REPORT OF THE SUBCOMMITTEE ON PERSONNEL STANDARDS

Prepared: April 12, 1996

Recognizing the coming changes in the practice of clinical laboratory science in California brought on by the implementation of the federal Clinical Laboratory Improvement Act (CLIA) of 1988, the Clinical Laboratory Technology Advisory Committee [CLTAC] appointed a subcommittee to evaluate and prepare recommendations for the implementation of a technician level of personnel in the clinical laboratory setting.

The subcommittee members selected represented a wide spectrum of experience in the practice of laboratory science including expertise in the areas of laboratory education, management, test performance and regulation. Further, the membership offered well rounded points of view from academacia, hospital based, clinic and commercial laboratories.

The goal of the Subcommittee on Personnel Standards was to prepare recommendations for CLTAC consideration that would define the routes of entry, scope of practice, educational and training requirements, and credential process deemed necessary for this level of laboratory practice. Further, the new technician category was to be defined in such a way that a natural career ladder structure was created in the clinical laboratory field reducing the barrier which currently exists between the categories of Unlicensed Personnel and the Clinical Laboratory Scientist (and related limited license categories).

The adoption into law of SB113 incorporates CLIA 88 into California law and has significantly altered the demands and expectations placed upon clinical laboratory testing personnel. It expands the practice of laboratory science to many categories of personnel who have heretofore been excluded from that practice. The creation of a Technician level of personnel in California is a natural adaptation to CLIA 88 for testing performed within clinical laboratories. The waived and moderate complexity test models fit well with this category. Adoption of the Technician category would provide the flexibility in staffing demanded by all forms of clinical laboratories and still provide for protection of the public through defined training, educational and credential requirements. It should also be noted that the Technician level is currently recognized in at least 45 states and has standards and certification processes defined by national level independent organizations.

The revisions of Section 1208 through the passage of SB113 gives the Department the authority to create this new licensed category using the regulatory process.

This paper sets forth the recommended routes of entry, scope of practice, minimal training and education requirements, and credential recommendations for the Clinical Laboratory Technician category.

SUBCOMMITTEE ON PERSONNEL STANDARDS [CLTAC]

RECOMMENDATIONS FOR CREATION OF TECHNICIAN CATEGORY

Date Prepared: April 12, 1996

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The Subcommittee on Personnel Standards has determined that significant justification exists for the creation of a personnel category of **Technician** in the clinical laboratory. This new position is herein defined.

DEFINITIONS:

Reporting of test results is intended to include the verification of the test value prior to release of information.

Verification as used in this document is intended to include proving the truth of or checking the accuracy of test results.

Abnormal results is intended to include all test values that fall outside of the reference range of any procedure as defined by individual laboratories. This criteria also includes any values that exceed defined critical value, delta check or linearity limits.

School is as defined in the Business and Professions Code, Article 1, Section 1213.

Clinical Laboratory is as defined in the Business and Professions Code, Article 1, Section 1213.

The **Department** is the Department of Health Services, Laboratory Field Services division.

SCOPE OF PRACTICE FOR THE CLINICAL LABORATORY TECHNICIAN [CLT]:

The subcommittee recommends the essential elements of the Scope of Practice for the Clinical Laboratory Technician level be based on the complexity model defined in the Clinical Laboratory Improvement Act of 1988 (with modification noted below). The following specific criteria are recommended:

1. All **wavered complexity testing** to be **included** as defined by HCFA as of January 1, 1994.

2. All **high complexity testing** to be **excluded.**

3. **Moderate complexity testing** to be **included** with the following modifications.

   Performance and reporting of moderate complexity testing is acceptable with the **exclusion** of:

   a. Verification of abnormal test results prior to reporting.
   b. All microscopic work is **excluded excepting** microscopic urinalysis.
   c. Validation, standardization and manual calibration of test procedures.
   d. All microbiology (culture processing) procedures beyond the primary inoculation of culture media from original specimen.
   e. All immunohematology procedures.
   f. The performance of all bleeding time methods.

ROUTES OF ENTRY FOR CLINICAL LABORATORY TECHNICIAN:

The subcommittee recommends that five (5) routes of entry be defined for this personnel category in regulations as follows:

ROUTE 1:

(1) Graduation from an Associate Degree program consisting of 60 semester (90 quarter) hours. The curriculum to include, at minimum, 36 semester (54 quarter) hours of physical and biological sciences appropriate for transfer to baccalaureate programs in science majors, **AND**

(2) Six months training experience, in a clinical laboratory or a school, approved by the Department for clinical laboratory technician instruction.

ROUTE 2:

Graduation from an Associate Degree clinical laboratory program accredited by the National Accrediting Agency for Clinical Laboratory Sciences [NAACLS].

ROUTE 3:

Possession of credentials from a foreign country attesting to clinical laboratory training, experience consistent with, or superior to, requirements for alternate routes as defined herein, and with the approval of the Department.

ROUTE 4:

Possession of a high school diploma (or equivalent), a certificate from an advanced military medical laboratory specialist program, a minimum of one (1) year clinical laboratory experience, and with the approval of the Department.

ROUTE 5:

Possession of a high school diploma (or equivalent) and four (4) years of full-time work experience, in a licensed clinical laboratory (or equivalent), which has encompassed the major disciplines of laboratory practice [including clinical chemistry, hematology and microbiology] within the last seven (7) years. Experiences to be reviewed and approved by the Department.

RECOMMENDATIONS FOR LICENSURE OF THE CLINICAL LABORATORY TECHNICIAN CATEGORY:

1. The subcommittee recommends **licensure** be required for the Clinical Laboratory Technician (CLT) category.

2. The subcommittee recommends **passage of an examination** for this category be required as a condition for licensure.

3. The subcommittee recommends **mandatory continuing education** be required at the level of **12 contact hours per year.**

4. The subcommittee recommends licensure application fees be set at such level as to be self-supporting.

CLINICAL LABORATORY TECHNICIAN TRAINING PROGRAM CURRICULA (GENERAL CONTENT):

1. Training programs should be constructed in a manner that provides for career ladder growth within the laboratory profession (articulation).

2. Training shall include the practical application of, and instruction in, the technical principles and practices of hematology, microbiology, immunology, clinical chemistry and urinalysis.

3. Facilities providing training for both Technician (CLT) and Scientist (CLS) levels of personnel must assure that the curriculum of each program is distinct and clearly defined for both didactic and practical instruction.

4. Training must include a didactic and practical experience component:

   a. Didactic training must include the following subjects:

      1. Quality control, quality assurance and performance improvement
      2. Safety and universal precautions
      3. Troubleshooting
      4. Documentation and legal requirements
      5. Preventive maintenance
      6. Reagent, control and calibrator material (stability, handling and storage requirements)
      7. Current environment of clinical practice (eg: effectiveness, cost containment)
      8. Preanalytic, analytic and postanalytic test performance considerations

   b. Practical training must include the following subjects:

      1. Instruction in the use of instruments and test performance
      2. Practical experience
      3. Clinical correlation
      4. Preventive maintenance
      5. Instrument and test specific parameters
      6. Successful completion of practical training must be documented by competency assessment

ESTABLISH A STAFFING RATIO FOR LICENSED LABORATORIES:

1. The ubcommittee recommends laboratory facilities be limited by regulation to employ no n ıre than one Clinical Laboratory Technician per each Clinical Laboratory Scientist on staff.

2. This ratio is specific to personnel performing laboratory testing procedures.

3. Specimen processing and clerical personnel are excluded from this ratio.

PHASING-IN OF EXISTING UNLICENSED TESTING PERSONNEL:

GRANDFATHER CLAUSE FOR PERSONNEL:

The subcommittee DOES NOT recommend a grandfather clause be incorporated into the regulations.

SUNSET CLAUSE FOR PERSONNEL:

The subcommittee recommends personnel currently performing laboratory testing be permitted **4 years to meet** one of the defined qualifying routes of entry and successfully pass the licensure examination.