ESSENTIALS AND GUIDELINES
OF AN ACCREDITED POSTGRADUATE RESIDENCY PROGRAM
IN MEDICAL LABORATORY IMMUNOLOGY

Established by the
American College of Microbiology
Committee on Postgraduate Educational Programs

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1. PREAMBLE

The Essentials of approved postgraduate residency programs in medical laboratory immunology have been established by the Committee on Postgraduate Educational Programs (CPEP), to which the American College of Microbiology has delegated responsibility to perform the duties and make the decisions concerning accreditation of training programs in this field. The Essentials represent the minimum requirement for CPEP-accredited educational programs. The present document has been developed and revised after extensive review by medical laboratory immunologists and other health care professionals. Advice and suggestions were solicited from a broad range of individuals, associations, and institutions, and from the boards and committees of the American Society for Microbiology. The Essentials are adopted by the Board of Governors, AAM, upon the recommendation of CPEP.

The purpose of CPEP in this effort is to promote and encourage excellence in the training of medical laboratory immunologists through the approval of postgraduate programs that can meet these Essentials. Ultimately, the goal is to improve the quality of clinical immunology laboratory service (diagnostic, educational, consultative, and investigative) in health-related fields and, thus, contribute to the health and welfare of the public. CPEP assesses each program's compliance with the Essentials through review of its application, by on-site evaluations, and by the monitoring of annual reports from approved programs. Lists of approved programs are published annually in the ASM News for the information of prospective students, employers, and the public. Copies of these Essentials are available to the public and are provided to Fellows who enter AAM/CPEP-approved programs.

1.1. Objective

ESSENTIALS ARE STATEMENTS OF POLICY AND, AS SUCH, CONSTITUTE MINIMUM STANDARDS OF QUALITY IN EDUCATIONAL PROGRAMS THAT ARE RECOGNIZED BY AAM/CPEP ACCREDITATION. THESE ESSENTIALS AND ACCOMPANYING GUIDELINES ARE INTENDED TO ASSIST CLINICAL IMMUNOLOGY TRAINING PROGRAMS IN MEETING AND EXCEEDING MINIMUM STANDARDS IN THE DESIGN AND CONDUCT OF SOUND EDUCATIONAL PROGRAMS. THESE ESSENTIALS REPRESENT POLICIES WHICH MUST BE CARRIED OUT AND STRICT ADHERENCE TO THE ESSENTIALS IS MANDATORY. GUIDELINES PRESENT PATHWAYS TOWARD FULFILLING THE ESSENTIALS. GUIDELINES USUALLY REPRESENT ONE OF SEVERAL WAYS TO SATISFY AN ESSENTIAL AND, THEREFORE, STRICT ADHERENCE TO GUIDELINES IS NOT REQUIRED.
1.2. Description of Profession

Medical laboratory immunologists are scientists and/or physicians who have developed expertise in immunology, clinical immunology, diagnostic immunology, and related subspecialties and sciences. These individuals are prepared for responsible positions in clinical immunology laboratories, governmental agencies, industry and in colleges and universities. Fellows of postgraduate residency programs in clinical laboratory immunology are prepared to be responsible for providing clinical laboratory data, consulting with physicians and health officials, training medical and allied health personnel, and conducting research. More specifically, they will be expected to be able to:

1. Develop and manage a diagnostic immunology service that will support, enhance or establish a clinical diagnosis or an epidemiological investigation.

2. Provide, communicate, and interpret immunological data and other relevant information for use in the diagnosis, management and treatment of patients and where indicated providing solutions to epidemiological problems.

3. Plan and conduct effective training programs in clinical immunology for technical and professional personnel.

4. Design and conduct research in the field of immunology to solve medical and public health problems.

2. ESSENTIALS AND GUIDELINES FOR ACCREDITATION

2.1. Sponsorship

2.1.1. Institutions-Essentials

Postgraduate residency programs must be established in institutions with complete clinical laboratories or in reference laboratories that perform clinical immunology procedures. The institution should have a sufficient volume of testing at an appropriate level of quality to provide adequate training for the fellows. Such institutions include:

1. Universities and other medical centers
2. Hospitals and Clinics
3. Public Health Laboratories
2.1.2. Affiliates-Essentials

In instances where significant aspects of the program cannot be provided by a single sponsoring institution, collaborative arrangements with other institutions must be established.

2.1.3. Accreditation-Essentials

In training programs that have the laboratory bench experience and the didactic instruction provided by two or more institutions, accreditation will be granted to the sponsoring institution that assumes primary responsibility for curriculum planning and mode of instruction; coordination of the various elements of the program and guidance of individual Fellows; selection of the faculty for the program; admission and registration of Fellows; and certification of successful completion of the program. The sponsoring institution must also be responsible for assuring that the activities assigned to residents in the clinical laboratories are appropriately educational and not merely service work.

2.1.3.1. Guidelines

1. In providing postgraduate training in medical laboratory immunology, it will be necessary for one institution to assume the major responsibility for the development and management of the program. Sponsoring institutions, however, may need collaborating institutions to provide a certain portion of the instruction. In some instances, it may be desirable to have an institution that provides a significant portion of the instruction to be listed as a co-sponsor of the program.

2. Sponsors may recognize the contribution of collaborating institutions by requesting AAM/CPEP to issue appropriate certificates recognizing the collaboration.

2.1.4. Certification-Essentials

The sponsoring and collaborating institutions must be accredited, certified, or licensed as required by existing laws or accepted practice by recognized agencies or be otherwise acceptable to the AAM/CPEP. The program/institution(s) (sponsor and collaborating institutions) must affirm adherence to non-discriminatory practices with regard to race, color, creed, sex, age, sexual preference, national origin, or handicap, in admission and treatment of students and postgraduate fellows and in appointment and employment of staff.
2.1.5. Responsibilities of the Sponsor and Affiliate Institution-Essentials

Responsibilities of the sponsor and each affiliate/collaborating institution for program administration, instruction, supervision, and documentation must be clearly described in written documents and made available for distribution and inspection.

2.2. Curriculum

2.2.1. Program Length-Essentials

The standard length of the program is two years.

2.2.1.1. Guidelines

1. Although ABMM and other accrediting boards may give credit for participating one year in an approved program in the certification of individuals, it is generally agreed that most persons need two years to cover the subject matter and develop the desired competencies in medical laboratory immunology. Fellows need not cover subjects that they have already mastered. Most individuals will have other training needs that can fill the available time.

2. The Fellow should receive customary leave and holidays of the parent institution.

3. The Fellow should be eligible for sick leave, maternity leave, and child daycare as provided to other employees of the parent institution.

2.2.2. Areas of Training-Essentials

The program must provide the necessary education and training in all of the specialty areas of medical laboratory immunology including:

- infectious disease serology
- autoantibody testing and autoimmune disorders
- immune deficiency and complement deficiency diseases
- histocompatibility testing and transplantation immunology
- flow cytometry
- molecular diagnostics
- instrumentation and automation
- allergy testing
- laboratory ethics, management and safety
- research and teaching methodologies
- immunoglobulin analysis, serum protein analysis, immunochemistry

In order for the Fellow to acquire the knowledge and skills of a medical laboratory immunologist, appropriate instruction must be made available through bench training and experience, clinical conferences, hospital rounds, workshops, organized courses, self-instructional materials, and administrative training. Ample diagnostic material (quantity and variety) must be available, with concomitant opportunity for the Fellow to learn how to correlate laboratory information with patient care and/or public health needs. Emphasis must be placed on laboratory diagnostic practice and clinical experience.

2.2.2.1. Guidelines

1. While it is the policy of AAM/CPEP that instructional methods are the prerogative of the sponsoring institutions, CPEP offers guidelines to assist the programs in developing sound and appropriate instruction that will enable a student to attain the program objectives.

2. In order to identify for the Fellow the knowledge and skills to be acquired by the end of the two-year residency, major training objectives should be developed for the total program. In preparing objectives, the program directors should consider the Essentials and accompanying guidelines in Section 2.2.3.

3. The postgraduate training in medical laboratory immunology should be organized on a broad basis to furnish instruction in each of the specialty areas. While instruction may be provided in organized courses and self-instructional materials, practical bench training and clinical experience should be emphasized. The Fellow should also become familiar with the clinical aspects of immunological disorders, infectious diseases, and hematologic malignancies. Fellows accepted in these programs may have prior training in specific areas. Therefore, the program should be individualized to meet the needs of each Fellow and also complement each Fellow's prior experience.

4. The second year should continue broad training but at a substantially higher level with emphasis on clinical significance and interpretation of laboratory results that assist in patient care. The program must also provide training in laboratory management and experience in dealing with interpersonal relationships and supervisory aspects of the clinical laboratory. Program directors should draw Fellows into the management decision-making process and provide increasing responsibility for at least some important aspects of the laboratory services. Attendance and participation at clinical conference and rounds should increase in frequency and level of participation.

5. To help the Fellow know whether or not an assignment or segment of the program is being adequately covered, modular or rotation objectives should be prepared for the major components of the program. The program director (or designate) should review objectives with the Fellow at the beginning of each component. The modular objectives should also help the faculty to organize content, learning experiences, and performance evaluations for various portions of the program.

6. The Fellows should have the opportunity to become acquainted with new immunological problems, epidemics of national or global concern, and major effects or trends in health care and maintenance. Aspects of other laboratory disciplines, such as microbiology, virology, hematology, clinical chemistry, and pathology should be an intrinsic component of the basic program in the context of discussions about specific disease processes.
7. An important aspect of training should be provided in research in immunology. Research activities may occur concomitantly with other training rotations. Research should not be so extensive as to preclude or preempt satisfactory completion of other essential rotations of the program.

8. Opportunity for attendance at a nationally recognized conference in clinical science is desirable. These meeting may include the following: American Association of Immunologists, Association of Medical Laboratory Immunologists, American Society for Microbiology, Federation of Clinical Immunology Societies (FOCIS), and Clinical Immunology Society.

2.2.3. Knowledge to Be Gained from Specialty Area Training

2.2.3.1. Specimen Collection-Essentials

The Fellows must know the proper collection of specimens for the detection of cells, antibodies, complement, or other components and must be able to discriminate which specimens are appropriate for testing. Universal precautions must be observed in all phases of collection and handling.
2.2.3.1. Guidelines

The Fellow should be familiar with transport devices and conditions for preserving the quality of the specimen.

2.2.3.2. Infectious Disease Serology-Essentials

The graduate of the program must be familiar with the theory and practice of agglutination, precipitation, enzyme immunoassay, complement fixation, immunofluorescence, immunoblotting, chemiluminescence, and multiplex bead-based techniques. The Fellow must know the application and interpretation of antibody and antigen detection tests for common bacterial, fungal, parasitic, and viral infections. The graduate must understand and be able to articulate the statistical methods needed to evaluate serologic assays including; sensitivity, specificity, etc.

2.2.3.2.1. Guidelines

1. The Fellow should know the established diagnostic criteria for common infectious diseases.

2. The Fellow should understand the methods used to standardize infectious disease serology testing and know the use of available proficiency testing materials.

3. The Fellow should understand the principles involved in the establishment of normal ranges of serologic tests and the influence of age on the population tested.

4. The Fellow should understand the appropriate methodologies to be used for the diagnosis of specific infectious diseases, for example when to apply serologic methods, direct antigen detection, or molecular diagnostic methods as the best diagnostic tool of choice for a specific pathogen.

5. The Fellow should have direct consultation with infectious disease clinicians to integrate/evaluate laboratory diagnostic tools and clinical diagnosis.

2.2.3.3. Autoantibodies and Autoimmune Diseases-Essentials

The graduate must understand the theory and technical aspects of immunofluorescence, Ouchterlony, nephelometry, hemagglutination, hemolytic complement, ELISA, immunoblot, chemiluminescence, and multiplex bead-based techniques for commonly used autoimmune diseases and understand the clinical relevance of laboratory testing in the diagnostic and monitoring of autoimmune diseases.

2.2.3.3.1. Guidelines

1. The Fellow should know the established diagnostic criteria for all autoimmune diseases.

2. The Fellow should know the autoantibody specificities present in serum from autoimmune disease patients and the methods used for detection of these antibodies.

3. The Fellow should understand methods used to standardize autoantibody testing and know the use of available standard and proficiency materials.

4. The Fellow should understand the laboratory assays which measure inflammation and must know the role of these tests in the monitoring of autoimmune diseases.
5. The Fellow should know the basis of the theory and application of HLA class I and II serologic and molecular based typing methods, know the associations between individual HLA types and some autoimmune diseases, and understand the theories concerning the role of HLA molecules in the development of autoimmune diseases.

6. The Fellow should understand the principles involved in the establishment of normal ranges of autoimmune disease testing, statistical effects of prevalence and disease incidence, and the influence of sex and age in the population tested.

7. The Fellow should understand the impact of interfering factors on immunoassays.

8. The Fellow should know the assays for complement component quantitation and function and be familiar with the association between complement deficiencies and autoimmune diseases.

9. The Fellow should have direct consultation with rheumatology clinicians to integrate/evaluate laboratory diagnostic tools and clinical diagnosis.

2.2.3.4. Immunodeficiency Disorders-Essentials

The graduate must understand the application of serum protein analysis as well as phenotypic and functional cell analysis used in the detection and categorization of immunodeficiency disorders.

2.2.3.4.1 Guidelines

1. The Fellow should be familiar with the developmental pathways for lymphocytes, monocytes, and granulocytes. The Fellow should know the disorders associated with blocks in the pathways and molecular defects that have been identified for each.

2. The Fellow should understand the role of screening assays for immunoglobulin or cellular deficiency detection. The Fellow must know the quantitative, functional, and molecular laboratory tests used to characterize the specific defects present in all defined primary immunodeficiency diseases.

3. The Fellow should know the clinical features and associated infectious disease risks for immunodeficiency diseases and the strategies used for therapy and disease prevention.

4. The Fellow should be familiar with the variety of secondary immunodeficiencies and their causes. The Fellow should be familiar with the laboratory tests used to evaluate the secondary immunodeficiency diseases caused by viruses, drugs, and nutritional deficiencies.

5. The Fellow should be familiar in viral-induced secondary immunodeficiency of the utility of viral load testing in diagnosis, disease staging and treatment decision making.

2.2.3.5. Flow Cytometry/Cellular Immunology-Essentials

The graduate must know the techniques and methods of flow cytometry, monoclonal antibodies, and immunofluorescence and their use in the phenotyping of lymphocytes and the white cell elements of the bone marrow, peripheral blood, lymph node tissue, and fluids. The graduate should be familiar with the surface and intracellular antigen markers which help to categorize hematological malignancies and those which define the developmental stages and functional role of lymphocyte subsets.

2.2.3.5.1. Guidelines
1. The Fellow should know the basic principles of flow cytometry and be familiar with standardized procedures required to correctly analyze and interpret flow cytometry data. The Fellow must understand instrument calibration, compensation, gating, bitmaps, and statistical data analysis.

2. The Fellow should be familiar with the variety of CD surface and intracellular antigens that define and are routinely used to categorize and differentiate lymphocytes and bone marrow derived cells.

3. The Fellow should be familiar with the hematological malignancies and their clinical presentations. The Fellow should be able to integrate information from surface and intracellular antigen testing of leukemia and lymphoma cells with clinical and pathological data to arrive at a final diagnostic category of malignancy. This may require that the Fellow work closely with a hematopathologist who has more data and benefits from the morphological aspects of the case.

4. The Fellow should understand the basis for the quantitative assessment of lymphocyte subsets in the peripheral blood. The Fellow should be familiar with the effects that malignancies, infectious diseases, and autoimmune diseases have on the phenotypic and functional characteristics of peripheral blood lymphocytes.

5. The Fellow should be familiar with the guidelines that have been defined by the NCCLS and CDC for lymphocyte phenotyping in peripheral blood and by the NCCLS for leukemia phenotyping.

6. The Fellow should understand the requirements for proper collection, handling, and processing of samples for flow cytometry testing.

2.2.3.6. Histocompatibility Testing and Transplantation Immunology-Essentials

The graduate must have a basic knowledge of the Major Histocompatibility Complex genes and proteins and their role in the immune system. In addition, the graduate should be familiar with the Killer Immunoglobulin-Like Receptor (KIR) family of genes and proteins on NK cells and their interaction with MHC proteins. The graduate should be familiar with histocompatibility testing methods including HLA typing by serologic and molecular methods, antibody detection and identification using serologic, ELISA and flow cytometric based methods, and cellular methods used to assess compatibility and immune responsiveness. The graduate should be able to assess level of risk for rejection and other immunologic complications based on the results of histocompatibility testing and participate in the decision making process.

2.2.3.6.1. Guidelines

1. The Fellow should have a thorough knowledge of the molecular and serological variations present for Class I and Class II HLA antigens, the genetic organization of the HLA locus, and the KIR family of genes and proteins. The Fellow should be familiar with the serologic, cellular, and molecular methods used to determine the HLA type of human samples.

2. The Fellow should know the principles of paternity testing and apply the information from HLA typing to determine probability of paternity.

3. The Fellow should understand the laboratory methods used in bone marrow and peripheral blood stem cells for transplantation. This should include methods of bone marrow and peripheral blood stem cell harvesting, cell separation, cell selection, cell
preservation, and reinfusion.

4. The Fellow should be familiar with changes that take place in lymphoid organs and the peripheral blood during bone marrow transplantation. The Fellow should know the stages of reengraftment as it recapitulates fetal development and know the cell types which are present in the peripheral blood at each stage.

5. The Fellow should be familiar with antibody screening assays and crossmatching assays to assess pre-sensitization to potential organ donors as well as their use for post-transplant monitoring.

6. The Fellow should be familiar with the clinical and laboratory findings seen during acute and chronic rejection episodes and the therapies used for control of rejection.

7. The Fellow should be familiar with the screening procedures which must be done on donor samples to ensure lack of transmission of infectious diseases through transplanted tissues. The Fellow should know the possible infectious diseases and malignancies which are risks of transplantation.

8. The Fellow should know the immunologic effects of chemotherapeutic and immunosuppressive agents used for transplantation and for control of rejection episodes.

2.2.3.7. Allergy Testing-Essentials

The graduate should understand the immunologic pathways which lead to type 1 hypersensitivity reactions. The graduate should know the available laboratory assays which can be used to monitor the likelihood of allergic reactions to a variety of allergic substances. The graduate should be familiar with the inflammatory mediators of allergic reactions and the modalities of the clinically available therapies.

2.2.3.7.1. Guidelines

1. The Fellow should know the basis for the IgE mediated allergic response at both the cellular and molecular level. The Fellow should be familiar with the mechanism of IgE crosslinking, intracellular stimulation pathways, and methods of granule release for basophils and mast cells. The Fellow should know the various mediators of inflammation and their pathologic effects.

2. The Fellow should know the in vivo skin test methods used by allergists and understand the immunologic response which leads to the positive skin test response in allergic individuals.

3. The Fellow should know the in vitro methods for measuring levels of IgE and allergen specific IgE and their interpretation in various clinical conditions. The Fellow should understand the scoring systems, the differences between scoring methods, and their use in the prediction of allergic responses as well as in the normal population.

4. The Fellow should be familiar with the variety of drugs and specific immunotherapies used in allergy and their effects on the allergic immune response.

5. The Fellow should be familiar with the variety of pathological conditions including allergy, asthma, parasitic infections, immunodeficiencies, and malignancies in which high levels of IgE are present.

6. The Fellow should have direct consultation with allergists/immunologists to
2.2.3.8. Immunoglobulin Analysis and Lymphocyte Malignancies-Essentials

The graduate must know the theory and technical methods of protein electrophoresis, nephelometry, immunoelectrophoresis, immunofixation, radial diffusion immunoassays for the quantitation of immunoglobulins and immunoglobulin subclasses and the analysis of light chain clonality. The graduate should understand the spectrum of clinical lymphoid malignancy diseases where monoclonal immunoglobulins are detected.

2.2.3.8.1. Guidelines

1. The Fellow should be able to integrate immunoglobulin quantitations, electrophoresis, immunoelectrophoresis, and immunofixation testing to determine immunoglobulin clonality for patients' serum, urine, body fluid, and CSF samples.

2. The Fellow should understand the analysis of CSF and serum immunoglobulin and albumin to determine the local oligoclonal synthesis of IgG in the CSF.

3. The Fellow should be familiar with the clinical presentations of the various lymphoid and hematologic malignancy diseases and the clinical and laboratory diagnostic criteria for this group of diseases.

2.2.3.9. Public health serology-Essentials (epidemiology)

The graduate of a program must be familiar with epidemiology and hospital infection control.

2.2.3.9.1. Guidelines

1. The Fellow should be familiar with the following principles of epidemiology and hospital infection control:
   - Role of the clinical immunology laboratory in hospital infection control
   - Retrospective studies
   - Prospective studies
   - Recognition, surveillance and control of nosocomial infections.

2. The Fellow should learn the serologic methods that help determine the causes of infectious diseases of public health importance.

3. The Fellow should be able to provide professional educational assistance to other clinical/diagnostic immunology laboratories throughout the state and where applicable to the general public.

4. The Fellow should be familiar with the following public health laboratory methods:
   - Sexually transmitted diseases testing
   - Rabies virus detection
   - Public health screening for immune status
   - HIV Testing and confidentiality
   - Vector-borne disease testing such as arboviruses

2.2.3.10. Molecular Diagnostics-Essentials
The graduate of the program must be familiar with the theory and application of molecular techniques such as:

- Use of nucleic acid probes
- Molecular amplification methods
- Plasmid isolation and detection
- Restriction analysis of eukaryotic DNA
- Hybridization and immunoblotting
- Nucleic acid-based array systems such as gene chips and bead-based arrays

2.2.3.10.1 Guidelines
1. The Fellow should have basic knowledge in molecular techniques used in molecular diagnostics such as the PCR, RT-PCR, NASBA, and real-time molecular techniques,
2. The Fellow should be aware of the major causes of incorrect molecular diagnostic test results such as cross-sample contamination and sample preparation/extraction efficiencies.
3. The Fellow should be knowledgeable in the use of infectious disease molecular tools such as viral load or viral genotyping in patient management.
4. The Fellow should be aware of the application of gene rearrangement information in the diagnosis of immune deficiency and hematologic malignancies.
5. As many current molecular diagnostic tools are “home-brew” assays, the Fellow should be familiar with the regulatory requirements to validate molecular “home-brew” assays.

2.2.3.11. Quality Management-Essentials

The graduate of the program must understand and describe the three elements: structure, process and outcome of a comprehensive laboratory quality management program. The graduate must demonstrate the ability to implement a laboratory quality control, quality assurance, and continuous quality improvement program.
2.2.3.11.1. Guidelines

1. The Fellow should become familiar with laboratory quality control procedures and be given the responsibility to review quality control data. The Fellow should help in the selection of quality assurance indicators and present the results in a written or verbal presentation.

2. The Fellow should become familiar with a hospital’s continuous quality improvement program.

2.2.3.12. Laboratory Safety-Essentials

The graduate of the program must be familiar with the theory and practice of laboratory safety that includes local, state, and federal regulations, and the design and implementation of a program that protects the health and safety of all laboratory employees. The graduate must be familiar with laboratory and hospital safety committees.

2.2.3.12.1. Guidelines

1. Fellows should attend a hospital, university or institutional safety orientation course.

2. Fellows should understand modes of transmission and acquisition of relatively common laboratory acquired infections.

3. Fellows should understand the principles and practices of the following safety issues:
   - Composition and use of a laboratory safety manual
   - Universal precautions
   - OSHA requirements
   - Biosafety hazards
   - Waste management, including disposal of biohazard material
   - Safe handling of radioactive materials
   - Physical and chemical hazards, including carcinogens
   - Methods of disinfection and sterilization
   - Baseline medical testing (immune status, protective immunization)
   - Laboratory design as it applies to safety
   - Biosafety hoods
   - Policy for managing laboratory accidents.
   - Biosafety and Chemical Hoods

2.2.3.13. Laboratory Management-Essentials

The graduate must demonstrate an understanding of:
- Personnel management principles and interpersonal relations
- Budgeting
- Workload assessment
- Space planning and laboratory design
- Techniques of policy change and implementation
- Preparation of job descriptions
- Interviewing
- Performance appraisals
- Disciplinary actions
- Medical ethics
- HIPPA and privacy legislation
The IRB approval practices for clinical research.

2.2.3.13.1 Guidelines

1. The Fellow should assume responsibility for direction of a section of the laboratory for a 2-3 month period and/or participate in the on call program for the clinical immunology laboratory.

2. The Fellow should participate in the annual budget planning process, e.g., by preparing a cost analysis of a piece of capital equipment or justification for a new technologist position.

3. The Fellow, whenever possible, should sit in on personnel actions, including interviewing and performance appraisals.

4. The Fellow should take management training courses that are available. Many institutions provide courses which help develop supervisory skills. Fellows are encouraged to participate.

5. The Fellow should participate in the implementation of internal and external clinical studies to learn the regulatory requirements concerning confidential patient information, limits on laboratory testing, and data reporting limitations.

2.2.3.14. Laboratory Regulations-Essentials

The Fellow must describe the major requirements of private and governmental (federal and local) agencies that accredit, certify or license clinical laboratories, or that have standards regarding employer/employee relationships. Such agencies include CLIA, JCAHO and CAP.

2.2.3.14.1 Guidelines

1. The Fellow is encouraged to meet and discuss regulations with individuals at the State Department of Health laboratory who are responsible for monitoring state and federal laws that affect laboratory testing.

2. The Fellow should complete some or all of the CAP accreditation self-inspection documents and actively participate in a CAP inspection of the laboratory.

3. If possible, the Fellow should participate with an inspection team in an off-site CAP inspection.

4. The Fellow should participate in an OSHA self-inspection of the laboratory and be familiar with the requirements of CLIA ‘88.

6. The Fellow should understand the role of proficiency testing in the certification process.

2.2.3.15. Laboratory Automation and Computerization-Essentials

The Fellow must understand the application and utilization of: a) automated or semi-automated systems for analyte detection, b) computerized information systems for recording, analyzing and reporting laboratory data, and c) computer and software which provide management, quality control, safety, and infection control data. The graduate must describe the basic principles and procedures used to evaluate the cost effectiveness of automated and semi-automated systems.
2.2.3.16. Communication and Clinical Consultation-Essentials

The Fellow must demonstrate the communicative skills necessary to consult and advise physicians, instruct technologists, and to justify personnel, equipment requirements and requests for space to the laboratory director and/or institutional administration.

2.2.3.16.1. Guidelines

1. The Fellow should be assigned the responsibility of handling phone calls from physicians regarding specimen collection, and interpretation of laboratory data. The Fellow should participate in the on-call rotations and be responsible for reporting significant results to physicians.

2. The Fellow should outline the steps involved in making and implementing a policy change.

3. The Fellow should participate in the laboratory's ongoing continuing education program.

2.2.3.17. Research Methodology-Essentials

The graduate must develop a protocol and describe the research methodology, controls and statistical considerations to test a hypothesis proposed as an answer to a basic or applied research problem in immunology. The research methodology may also be applicable to development and regulatory requirements for "home-brew" assays.

2.2.3.17.1. Guidelines

1. Fellows should be encouraged to attend and participate in local, regional and national scientific meetings where research data is submitted for presentation. The program should assist Fellows to the extent possible in funding for meeting attendance.

2. The Fellow should learn the use of basic analytical tools for laboratory assays such ROC curves and basic statistical methods.

3. The Fellow should understand the basic parameters used to establish expected/normal ranges and predictive value analysis.

4. The Fellow should be aware of validation requirements from regulatory agencies such as CLIA, CAP, the FDA for "home-brew".

2.2.4. Time Each Fellow Must Spend in Specialty Areas-Essentials and Guidelines

The table below lists the amount of time a Fellow spends in each of the major training areas during a two-year program. The minimum essential or requirement times are intended for individuals who enter a program with little or no previous experience in clinical immunology and represent the time needed to achieve the objectives stated in the Essentials. The ranges of time or guidelines for each area provide flexibility which may be necessary due to prior experience of the Fellow.
### Essentials and Guidelines for Length of Time in Major Training Areas

<table>
<thead>
<tr>
<th>Major Training Areas</th>
<th>Essentials</th>
<th>Guidelines</th>
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<tbody>
<tr>
<td></td>
<td>Minimum (Months)</td>
<td>Range (Months)</td>
</tr>
<tr>
<td>Infectious Disease Serology</td>
<td>2</td>
<td>2-3</td>
</tr>
<tr>
<td>Autoantibody Testing</td>
<td>2</td>
<td>2-3</td>
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<tr>
<td>Histocompatibility Testing and Transplantation Immunology</td>
<td>2</td>
<td>2-3</td>
</tr>
<tr>
<td>Flow Cytometry/Cellular Immunology</td>
<td>2</td>
<td>2-3</td>
</tr>
<tr>
<td>Immunoglobulin Analysis</td>
<td>1</td>
<td>1-2</td>
</tr>
<tr>
<td>Molecular Diagnostics</td>
<td>1</td>
<td>1-2</td>
</tr>
<tr>
<td>Immunodeficiency Disorders</td>
<td>1</td>
<td>1-2</td>
</tr>
<tr>
<td>Public Health Serology</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Allergy Testing</td>
<td>0.5</td>
<td>0.5</td>
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<tr>
<td>Laboratory Management</td>
<td>2</td>
<td>2-3</td>
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<tr>
<td>(Also includes laboratory safety, management, and regulations, quality management, automation, and specimen collection)</td>
<td>2</td>
<td>2-3</td>
</tr>
<tr>
<td>On-Call</td>
<td>2</td>
<td>2-3</td>
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<tr>
<td>(Also includes communication and clinical consultation)</td>
<td>2</td>
<td>2-3</td>
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<tr>
<td>Research</td>
<td>Open</td>
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<tr>
<td>Teaching</td>
<td>Open</td>
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</tbody>
</table>
2.2.5. Evaluation of Instruction-Essentials

Programs must develop and implement means to evaluate all phases of the instruction. Fellow performance and competence must be documented in relation to stated program objectives that are made known to the Fellow in the beginning of the program. Performance must be documented and reviewed with the Fellow. Documentation of reviews must be maintained for at least 7 years (length of the reaccreditation period).

2.2.5.1. Guidelines

1. A clear definition of program objectives is essential. A program cannot evaluate the knowledge and proficiency which Fellows have acquired unless it has first defined the specific functions and skills that they are expected to learn (see Section 2.2.3). Consequently, a program should define the objectives for the rotations and didactic instruction in such a way that the Fellows, faculty, and evaluators can recognize the level of proficiency and knowledge Fellows are expected to attain from various segments and from the program as a whole.

2. Program directors should develop means for evaluating Fellow accomplishments and preparedness for a career as a medical laboratory immunologist (see Preamble). Periodic review should occur at the completion of each specialty area. This process should provide evidence that each graduate has been fully trained and has substantially met all of the program's objectives. Such evidence should be documented and retained in the file of each graduate.

2.2.6. Program and Performance Records-Essentials

The parent institution must maintain a record of the training program and/or performance of each Fellow for at least 7 years, the length of the reaccreditation period.

2.2.6.1. Guidelines

1. Because a standard curriculum for all Fellows is inappropriate, the parent institution should record the bench and clinical rotations, research, organized courses, and individual study that engaged the time of each Fellow. A list of these program components and other information on Fellow activities and performance should be retained by the institution.
2.3. RESOURCES

2.3.1. General Resources-Essentials

Resources must be adequate to support the number of Fellows admitted to the program.

2.3.1.1. Guidelines

1. Care should be taken to ensure that the supervisory and instructional staff, and other resources are available for all Fellows enrolled in the program and are adequate to provide quality instruction for this advanced, professional level of training.

2.3.2. Program Staff-Essentials

The program must have a qualified program director(s) and adequate support staff. The program director must assume overall responsibility. When the program director is changed, or is on leave for longer than one month, AAM/CPEP must receive immediate notification. The interim/acting director would be responsible for all components of the program. The curriculum vitae of the new director, giving details of his/her education, training, and experience must be submitted to AAM/CPEP. If the new director's credentials are in order, accreditation of the program will be continued.

2.3.2.1. Guidelines

1. Primary responsibilities of the director shall include program development, organization, administration, evaluation, and revision. In some instances, it may be desirable to have an assistant or deputy program director.

2. Program officials should have time to fulfill the administrative and educational duties of the program. Adequate clerical and other support staff should be available.

2.3.3. Program Director Responsibilities-Essentials

The director of the post doctoral program must be responsible for organization and administration, periodic review, continued development, and general effectiveness of the program. In this activity, the program director must cooperate and collaborate fully with the program and instructional officials at the parent and collaborating institutions. The program director shall be responsible for ensuring
that appropriate evaluation instruments are developed and applied regularly and consistently and that appropriate records of all Fellows in the program are maintained.

2.3.3.1. Guidelines

1. The program director shall assume ultimate responsibility for the didactic instruction, laboratory experience, and clinical phase of the program. Although other officials at the sponsoring and collaborating institutions should be delegated specific responsibilities, it is the director's responsibility that all phases of the program are appropriate and successful in meeting program goals and objectives.

2.3.4. Program Director Qualifications-Essentials

The director of the program must be (a) a medical laboratory immunologist who holds a responsible leadership position in the sponsoring institution and (b) certified as a Diplomate by the American Board of Medical Laboratory Immunology (ABMLI) or the American Board of Medical Microbiology (ABMM). The director may be certified by another board that is acceptable to AAM/CPEP, provided the program has a deputy director at the sponsoring institution who is certified by ABMLI or ABMM. The director must be engaged full time in immunological work (diagnostic, research, teaching, program administration) at the sponsoring institution.

2.3.5. Assistant or Deputy Program Director Qualifications-Essentials

If the program has a designated assistant or deputy program director, that person must be certified by the ABMLI, the ABMM, or a board acceptable to AAM/CPEP. The program director(s) must have appropriate credentials which are acceptable for faculty appointments at the sponsoring and/or collaborating institutions.

2.3.6. Instructional Staff

2.3.6.1. General Qualifications-Essentials

All instructional staff must be qualified through academic preparation, experience, and appointment to teach the subjects assigned effectively.

2.3.6.1.1. Guidelines

1. The breadth or competency of the staff of the sponsoring and/or collaborating institutions should be such that all areas of medical laboratory immunology can be covered satisfactorily to meet the objectives of the program. In addition to physicians and scientists who are immunologists, the staff may include specialists in management and education as well as physicians with interest and expertise in clinical immunology who are specialists in infectious diseases, rheumatology, pathology, pediatrics, or epidemiology.

2.3.6.2. Program Officials-Essentials

In addition to the director of the training program, the program officials of the sponsoring and/or collaborating institutions must include at least two doctoral level, full-time staff members with expertise and interest in clinical immunology. These people do not have to be part of the clinical immunology laboratory staff.

2.3.6.2.1. Guidelines

1. Their special fields of competence should supplement rather than duplicate those of the
2.3.6.3. Technical and Clinical Personnel-Essentials

The director must be assisted by sufficient professional, technical, and clinical personnel to permit the laboratory to carry out all of the responsibilities in service, teaching, consultation and research in an efficient and effective manner.

2.3.6.3.1. Guidelines

1. The technical personnel should be certified by appropriate agencies (e.g., Board of Registry (ASCP), or be eligible for such certification.

2.3.7. Financial Resources-Essentials

The financial resources of the sponsoring institution must be such that continued operation of the educational program is assured for completion of the program by current and newly accepted Fellows.

2.3.7.1. Guidelines

1. In addition to adequate budgetary support for the teaching and diagnostic operations of the laboratory, adequate stipend support for Fellows should be provided.

2.3.8. Physical Resources-Essentials

Adequate laboratories, classrooms, office space, and other facilities must be provided.

2.3.8.1. Guidelines

1. The laboratories should have sufficient space to accommodate both the staff and Fellows without interfering with the regular activities of the laboratory. A separate office/laboratory area for Fellows is desirable.

2.3.9. Equipment and Supplies-Essentials

Appropriate, modern equipment and supplies in sufficient quantity must be provided.

2.3.9.1. Guidelines

1. Institutions lacking state of the art automated instruments and computer facilities should make Fellows aware of such technology by having them rotate through other institutions and/or attend lectures and workshops dealing with these subject areas. Adequate instructional materials should be available, including clinical materials that are not available on a regular basis. Programs should provide electronic or internet access to teaching materials as well as maintain collections of digital media, 35 mm color slides, video tapes, movies, and self-instructional materials to supplement the instruction available in the program.

2.3.10. Library-Essentials

A library must be readily accessible and contain an adequate supply of current books, journals, and reference materials related to the curriculum. Computerized search services must be available and the Fellow must be trained in their application and use.
2.3.10.1. Guidelines

1. The sponsoring and collaborating institutions should maintain or have available adequate libraries containing carefully selected, authoritative textbooks, monographs, and current journals in the various disciplines related to and associated with clinical laboratory medicines. The library should provide electronic or on-line access to journals and technical publications.

2.3.11. Records-Essentials

Satisfactory records must be maintained on Fellow admission, health, attendance, participation, achievement, and evaluation. Detailed records on each Fellow must be on file at the sponsoring institution for at least 7 years. A summary record on each Fellow must be permanently kept by the sponsoring institution and sent to the AAM/CPEP headquarters office after completion of the training program.
2.3.12. Advisory Committee-Essentials

An advisory committee must be composed of key program officials from the parent and collaborative institutions. The purpose of this committee is to review and establish policy, continuing program development and evaluation, and to help maximize utilization of resources at the sponsoring and collaborating institutions. At least one meeting each year must be held to assess the program. More frequent meetings may be necessary to resolve certain issues that arise during the year. Minutes of these meetings must be prepared and submitted to CPEP. The annual report requests the minutes every four years.

2.3.12.1. Guidelines

1. The advisory committee should be relatively small, consisting of the program director, one or two associates at the sponsoring institution, and one representative from each collaborating institution. One of the more senior Fellows in the training program may also serve.

2.4. Fellows

2.4.1. Program Description-Essentials

Prospective Fellows must be provided with a clear description of the program and its contents, including the program objectives and competencies that the Fellows are expected to attain. There must be no deceptive publicity concerning job placement or income expectations for Fellows of programs. Fellows must be given a copy of the AAM/CPEP Essentials upon entering the program, if not before.

2.4.1.1. Guidelines

1. The program should have a printed document that clearly describes the training program that is offered. Additional information on stipend, travel, health insurance, and scheduled time off should be disclosed in writing to each Fellow.

2.4.2. Admission-Essentials

The Fellow must have earned a doctoral degree (Ph.D., M.D., D.O., Sc.D., Dr. P.H.) with graduate education in immunology to qualify for admission to the training program. Fellow recruitment and selection must be nondiscriminatory with respect to race, color, creed, age, sex, sexual preference, or national origin; appropriate consideration must be given to the physically handicapped. Matriculation practices must be consistent with all applicable laws regarding nondiscrimination.
The decision for selecting a Fellow must be documented in writing and retained for 7 years.

2.4.2.1. Guidelines

1. Educational prerequisites, other criteria for selection, and the method of selection should be explained to prospective candidates. Desirable prerequisites for the postgraduate training programs include courses in immunology, epidemiology, microbiology, histology, and statistics. Previous work experience in medical and/or public health diagnostic laboratories may be considered when evaluating candidates for the program.

2. A Fellow selection committee consisting of two, and preferably three, members should participate in the selection process. It is usually desirable to have members of the advisory committee serve on the selection committee. If possible, all members of the Fellow selection committee should interview candidates. Current Fellows should have the opportunity to meet with prospective candidates and answer their questions on all phases of the program.

3. Documentation of the selection process and the decision to select a candidate may consist of the minutes from the meeting of the Selection Committee. These written minutes should be retained for a period of 7 years.

2.4.3. Scheduled Time-Essentials

The program must be educational, and the Fellows must use their scheduled time for educational experiences. The laboratory diagnostic work performed by the Fellows must be primarily for the purpose of developing competency rather than to provide routine diagnostic services.

2.4.3.1. Guidelines

1. Exceptions to this Essential may be necessary to provide emergency services for brief periods. The Fellows may assume other managerial, supervisory, and professional responsibilities as assignments to meet the training objectives of the program.

2.4.4. Health and Safety-Essentials

The program director must assure that the Fellows' health and safety is protected by appropriate immunization, protective clothing, chemical hygiene program, and safe working conditions. The health, safety, and infection control policies and procedures pertaining to institutional employees and department faculty must also apply to Fellows.

2.4.4.1. Guidelines

1. If personnel regulations at the institution permit, Fellows should have the option to participate in health and hospitalization insurance programs available to the employees at the facility. In any event Fellows must have health and hospitalization insurance.

2. It is recommended that Fellows have a serum specimen collected at the beginning of their training and stored at -70°C as a baseline serum. A annual PPD skin test should be encouraged as well as immunization to hepatitis B virus.

2.4.5. Costs to Fellows-Essentials

Any costs to the Fellows must be reasonable and accurately stated and published.

2.4.5.1. Guidelines
1. In most approved programs, the Fellows receive stipends and incur no cost for courses and other educational opportunities. Any expenses that the Fellow might incur with regard to travel and subsistence for any phase of the program or for attendance at meetings, transportation of family and personal effects, health and hospital insurance, should be explained to applicants.

2.4.6. Fellow Guidance-Essentials

Program directors (or associates) must be readily available to assist the Fellow in meeting the program's training objectives and addressing the Fellow's career goals.

2.4.6.1. Guidelines

1. Although the program director(s) may see the Fellows in these postgraduate programs almost on a daily basis, it is advisable to have regularly scheduled standing appointments to provide formal guidance. These meetings may be on a monthly basis or coincide with the completion of a rotation.

2.4.7. Appeal Mechanism-Essentials

In the event a Fellow has a grievance with the program, an appropriate appeal mechanism must be available and made known to the Fellow.

2.4.7.1. Guidelines

1. Every attempt should be made to resolve the Fellows' complaints and concerns within the department or within the institution. A more formal appeal mechanism is available through AAM/CPEP. Details of this process are described in the Operational Procedures of AAM/CPEP which may be obtained from a program director or ASM.

2.4.8. Withdrawal or Termination-Essentials

Policies and procedures for Fellow withdrawal or termination must be fair, published, and made known to all applicants. Written documentation of any disciplinary action must be included as part of the Fellow's record and included in the permanent record forwarded to AAM/CPEP.

2.4.8.1. Guidelines

1. Policies and procedures for withdrawal and termination should closely parallel those of the sponsoring institution.

2.5. CONTINUING PROGRAM EVALUATION

2.5.1. Periodic Program Review-Essentials

Periodic and systematic review of the program's effectiveness must be performed and documented. A self-study (analysis, evaluation) conducted by the sponsoring institution must be undertaken for initial program approval or reapproval. Guidelines for Self-Evaluation are available from AAM/CPEP. This documentation must be maintained for seven years. The results of these reviews must be carefully considered and reflected in policies and procedures developed for the program.

2.5.1.1. Guidelines
1. Less formal program evaluation should be conducted on a continuing basis.

2. An evaluation of the program by all Fellows should be obtained within the first two years after completion of the program. The information obtained in these evaluations should be considered in the annual review by the advisory committee.

2.5.2. Employment and Certification Records-Essentials

The programs must maintain the current address list of Fellows showing their employment status in accordance with Department of Education requirements. The files on Fellows of programs must record the certification of Fellows by national registries and boards.

2.6. MAINTAINING PROGRAM ACCREDITATION

2.6.1. Annual Report-Essentials

The annual report form provided by the AAM/CPEP must be completed, signed by the program director, and returned by the established deadline.

2.6.1.1. Guidelines

1. Items on the annual report include information on recruitment and selection of Fellows, names of Fellows passing board examinations during the preceding year, and innovative changes in the educational program. In addition, the report requests the names of all individuals applying to the program during the year so that AAM/CPEP can determine the total demand for this type of training. One major aspect of the program will be addressed each year. These aspects are recruitment and selection, administrative structure, education and training, and self assessment.

2.6.2. Annual Meeting of Program Directors-Essentials

Each approved program should have a representative attend the annual meeting of program directors. The director or designated representative must attend a majority of the meetings and must not be absent two consecutive years.

2.6.3. Replacement of Director or Deputy Director-Essentials

If the director or deputy director of an approved program leaves the sponsoring institution or a new director or deputy director is appointed, AAM/CPEP must receive notification within one month.

2.6.4. Accreditation Withdrawal-Essentials

The AAM/CPEP must consider withdrawal of accreditation whenever:

1. The educational program is not maintained in substantial compliance with the Essentials and the Operational Procedures of AAM/CPEP.
2. There are no Fellows in the program for 2 consecutive years.
3. The program director does not submit the annual report within three months of the deadline.

2.6.5. Notification of Withdrawal

Accreditation will be withdrawn only after notice (with the reasons for withdrawal) has been given to the Chief Executive Officer of the sponsoring institution and after sufficient time has elapsed to permit
a considered response. The operating procedures established by AAM/CPEP regarding appeal and review shall be followed.

Program Directors are required to notify the Fellows of their withdrawal of CPEP accreditation. Fellows may contact CPEP to ascertain the status of their training to date.