames, locations, and status
- Perform:
    - Qualification (IQ/OQ) before use
    - Reverification or full validation as required by CLIA status

- Use visual status indicators (e.g., red/green tags) to communicate readiness

Information technology

- Test networks, LIS integration, and software licenses

Purchasing and inventory

- Balance maintaining patient testing at the old site with stocking the new site
- Designate personnel to manage inventory and order tracking
- Confirm all reagents pass QC before use
- Consider the implementation of an inventory management system (In-house built, customized to the laboratory's needs, or commercial software). A summary of asset and inventory management systems specifically suited for clinical laboratories is provided in Appendix 3.

Process control and task tracking

- Use shared task management tools to track dependencies and timelines
- Keep staff aligned on specimen availability, validation sequences, and go-live criteria

Reagent Management and Safe Transport of Temperature-Sensitive and Light-Sensitive Materials

- Create a detailed reagent inventory before packing: Document storage requirements (e.g., 2–8 °C, −20 °C, −80 °C, protect from light), lot numbers, expiration dates, and quantities
- Use validated transport containers:
    - For refrigerated or frozen materials, use coolers, insulated shippers, or dry-ice containers capable of maintaining required temperatures for the full transport duration
- Include temperature-monitoring devices inside each container
    - Single-use loggers
    - Bluetooth probes
- For light-sensitive reagents, use amber secondary containers or wrap primary containers in foil
- Pack reagents using a layered, stability-preserving approach
- Pre-condition cold packs or dry ice
- Separate reagents from direct contact with ice/dry ice using cardboard or bubble wrap to prevent freezing damage
- Maintain upright orientation for antibody cocktails or fragile reagents
- Maintain chain-of-custody and documentation and use a move log
- Record packing time, temperature at departure, and personnel involved
- Minimize transit time and avoid unnecessary temperature excursions
- Transport reagents last-on/first-off during the move
- For off-site moves, use direct courier transport rather than general freight
- Ensure the receiving site has validated refrigerators/freezers powered and monitored before materials arrive

- Verify reagent integrity upon arrival
- Review temperature-logger data before releasing reagents for use
- Perform QC checks on critical reagents (e.g., antibody panels, viability dyes) before incorporating them into validation or patient testing
- Document all deviations and corrective actions
- Any temperature excursion or suspected degradation should be logged as an occurrence, with risk assessment and mitigation steps

Documentation and record keeping

- Document activities in real time
- Ensure all staff use the same organizational system
- Remember: "***if it is not documented, it did not happen***"

Approval of the Validation/Verification

- All necessary Medical Director approvals must be completed before running any specimen.

Phase 3: Post-move Stabilization

After go-live, the focus shifts to stabilizing operations and confirming continued quality and compliance.

Assessment

- Complete remaining validations and LIS testing
- Ensure that instruments, workflows, and reports are performing consistently using the same (pre-move) monitoring methods as per laboratory procedures and policies
- Enroll in PT for each testing site and CLIA number
- Review initial performance data (QC, TATs, error rates)

Process improvement

- Identify workflow inefficiencies revealed after go-live
- Revise SOPs as applicable to reflect actual practice
- Implement corrective actions as needed

Customer service and communication

- Reengage stakeholders to confirm expectations are met
- Address lingering issues proactively
- Complete all required communications with regulatory and accreditations agencies about the relocation or operational changes

Inspection readiness

- Ensure documentation is complete, traceable, and inspection-ready
- Be prepared to justify decisions and validation scope

References and resources

- CLSI. A Quality Management System Model for Laboratory Services. 5th ed. CLSI guideline QMS01. Wayne, PA: Clinical and Laboratory Standards Institute, 2019.
- International Organization for Standardization. (2022). Medical laboratories-Requirements for quality and competence (ISO Standard No. 15189-4:2022).
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- Local institutional policies for facilities, safety, emergency management, and information security.
- Local laboratory quality management system policies for document control, validation/verification, training/competency, and occurrence management.

Summary

A successful laboratory move depends on early and comprehensive planning, effective engagement and communication with internal and external stakeholders and personnel, defined verification/validation activities, controlled execution, and complete documentation.

Organizing work across the three phases described above and aligning tasks with the Quality System Essentials helps maintain testing quality and regulatory compliance throughout the transition.

A summary “relocation checklist” with a list of key activities and evidence/records required is provided in Appendix 2.

Appendix 1: Overview of the Quality System Essentials (QSEs)

The Quality System Essentials (QSEs) are the fundamental building blocks of a laboratory Quality Management System (QMS)-a framework to ensure accurate, reliable, and safe test results. These processes are aligned with the 12 quality building blocks, or QSEs:

- Organization and Leadership
- Customer Focus
- Facilities and Safety Management
- Personnel Management
- Supplier and Inventory Management
- Equipment Management
- Process Management
- Documents and Records Management
- Information Management
- Nonconforming Event Management
- Assessments
- Continual Improvement

The QMS model and the individual QSEs are described in detail in CLSI document QMS01 (CLSI. A Quality Management System Model for Laboratory Services. 5th ed. CLSI guideline QMS01. Wayne, PA: Clinical and Laboratory Standards Institute, 2019).

Appendix 2: Relocation Checklist

Phase	Key activities	Evidence/record
Pre-move planning	▪ Define governance and workstreams ▪ Inventory instruments; confirm vendor support and timeline ▪ Finalize space, utilities, and safety requirements ▪ Map workflows; define downtime and contingency testing ▪ Plan LIS changes and validation	▫ Project plan and risk register ▫ Equipment inventory and service tickets ▫ Floor plan/utility sign-offs ▫ Communication plan for stakeholders ▫ Validation plans and acceptance criteria
Move execution	▪ Pack/move with chain-of-custody where needed ▪ Perform IQ/OQ prior to use ▪ Execute verification/validation per scope ▪ Confirm safety readiness and staff orientation	▫ Move log and asset tracking ▫ IQ/OQ/PQ documentation ▫ Go-live readiness assessment ▫ Training/orientation records
Post-move stabilization	▪ Complete remaining validations and LIS testing ▪ Monitor QC, TAT, and error trends ▪ Update SOPs to reflect finalized workflow ▪ Confirm inspection readiness	▫ QC and performance dashboard ▫ Revised SOPs and document control ▫ PT enrollment/records (as applicable) ▫ Internal audit or readiness checklist

Appendix 3: Comparison of asset and inventory management systems specifically suited for clinical laboratories

System	Instrument Tracking	PM / Calibration	Reagent Inventory	Scheduling	CAP/CLIA Fit	Best For
Agilent SLIMS	✓	✓	✓	✓	✓	Clinical + core labs
LabWare LIMS	✓	✓	✓	–	✓	Clinical labs
LabVantage	✓	✓	✓	–	✓	Hospital systems
Labguru	✓	✓	✓	–	✓	Clinical + research
Lab Symplified	✓	✓	✓	✓	✓	Small–mid clinical labs needing unified ops
iLab Operations	✓	✓	–	✓	–	Core facilities
Benchling	✓	–	✓	–	–	Research labs
Quartzy	–	–	✓	–	–	Inventory-heavy labs
Scispot	✓	–	✓	–	–	Automation-focused labs

Disclaimer: The systems listed are provided as examples only and their inclusion does not constitute endorsement by the authors or by the ICCS; laboratories should select the approach that best fits their operational, regulatory, and budgetary needs, recognizing that home-made or internally developed inventory management systems tailored to local workflows may be preferable and are often highly effective options.

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