# Clinical Laboratory Regulation in Florida

## *Index*

# Clinical Laboratory Regulation in Florida
## *The Beginning*

In October of 1993, the State of Florida passed legislation requiring all facilities, including doctor's offices, performing clinical laboratory testing to be licensed under Chapter 483, Part I of the Florida Statutes. The Agency for Health Care Administration (AHCA or Agency) was directed to adopt rules for the regulation of clinical laboratories. The first rules for clinical laboratories were adopted in 1994 in what is now Chapter 59A-7 of the Florida Administrative Code (F.A.C.).

Previously, in September of 1992, the federal government required all facilities, including doctor's offices, performing clinical laboratory testing to register with the Clinical Laboratory Improvement Amendments (CLIA) program.

The Agency issued two types of clinical laboratory licenses: *waived* and *non-waived*. In July of 2009, the requirement for laboratories that performed *waived* testing to obtain a state license was repealed. After July of 2009, the state issued one type of clinical laboratory license: *non-waived*. Authorized specialties/ subspecialties, which may be limited to specific tests, are placed on the face of the state *non-waived* license. Clinical laboratories may only perform testing as authorized on the license. Testing outside of that authorized is unlicensed activity and subject to fines and penalties, including criminal penalties.

The federal CLIA program issues four (4) types of CLIA certificates:

1. *Certificate of Waiver* – This certificate is issued to a laboratory to perform only waived tests.
2. *Certificate of Provider-Performed Microscopy Procedures (PPMP)* - This certificate is issued to a laboratory in which a physician, midlevel practitioner or dentist performs no tests other than the microscopy procedures. This certificate permits the laboratory to also perform waived tests.
3. *Certificate of Compliance* - This certificate is issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable CLIA requirements.
4. *Certificate of Accreditation* - This is a certificate that is issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by the Centers for Medicare and Medicaid.

In July of 2006, in an effort to streamline and make consistent basic licensing requirements, Florida passed public health legislation under Chapter 408, Part II, Florida Statutes (F.S.) that impacted all facilities licensed by the Agency, including clinical laboratories. The Health Care Licensing Procedures rule was adopted July 14, 2010 under Chapter 59A-35, F.A.C.

*Laws and rules are not static*. Laws can be amended as often as annually and rules more frequently than annually. Changes are posted on the Agency's clinical laboratory website at: http://ahca.myflorida.com/labs. Anyone wishing to be advised of changes in Agency rules as they are being developed may request to be added to the unit's "interested parties" listing by contacting the unit. Unit staff may be contacted at LABSTAFF@ahca.myflorida.com or 850.412.4500. Unit address: AHCA Laboratory Unit
2727 Mahan Drive, MS 32
Tallahassee, FL 32308

*Federal regulations for clinical laboratories and state regulations are not the same*. In some instances state requirements exceed federal. Obtaining a state license in Florida and renewing that license is not the same as obtaining a federal CLIA certificate and renewing the certificate. All clinical laboratories performing non-waived testing in Florida must hold both a valid state license and federal CLIA certificate. The Agency is the single contact for information about both state and federal clinical laboratory regulations.

Back to Index

# Federal CLIA & Florida Clinical Laboratory Regulation
## *A Comparison*

| Subject | Clinical Laboratory Improvement Amendments (CLIA) Requirements | State of Florida Clinical Laboratory Requirements |
|---|---|---|
| Regulatory Mandate | Federal Government | Florida State Legislature |
| Regulatory Authority | 42 Code of Federal Regulation (CFR), Part 493 | Chapter 483, Part I, Florida Statutes (F.S.)<br>Chapter 59A-7, Florida Administrative Code (F.A.C.)<br>Chapter 408, Part II, F.S.<br>Chapter 59A-35, F.A.C. |
| Responsible for Enforcement | In Florida: Agency for Health Care Administration (AHCA) under contract with the Centers for Medicare and Medicaid Services (CMS). | Agency for Health Care Administration (AHCA or Agency) |
| Contact | AHCA – Laboratory Unit<br>2727 Mahan Drive MS 32<br>Tallahassee, FL 32308<br>(850) 412.4500<br>LABSTAFF@ahca.myflorida.com | AHCA – Laboratory Unit<br>2727 Mahan Drive MS 32<br>Tallahassee, FL 32308<br>(850) 412.4500<br>LABSTAFF@ahca.myflorida.com |
| Who Must Comply? | Any person or entity doing laboratory testing on specimens derived from humans to give information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. | Any person or entity doing laboratory testing on specimens derived from humans to give information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. |
| How to Apply? | Application and instruction available at: http://ahca.myflorida.com/labs (select "Clinical Laboratories Application Download" on the local navigation bar). | Application and instruction available at: http://ahca.myflorida.com/labs (select "Clinical Laboratories Application Download" on the local navigation bar). |
| Fees | CLIA program sends invoice. Application and renewal fees paid directly to federal CLIA program. All checks and money orders made payable to CLIA. (see fee schedule) | Application fee due at time of application. Applications submitted without fees are returned. Fees submitted without applications are returned. Fees are based on volume for non-accredited applicants. (see fee schedule) Accredited applicant's fee is $100 regardless of volume. All checks/money orders made payable to AHCA. |

| Subject | Clinical Laboratory Improvement Amendments (CLIA) Requirements | State of Florida Clinical Laboratory Requirements |
|---|---|---|
| Certificate & Licensure Period | Biennial | Biennial |
| Approved Accrediting Organizations | • American Association of Blood Banks (AABB)<br>• American Osteopathic Association (AOA)<br>• American Society of Histocompatibility & Immunogenetics (ASHI)<br>• COLA<br>• College of American Pathologists (CAP)<br>• The Joint Commission (TJC) | CLIA approved organizations |
| 4 Test Categories & Certificate or License Type | 1. Waived – *Certificate of Waiver*<br>2. Provider Preformed Microscopy (PPM) – *Certificate of PPM*<br>3. Moderately Complex – **Certificate of Compliance or Accreditation*<br>4. High Complexity – **Certificate of Compliance or Accreditation*<br><br>**Certificate of Accreditation* issued to moderate or high complexity accredited laboratories only. | 1. Waived - *No State License Required*<br>2. PPM - *Non-Waived state license*<br>3. Moderately Complex - *Non-Waived state license*<br>4. High Complexity - *Non-Waived state license* |
| Specialties & Subspecialties | Printed on CLIA certificate. Written notification required for existing providers wanting to add a specialty or subspecialty. CLIA requires compliance with state regulations. | Printed on state license. Addition of specialty or subspecialty once licensed, requires specialty application and any required fees. An amended state license will be issued before any testing in the new area can be performed. State specialty and subspecialty requirements exceeds CLIA. [*see* 59A-7.030 F.A.C.] |
| When can testing begin? | CLIA requires compliance with state regulation. | State regulations require completion of successful on-site survey before *non-waived license is issued. Labs must hold to valid license in the specialties/subspecialties before testing may begin.<br><br>**For PPM providers*: The survey is off-site and contained within application. |

| Subject | Clinical Laboratory Improvement Amendments (CLIA) Requirements | State of Florida Clinical Laboratory Requirements |
|---|---|---|
| Ownership Changes | Written notification required. | *Change of Ownership* application received by the Agency 60 to 120 days prior to effective date of change along with required fee. [*see* s. 408.807, F.S. and 59A-35.070, F.A.C.]<br><br>**Definition**: An event in which the licensee sells or otherwise transfers its ownership to a different individual or entity as evidenced by a change in federal employer identification number or taxpayer identification number; or an event in which 51 percent or more of the ownership, shares, membership, or controlling interest of a licensee is in any manner transferred or otherwise assigned. This paragraph does not apply to a licensee that is publicly traded on a recognized stock exchange.<br><br>A state license cannot be sold, assigned or otherwise transferred [*see* s. 408.804, F.S.] |
| Address Changes | Written notification required. | Written request and a fee of $25 must be received by the Agency 60 – 120 days prior to move or provider is subject to a $500 late fine. Providers cannot operate at the new location without the amended license. To do so constitutes "unlicensed activity" under s. 408.812, F.S. |
| Director Changes | CLIA Form CMS-116 required unless accredited. | Written notification on company letterhead immediately. |
| Other Changes | Written notification required for tax ID, volume, name, telephone/fax, multiple site, change in accrediting organization, closure or termination of services, personnel-technical supervisor. | Other changes must be reported 60-120 days prior to change. Any change that requires a change to the state license must be received timely along with a check for $25 or receive a $500 late fine. [*see* 59A-35.040, F.A.C] |
| Closures, Revocations, Denials, Voluntary Discontinuance of Operation | No requirement to return the CLIA certificate. | Whether voluntary, administrative or other action, in addition to notification to the Agency (see above "other changes"), the provider is required by state law to return the state license. |
| Required Registration | No requirement. | Florida Department of State requires certain entities to register in Florida. [*see* http://sunbiz.org/] |

| Subject | Clinical Laboratory Improvement Amendments (CLIA) Requirements | State of Florida Clinical Laboratory Requirements |
|---|---|---|
| Who can order, accept and examine tests? | Requirements in Subpart A of 42 CFR 493 and defer to state regulations. | Regulation under s. 483.181, F.S.] |
| Background Screening | No requirement. | The laboratory director and financial officer in a clinical laboratory must have a successful level 2 background screening every 5-years and biennially attest that no offences have been committed with provider renewal applications. [ *see* Agency background screening website.] |
| Proficiency Testing (PT) for non-waived labs & Quality Assurance (QA) for PPM and other labs | Requirements in 42 CFR 493. CLIA brochure on proficiency testing (PT). Quality Assurance (QA) information for providers not required to do PT is online. | Florida requirements exceed CLIA requirements under s. 59A-7.025, F.A.C. for independent and hospital labs regarding unsuccessful PT performance resulting in limitation of licensure for the applicable specialty, subspecialty, analyte, or test. |
| Histopathology | A lab that only performs the "technical component" which is the slide preparation and staining, is not required to hold a CLIA certificate because CLIA does not consider this technical component to be testing. | Florida requirements exceed CLIA requiring licensure for any free-standing Histology, Oral Pathology, or Cytology Center which is engaged in and limits its activities to the preparation of human cellular material for microscopic interpretation by laboratories licensed in the specialty of pathology or subspecialties of histopathology, oral pathology and cytology. |
| Director Qualifications | Requirements in Subpart M of 42 CFR 493. | Regulation under Chapter 483, Part III F.S. by the Department of Health, Board of Clinical Laboratory Personnel and exceeds CLIA requirements. |
| Record Retention | Requirements in Subpart J of 42 CFR 493. | Florida requirements exceed CLIA requirements under 59A-7.030, F.A.C. for Pathology, Cytology, Histopathology, and Free-standing Histology and Cytology Centers. All patient and control stained slides or their visual representation must be maintained by the entity that interpreted the specimen for at least ten years from the date of examination. |
| Quality Control | Requirements in Subpart K in s. 493.1256 CFR and on CLIA website | Florida requirements exceed CLIA requirements under 59A-7.029 F.A.C. |

| Subject | Clinical Laboratory Improvement Amendments (CLIA) Requirements | State of Florida Clinical Laboratory Requirements |
|---|---|---|
| Hospital Alternate-Sites | Must be within hospital main address or contiguous grounds. | Must meet requirements of s. 59A-7.034, F.A.C. State requirements exceed CLIA. |
| Inspection | Under 6106 – Survey Policy, in the State Operations Manual (SOM): It is CMS policy to give notice to laboratories (up to two weeks) when conducting surveys to determine compliance. | Florida requirements exceed CLIA requirements under s. 408.811 F.S. Inspections of independent and hospital labs will be unannounced.<br>NOTE: Exclusive Use Providers, those licensed medical practitioners who only provide clinical laboratory services to their own patients, are excluded from this state inspection requirement. |
| Certificate and License – Both Required for Non-Waived Testing |  |  |
| Mobile Units | Mobile units may be covered under the certificate of the designated primary site. [*see* 493.35(b)(1)] | Florida requirements exceed CLIA requirements under 59A-7.021, F.A.C. and require separate licensure. |
| Collection Stations | No additional requirements. | Florida must be notified of location and stations must be approved before collection can begin. [*see* s. 59A-7.024 F.A.C.] |

Back to Index

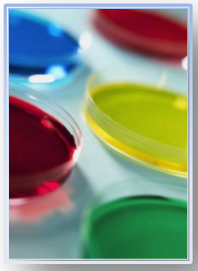
# Florida Laboratory Licensing
## *Recommendations for Application Submission*

Download applications

- Review the application to ensure that you have properly entered Tax ID numbers and other information and that it is signed by the laboratory director, prior to mailing.
- Send any correspondence to the Agency with some type of mail receipt so that proof of date of delivery can be demonstrated.
- Ensure that you have paid any outstanding fees/fines to the agency. If you are on a payment plan, make sure that you are current in your payments. If you owe the Agency money, your license will be not issued until the money is paid, or your payments are current, if on a payment plan.
- Ensure that you have submitted the proper application. If you are mailing your "renewal" application to the Agency on the day your current license expires, for example, even if sending it overnight, it cannot be accepted as a "renewal" application. In that case you must submit an "initial" application even though the application was mailed on the day your license expired because the Agency will not receive it until after your license expired.
- Ensure that your physical location is ready for survey prior to the Agency scheduling the survey.
- Ensure that you have paid your CLIA fees. Applicants wishing to establish non-waived laboratories will not be surveyed until their CLIA fee is paid.
- Fines are imposed on existing laboratories that fail to file an application at least 60 days before the expiration of the current license. The fine can be as much as $500 and must be paid before the license is issued.
- Change of ownership applications must also be filed 60 days prior to the effective date of the change and must always be filed prior to the effective date of the change. If an application is not filed prior to the effective date of the change, the new owner cannot operate the laboratory without a license, and may be fined up to $1,000 per day with each day constituting a separate violation.


Back to Index

# Reporting Tests and Volumes
## *How to Complete the "List of Tests Performed" Section of the Clinical Laboratory Application*



The test menu section of the clinical laboratory application can be challenging to complete. It is important that this section and the section preceding it where specialties and subspecialties are reported, are properly completed on the application. Proper completion will ensure that the correct license is issued, the correct fees are paid and the laboratory director has the proper training and credentials. State licenses limit laboratory testing areas to those specialties and subspecialties (and occasionally tests) that have been reviewed and approved and listed on the face of the license. Laboratories may not test outside of areas listed on the face of the state license. Instructions for completing the *list of tests performed* section are provided in the application just above the actual listing and should be read carefully to avoid a letter of omission from the assigned laboratory consultant.

The example below is for a *provider performed microscopy* (PPM) laboratory:

| Tests Performed On-Site (Waived and Non-waived Tests Required) | Exact Instrument, Test Kit, Dipstick, Etc. (reference FDA & CLIA Databases) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm | Annual Test Volume per test | Proficiency Testing Company (PT) and Program Set (not required for waived tests) |
|---|---|---|---|
| This column should contain the actual test not the test specialty or subspecialty. Providing PPM here is incorrect. "KOH" is one example of an appropriate listing. | The instrument would be "microscope" in this example. | The anticipated volume for the upcoming year is needed here. If the lab is renewing the license, the estimate is based on past history. | PPM labs may enroll with a PT program, but if they do not, a quality assurance program is required. See information at: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/PPMP.shtml |
| Another example would be "Fern". | One example could be: "Luna Fertility Indicator". (NOTE: This is not an endorsement of any test.) | See above | See above |

The example below is for a *pathology* laboratory:

| Tests Performed On-Site (Waived and Non-waived Tests Required) | Exact Instrument, Test Kit, Dipstick, Etc. (reference FDA & CLIA Databases) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm | Annual Test Volume per test | Proficiency Testing (PT) Company and Program Set (not required for waived tests) |
|---|---|---|---|
| A lab seeking licensure for histopathology for example might indicate "Mohs" and/or "H&E stains" here. If the lab is only performing the professional component, tests must still be listed by staining technique. | The instrument to list in this column for the professional component for a Mohs test, in this example, would be "microscope".<br><br>The instrument/kit for the technical component of H&E would be "staining kit".<br><br>Labs doing *global* testing for H&E would list "staining kit *and* microscope" here. | The anticipated volume for the upcoming year is needed here. If the lab is renewing the license, the estimate is based on past history.<br><br>Refer to s. 59A-7.036 F.A.C. for instruction on how to count tests. (If you are not doing *global* and have questions, call the consultant assigned to your area.) | There is no PT program for pathology; a quality assurance program is required. See information at: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/PPMP.shtml |

The example below is for laboratories performing *hematology & chemistry* testing:

| Tests Performed On-Site (Waived and Non-waived Tests Required) | Exact Instrument, Test Kit, Dipstick, Etc. (reference FDA & CLIA Databases) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm | Annual Test Volume per test | Proficiency Testing (PT) Company and Program Set (not required for waived tests) |
|---|---|---|---|
| This column should contain the component test of a panel. Do **not** list "CBC", "BMP",etc.<br><br>Only measured analytes should be listed. For example: "WBC" could be given as a measured analyte for CBCs in this column and "Glucose" could be given as a measured analyte for BMPs. | The instrument must be the actual instrument used. If the provider was doing CBCs and using the **Abbott Cell-Dyn 1800*, then *"Abbott Cell-Dyn 1800" would be placed in this column.<br><br>For BMP, *"Roche Diagnostics COBAS MIRA" might be used by the lab and would need to be entered here.<br><br>*These are only used as examples and are not an endorsement of any test or instrument. | The anticipated volume for the upcoming year is needed here. If the lab is renewing the license, the estimate is based on past history.<br><br>Annual volume is measured for analytes only.<br><br>For hematology: differentials count as one test. Refer to s. 59A-7.036 F.A.C. | Proficiency Testing is required and must be conducted by a CLIA approved PT company. See information at: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/PT.shtml |

Back to Index



# Florida Laboratory Testing Regulations
## *An Overview*[1]

*Chapter 59A-7, F.A.C.* https://www.flrules.org/gateway/ChapterHome.asp?Chapter=59A-7

### 59A-7.019 Application of Act – Exemption and Exclusions

- Clinical laboratories operated by the United States Government.
- Clinical laboratories that perform *only* waived testing. [*However, these laboratories are required to hold a federal CLIA Certificate of Waiver*.]
- Research or teaching laboratories.
- The term "clinical laboratory procedures" *does not* include performing
  - Electrocardiogram
  - Electroencephalogram
  - In-vivo imaging
  - Scanning or body counting procedures
  - In-vivo cardiopulmonary
  - Cardiovascular
  - Cardiac catheterization
  - Respiratory therapy
  - Pulmonary function procedures
- Blood banks offering *only* transfusion services. [*However, facilities where cross-matching, prenatal immunohematology procedures, donor processing or other procedures required for therapeutic administration or collection of blood or blood products are performed are required to be licensed if doing non-waived testing*.]

### 59A-7.021 Laboratory Licensure – Qualifications, Licensure, Operation and Application

- Contains a listing of information required to be included on an application for licensure.
- Separate licenses are required for each physical location.
- Application fees must be submitted with the application.
- Renewal applications must be submitted 60 prior to the expiration of the license.
- Change of ownership applications must be submitted 60 days prior to the effective date of the change and the effective date must be on the application.
- Licenses cannot be transferred, sold or assigned and are only valid to the entity to whom they are issued, the location to which it is issued and for the time period specified on the license.
- Laboratory testing is limited to that authorized on the face of the license.
- Laboratory services provided at temporary testing locations are covered under the license of the primary site or home base.
- The Agency must be timely notified of any changes [*also see* Chapter 59A-35, Florida Administrative Code for what constitutes timely notification.]
- Licenses must be returned to the Agency when the laboratory changes ownership or has a change in classification and when the license is suspended, revoked or there is a voluntary cessation of operations.

[1] Bullets highlight elements of the rules and do not provide a complete review of any section. Clinical laboratories should be familiar with rules. This is an overview to expedite locating sections of the rule.

### 59A-7.022 Laboratory Construction

- Construction must comply with local, county, state and federal building, fire and safety codes.

### 59A-7.023 Laboratory Safety and Sanitary Conditions

- Biomedical waste must be processed in accordance with Florida Department of Health requirements under s. 381.0098, F.S.
- Listing provided for room and department requirements for laboratories.
- Listing provided of what is required in the written emergency plan for laboratories.
- No food or drink in laboratory testing areas or refrigerators.
- No mouth pipetting.

### 59A-7.024 Clinical Laboratories, Collection Stations, Collection, Storage and Shipment of Specimens

- No person can maintain an office, specimen collection station or other facilities for the representation of any clinical laboratory in this state or in any other state unless the clinical laboratory is licensed in accordance with the provisions of Rule 59A-7 and Chapter 483, Part I, F.S.
- Collection stations must have written instruction for the handling, preserving, storage and transportation of specimens and must receive prior approval from the agency before beginning operations.
- Listing provided of requirements for collection stations forwarding specimens to the clinical laboratory.
- Collection stations may not perform non-waived tests and may only perform waived tests with a CLIA *Certificate of Waiver* for the physical location.
- Collection stations are inspected by the agency.

### 59A-7.025, .026, and .027 Proficiency Testing

- Florida regulations exceed CLIA requirements as outlined in 59A-7.025, F.A.C. for independent and hospital labs regarding unsuccessful PT performance resulting in limitation of licensure for the applicable specialty, subspecialty, analyte, or test.
- CLIA has published a brochure on proficiency testing (PT). Quality Assurance (QA) information for PPM providers is also online.

### 59A-7.029 General Quality Control Requirements for Non-waived Testing

- Requires the testing environment to be appropriate for testing conducted.
- Requires the lab to develop a procedure manual that is available for all testing personnel for all test methods used in the laboratory.
- Requires the lab to verify performance specifications for test systems and perform maintenance and function checks as well as calibration studies.
- Controls are required to be used that test each phase of the test system daily (except for PPM tests as long at the PPM provider has a QA program outlined in 59A-7.031 F.A.C.).
- Equivalent Quality Control (EQC) is addressed.

### 59A-7.030 Special Requirements for Licensure: Specialties and Subspecialties

- Requirements exceed CLIA and require licensure for freestanding histology laboratories.
- Record retention is specified for specialties.

### 59A-7.031 Quality Assurance

- Requires laboratories to establish and follow written quality assurance plan that includes:
  - Patient test assessment
  - Quality control assessment
  - Proficiency testing assessment
  - Comparison of test results
  - Relationship of patient information results
  - Personnel assessment
  - Communications
  - Complaint investigations
  - Quality assurance review with staff
  - Documentation of quality assurance records

### 59A-7.032 Inspection of Laboratories

- Laboratories must have a successful inspection and the state license issued prior to testing. [*also see* Chapter 408, Part II, F.S.] For PPM laboratories completing a paper inspection, the license must be issued prior to testing.
- Inspections are conducted biennially and with one exception are *unannounced*.
- Provision for acceptance of inspections by *approved* accrediting organization.

### 59A-7.033 Acceptance of Accreditation Inspections

- Inspections are accepted only for CLIA approved accreditation organizations:
- Requirements listed for accrediting organizations to have accreditation accepted in Florida.

### 59A-7.034 Alternate-Site Testing

- Only applies to laboratories located within hospitals licensed under Chapter 395, F.S.
- Requires clinical laboratory director to determine appropriateness of establishing an alternate site within the hospital and create an internal needs assessment.
- Outlines parameters around which the laboratory director can set up an alternate site including who can perform the testing and what tests can be performed.

### 59A-7.035 Staffing Requirements

- Requires all licensed laboratories with the exception of those qualified under s. 483.035, F.S. as exclusive use providers, to comply with Chapter 483, Part III, F.S.

### 59A-7.036 Fees

- Fees are stipulated in s. 483.172, F.S.
- Outlines how to calculate fees.

### 59A-7.037 Rebates Prohibited - Penalties

- Outlines administrative penalties authorized under s. 483.245, F.S. for prohibited acts. There was legislation passed under HB 787 in 2012 to add language to this section of the Florida Statutes regarding specimen collection in physician offices among other things. [*see* section 34, page 28 in Ch. 2012-160, Laws of Florida]