



Laboratory Certification Preparation Checklist

→ General Considerations

- General safety/PPE policies
- Shipping/receiving policies
- Chemical hygiene plan
- Hazardous waste management plan
- Compliance with local regulations

→ Location Requirements

- Adequate security
- Laboratory safety equipment
- Evacuation plan

→ Quality Assurance Manual (to include the following)

- A description of laboratory management and the responsibilities of personnel related to the certification
- Procedures for receiving and handling samples
- Procedures for purchasing, receiving and storing reagents and laboratory consumable materials that affect the quality of tests
- A written standard operating procedure for each test as prescribed in R3-5-106
- Procedures for documenting applicable reference material, standards, and biological specimens
- A description of an equipment maintenance program
- Procedures for quality control activity

→ Documentation (in addition to the Quality Assurance Manual)

- Organizational chart
- Name and resume of those identified in the organization chart
- Training documentation for staff performing all or part of the laboratory service(s)
- Competency documentation
- Equipment list (type, manufacturer, serial number, model number)
- Calibration data
- Maintenance records
- Chain of custody form
- Quality control records