



Division of Public Health Services

Public Health Preparedness Services

Bureau of Laboratory Services

250 N. 17th Avenue
Phoenix, Arizona 85007-3231
(602) 364-0720
(602) 364-0759 FAX

JANICE K. BREWER, GOVERNOR
WILL HUMBLE, DIRECTOR

Small Business Bill of Rights

The Department has been provided the legal authority pursuant in A.R.S. § 36-463.02(A) to inspect the premises and operations of clinical laboratories to determine if it is in substantial compliance with this article and rules adopted pursuant to this article. Pursuant to A.A.C. R9-14-701(A4) and (B), all clinical laboratories, unless exempted, must be certified pursuant to A.R.S. § 36-451 which requires that they are certified by the United States Department of Health and Human Services.

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendment of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. 263a) and 42 Code of Federal Regulations, Part 493 (42 CFR 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

Pursuant to Arizona Revised Statutes (A.R.S.) § 41-1009, “on initiation of an inspection of any premises of a regulated person, an agency person or regulator shall provide the following in writing:”

1. The authority under the law given to the Department as provided above;
2. That an inspector must present photo identification on entry of the premises;
3. That the regulated person is afforded an opportunity to have an authorized on-site representative of the regulated person accompany the agency inspector or regulator on the premises, except during confidential interviews;
4. Inform each person interviewed during the inspection that statements made by the person may be included in the inspection report;
5. The name and telephone number of a contact person available to answer questions regarding the inspection [Denise Barbeau (602) 364-0726];
6. That the regulated person may also contact the ADHS Ombudsman: Colby Bower at 150 N. 18th Ave., Suite 500, Phoenix, AZ 85007-3242; (602) 542-1062; Colby.Bower@azdhs.gov. If you have an issue that you cannot resolve with the Department, you may contact the Office of Ombudsman-Citizens' Aide at 3737 N. 7th St., Suite 209, Phoenix, AZ 85014; (602) 277-7292.
7. That the regulated person may contact the Centers for Medicare and Medicaid Services (CMS) Region IX, to get further information about due process rights of a regulated person relating to an appeal of a final decision of CMS based on the results of the inspection.