



Commissioner's Corner May 2023

Q: What are the requirements for relocating an ASHI accredited laboratory?

A: Relocation of a laboratory takes planning and coordinated timing to minimize the impact on test operations. Before making that leap you first need to notify your accreditation organization (ASHI) about your intent to move.

B.2.1 Laboratories issued with ASHI accreditation must notify the ASHI Accreditation Program and HHS if using ASHI for compliance with CLIA regulations within 30 days of any changes in ownership, name, location.

Q: Will relocating a laboratory require an on-site inspection?

A: On-site inspections are required for labs even if the new location is within the same building. Inspections can be completed by your assigned accreditation organization or by a state agency.

Once you have confirmed your intent to move, notify your ASHI Accreditation Officer or Regional Commissioner to determine when your next on-site inspection is scheduled. Inspections typically are scheduled 3-6 months after the move, and this may align with your current inspection cycle.

Inspections for re-locations may be waived by a vote from the ARB, if the following documentation is submitted to your assigned Commissioner within 3 months of relocation and the following criteria are met:

- Square footage assessment is equivalent or better than the previous laboratory
- Photographs detailing the content and layout of the new space
- Policy describing the handling of Protected Health Information (PHI)
- Plans detailing the hazardous waste storage and disposal
- Explanation of the refrigerator/freezer alarm system
- Documentation demonstrating the relocation of testing equipment maintains performance requirements
- Floor Plan illustrates:
 - Appropriateness of space
 - Location of safety equipment
 - Fire exit routes
 - Office space/paperwork areas
 - Location of wet lab areas

- Equipment locations
- Traffic flow
- Location of pre and post-amplification areas
- Environmental monitoring