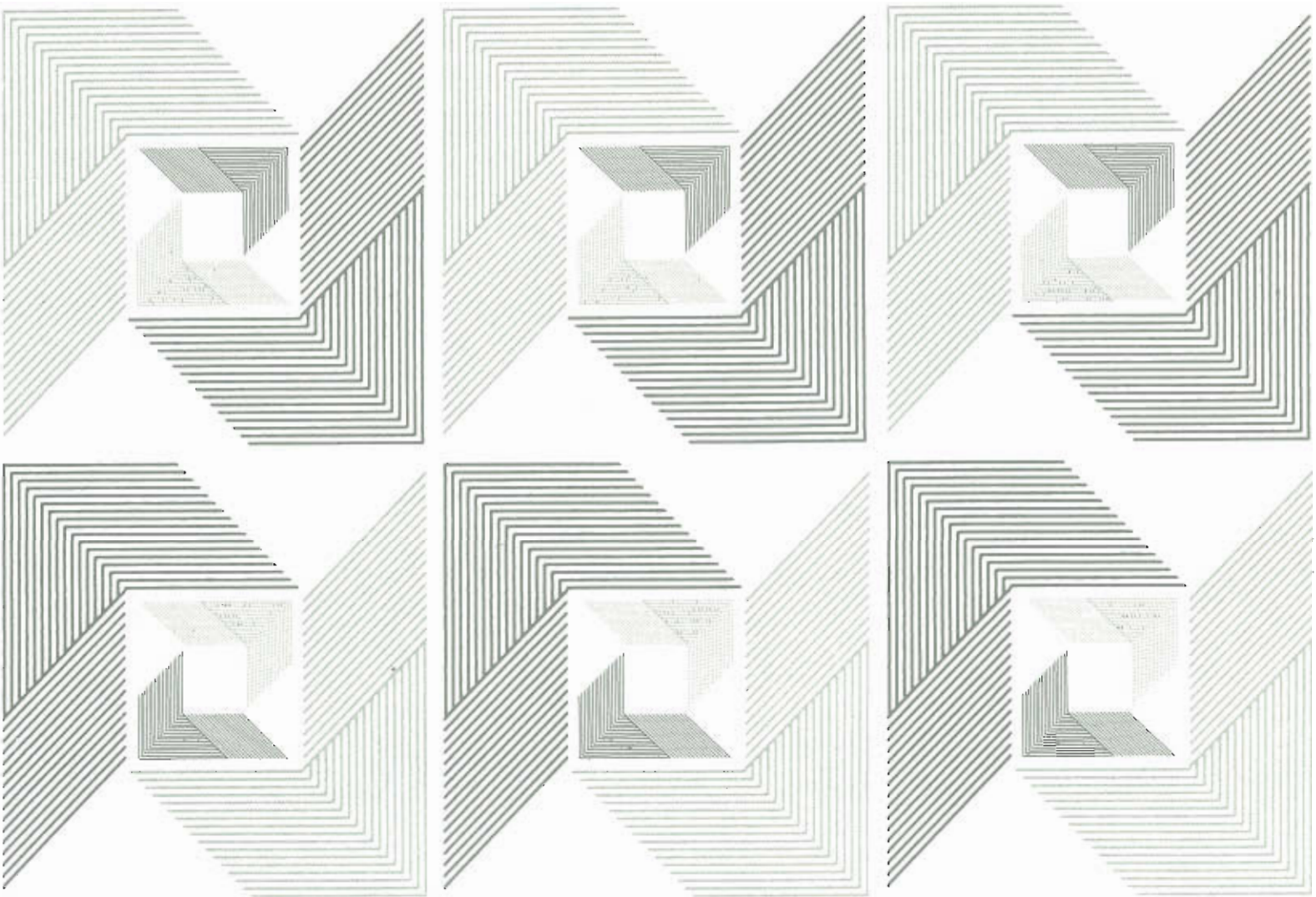
Report No. 89-20
December 1989

SUNSET EVALUATION REPORT REGULATION OF CLINICAL LABORATORY PERSONNEL

A REPORT TO THE GOVERNOR AND THE LEGISLATURE OF THE STATE OF HAWAII



SUBMITTED BY THE LEGISLATIVE AUDITOR OF THE STATE OF HAWAII

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LEGISLATIVE AUDITOR
KEKUANAO'A BUILDING, RM. 500
465 SOUTH KING STREET
HONOLULU, HAWAII 96813

Legislative Auditor

OVERVIEW

SUNSET EVALUATION REPORT: REGULATION OF CLINICAL LABORATORY PERSONNEL

Honolulu, Hawaii

December 1989

Summary

Clinical laboratories employ a range of professional and technical personnel--from laboratory directors to technologists and technicians--whose job it is to examine substances of the human body and report their findings to physicians. Physicians use this information to diagnose, treat, and prevent diseases and disabilities.

Because of the importance of this field of work, many private agencies certify clinical laboratory personnel. Some, such as the National Registry of Microbiologists, focus on a particular type of worker. Others, such as the American Medical Technologists, certify a variety of laboratory workers and promote their interests. In addition, federal and state laws and rules govern their practice in many ways. Congress recently enacted the Clinical Laboratory Improvement Amendments of 1988, which significantly strengthened the standards and regulatory requirements for clinical laboratories.

There is little uniformity in the way different states regulate these personnel. Hawaii is one of only five states that license clinical laboratory directors and technical personnel. The Laboratories Branch of the Department of Health administers the program.

As required by the Sunset Law, the auditor reviewed the need to regulate the practices of these workers. Clinical laboratory practice was found to be potentially harmful. Inaccurate tests can mask serious illnesses, lead to unnecessary treatment, and result in death, disability, stress, and financial ruin. However, the best way to protect the public is to license the laboratories, not the many types of workers. Standards can then be set for key technical personnel working in these facilities. This approach can avoid the inefficiencies and problems of the current program.

FINDINGS

Because of the potential for harm, clinical laboratory practice needs to be regulated. However, licensing all personnel is ineffective, difficult to enforce, expensive, and redundant. It is difficult to define the scope of practice and standard of training for each of the many specialties in the field. Licensing of personnel can limit the supply of professionals, keep laboratories from responding to changing demands, and lead to higher costs.

Clinical laboratory testing is a process that must be effective in its entirety. Licensing of laboratories is the best way to protect the public against inaccurate and unreliable test results. It encompasses the entire testing process and avoids the pitfalls of licensing individual laboratory workers.

The licensing program faces some serious problems. The statutes are too vague to support a licensing effort, and the rules are outdated and inappropriate. The administration of the program has been unsystematic, often characterized by arbitrary decisions and inadequate documentation.

RECOMMENDATIONS

The Legislature should remove the regulation of laboratory personnel from the statutes. The best way to protect the public is to license clinical laboratories and to set standards for key personnel in these facilities.

The Department of Health should discontinue the current program that licenses laboratory personnel. It should revise the rules on clinical laboratories to conform with and complement the federal Clinical Laboratory Improvement Amendments of 1988. This new law establishes a mandatory certification (licensing) program for all clinical laboratories in the United States. It requires labs to meet federal standards that include personnel standards, undergo periodic inspections, and participate in proficiency testing programs.

RESPONSE

The Department of Health disagrees with the recommendation to discontinue licensing clinical laboratory personnel. It feels regulation is needed to prevent unqualified persons from practicing. We continue to maintain that the public can be best protected by federal and state licensing of laboratories.

The department plans to remedy the limitations in the current regulatory program by adopting new rules and studying a bill to establish a licensing board. We do not believe these approaches are sufficient.

SUNSET EVALUATION REPORT
REGULATION OF
CLINICAL LABORATORY PERSONNEL

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A Report to the Governor and the Legislature of the State of Hawaii

Submitted by

Legislative Auditor of the State of Hawaii
Honolulu, Hawaii

Report No. 89-20
December 1989

FOREWORD

Under the "Sunset Law," licensing boards and commissions and regulated programs are terminated at specific times unless they are reestablished by the Legislature. Hawaii's Sunset Law, or the Hawaii Regulatory Licensing Reform Act of 1977, schedules for termination licensing programs over a six-year period. These programs are repealed unless they are specifically reenacted by the Legislature. In 1979, the Legislature assigned the Office of the Legislative Auditor responsibility for evaluating each program prior to its repeal.

This report evaluates the regulation of clinical laboratory personnel under Sections 321-13 to 321-15, Hawaii Revised Statutes. It presents our findings as to whether the program complies with the Sunset Law and whether there is a reasonable need to regulate them to protect public health, safety, or welfare. It includes our recommendation on whether the program should be continued, modified, or repealed. Draft legislation intended to improve the regulatory program is incorporated in this report as Appendix B.

We acknowledge the cooperation and assistance extended to our staff by the Department of Health and other officials contacted during the course of our examination. We also appreciate the assistance of the Legislative Reference Bureau which drafted the recommended legislation.

Newton Sue
Acting Legislative Auditor
State of Hawaii

December 1989

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Chapter 1

INTRODUCTION

The Hawaii Regulatory Licensing Reform Act of 1977, or Sunset Law, repeals statutes concerning 38 occupational licensing programs over a six-year period. Each year, six to eight licensing statutes are scheduled to be repealed unless specifically reenacted by the Legislature.

In 1979, the Legislature amended the law (Chapter 26H, *Hawaii Revised Statutes*) to make the Legislative Auditor responsible for evaluating each licensing program prior to its repeal and to recommend to the Legislature whether the statute should be reenacted, modified, or permitted to expire as scheduled. In 1980, the Legislature further amended the law to require the Legislative Auditor to evaluate the effectiveness and efficiency of the licensing program, even if he determines that the program should not be reenacted.

Objective of the Evaluation

The Legislature in 1988 added certain licensing programs administered by the Department of Health under Sections 321-13 to 321-15, HRS, to the Sunset review schedule. The objective of this evaluation is to determine whether, in light of the policies set forth in the Sunset Law, the public interest is best served by reenactment, modification, or repeal.

Scope of the Evaluation

This report examines the occupational characteristics of clinical laboratory practice, the history of the statute on licensing of clinical laboratory personnel, and the public health, safety, or welfare that the statute was designed to protect. It then assesses the effectiveness of the statute in preventing public injury and the continuing need for regulation.

Organization of the Report

This report consists of three chapters: Chapter 1, this introduction and the framework for evaluating the licensing program; Chapter 2, background information on the regulated industry and the enabling legislation; and Chapter 3, our evaluation and recommendations.

Framework for Evaluation

Hawaii's Regulatory Licensing Reform Act of 1977, or Sunset Law, reflects rising public antipathy toward what is seen as unwarranted government interference in citizens' lives. The Sunset Law sets up a timetable terminating various occupational licensing programs. Unless reestablished, the programs disappear or "sunset" on a prescribed date.

In the Sunset Law, the Legislature established policies on the regulation of professions and vocations. The law requires each occupational licensing program to be assessed against these policies in determining whether the program should be reestablished or permitted to expire as scheduled. These policies, as amended in 1980, are:

1. The regulation and licensing of professions and vocations by the State shall be undertaken only where reasonably necessary to protect the health, safety, or welfare of consumers of the services; the purpose of regulation shall be the protection of the public welfare and not that of the regulated profession or vocation.

2. Where regulation of professions and vocations is reasonably necessary to protect consumers, government regulation in the form of full licensure or other restrictions on the professions or vocations should be retained or adopted.

3. Professional and vocational regulation shall be imposed where necessary to protect consumers who, because of a variety of circumstances, may be at a disadvantage in choosing or relying on the provider of the services.

4. Evidence of abuses by providers of the services shall be accorded great weight in determining whether government regulation is desirable.

5. Professional and vocational regulation which artificially increases the costs of goods and services to the consumer should be avoided.

6. Professional and vocational regulation should be eliminated where its benefits to consumers are outweighed by its costs to taxpayers.

7. Regulation shall not unreasonably restrict entry into professions and vocations by all qualified persons.

We translated these policy statements into the following framework for evaluating the continuing need for the various occupational licensing statutes.

Licensing of an occupation or profession is warranted if:

1. There exists an identifiable potential danger to public health, safety, or welfare from the operation or conduct of the occupation or profession.

2. The public that is likely to be harmed is the consuming public.

3. The potential harm is one against which the public cannot reasonably be expected to protect itself.

4. There is a reasonable relationship between licensing and protection of the public from potential harm.

5. Licensing is superior to other alternative ways of restricting the profession or vocation to protect the public from the potential harm.

6. The benefits of licensing outweigh its costs.

The potential harm. For each regulatory program under review, the initial task is to identify the purpose of regulation and the dangers from which the public is to be protected.

Not all potential dangers warrant the exercise of the State's licensing powers. The exercise of such powers is justified only when the potential harm is to public health, safety, or welfare. "Health" and "safety" are fairly well understood. "Welfare" means well-being in any respect and includes physical, social, and economic well-being.

This policy that the potential danger be to the public health, safety, or welfare is a restatement of general case law. As a general rule, a state may exercise its police power and impose occupational licensing requirements only if such requirements tend to promote the public health, safety, or welfare. Courts have held that licensing requirements for paperhangers, housepainters, operators of public dancing schools, florists, and private land surveyors could not be justified.[1] In Hawaii, the State Supreme Court ruled in 1935 that legislation requiring photographers to be licensed bore no reasonable relationship to public health, safety, or welfare and constituted an unconstitutional encroachment on the right of individuals to pursue an innocent profession.[2] The court held

that mere interest in the practice of photography or in ensuring quality in professional photography did not justify the use of the State's licensing powers.

The public. The Sunset Law further states that for the exercise of the State's licensing powers to be justified, the potential harm must be to the health, safety, or welfare of that segment of the public consisting mainly of consumers of the services provided by the regulated occupation. The law makes it clear that the focus of protection should be the consuming public and not the regulated occupation or profession itself.

Consumers are all those who may be affected by the services provided by the regulated occupation. Consumers do not have to purchase the services directly. The provider of services may have a direct contractual relationship with a third party and not with the consumer, but the criterion is met if the provider's services ultimately flow to and adversely affect the consumer. For example, the services of an automobile mechanic working for a garage or for a U-drive establishment flow directly to the employer, but the mechanic's workmanship ultimately affects the consumer who brings a car in for repairs or who rents a car from the employer.

Consumer disadvantage. The exercise of the State's licensing powers is not warranted if the potential harm is one against which the consumers can reasonably be expected to protect themselves. Consumers are expected to be able to protect themselves unless they are at a disadvantage in selecting or dealing with the providers of services.

Consumer disadvantage can arise from a variety of circumstances. It may result from a characteristic of the consumer or from the nature of the occupation or profession being regulated. Age is an example of a consumer characteristic which may cause the consumer to be at a disadvantage. The highly technical and complex nature of an occupation is an illustration of occupational characteristic that may place the consumer at a disadvantage. Medicine and law fit into the latter illustration. Medicine and law were the first occupations to be licensed on the theory that the general public lacked sufficient knowledge about medicine and law to be able to make judgments about the relative competencies and about the quality of services provided to them by the doctors and lawyers of their choice.

However, unless otherwise indicated, consumers are generally assumed to be knowledgeable and able to make rational choices and to assess the quality of services being provided them.

Relationship between licensing and protection. Occupational licensing cannot be justified unless it reasonably protects the consumers from the identified potential harm. If the potential harm to the consumer is physical injury arising from possible lack of competence on the part of the provider of service, the licensing requirements must ensure the competence of the provider. If, on the other hand, the potential harm is the likelihood of fraud, the licensing requirements must be such as to minimize the opportunities for fraud.

Alternatives. Licensing may not be the most appropriate method for protecting consumers. Instead, prohibiting certain business practices, governmental inspection, or the inclusion of the occupation within another existing business regulatory statute may be preferable, appropriate, or more effective in protecting the consumers. Increasing the powers, duties, or role of the consumer protector is another possibility. For some programs, a nonregulatory approach may be appropriate, such as consumer education.

Benefit-costs. Even when all other criteria set forth in this framework are met, the exercise of the State's licensing powers may not be justified if the costs of doing so outweigh the benefits to be gained. The term "costs" in this regard

means more than direct money outlays or expenditure for a licensing program. "Costs" include opportunity costs or all real resources used up by the licensing program; they include indirect, spillover, and secondary costs. Thus, the Sunset Law asserts that regulation which artificially increases the costs of goods and services to the consumer should be avoided; and regulation should not unreasonably restrict entry into professions and vocations by all qualified persons.

Chapter 2

BACKGROUND

The Department of Health licenses clinical laboratory personnel under Sections 321-13 to 321-15, *Hawaii Revised Statutes*, which authorize the department to regulate laboratory directors, supervisors, technologists, and technicians. This chapter reviews the occupational characteristics of clinical laboratory personnel and describes Hawaii's regulatory program.

Occupational Characteristics

Clinical laboratory personnel examine substances obtained from the human body and provide physicians (or other independent medical practitioners) with scientific information on the health status of patients. This information is used in diagnosing, treating, and preventing disease or disability.

Most clinical laboratory personnel work in hospital, independent, or physician-office laboratories. Some work in laboratories run by medical facilities, public health agencies, pharmaceutical companies, or other research organizations.

In Hawaii, there are more than 1,100 licensed clinical laboratory personnel.[1]

History. Clinical laboratories were first established in the United States in the late nineteenth century. They were based in hospitals and directed by physicians. These physicians often delegated routine work to laboratory technicians who were trained as apprentices.

As the health care system expanded, more highly trained scientists, technologists, and specialists began to perform complex tests. Assistants were hired to handle routine tasks. Independent laboratories were established, and physician-office laboratories assumed greater responsibility for testing.

Today, hospital and independent laboratories conduct diagnostic tests in scientific disciplines such as clinical chemistry (the study of body fluids), histology (the study of body tissues), and hematology (the study of blood cells). They are directed by physicians or bioanalysts (scientists with advanced degrees) and they employ a wide range of supervisory and nonsupervisory personnel. Hospital laboratories provide about half of the nation's clinical testing services and employ nearly two-thirds of the laboratory workforce.[2] Independent laboratories provide about 25 percent of the clinical testing services in the U.S.[3]

Physician-office laboratories are often staffed by part-time laboratory personnel or office personnel who also do non-laboratory work. They provide about 25 percent of the nation's clinical testing services.[4]

Training programs. Clinical laboratory personnel are trained in hospitals, vocational schools, colleges, and universities. Hospitals traditionally have operated most clinical laboratory training programs, but many of these training programs are closing due to the cost.

Most training programs for specialists, technologists, technicians, and assistants are accredited by the American Medical Association's Committee on Allied Health Education and Accreditation or the Accrediting Bureau of Health Education Schools/Programs. Scientists employed by clinical laboratories usually obtain academic degrees from regionally accredited colleges or universities.

National certification programs. A number of private agencies certify clinical laboratory personnel. These include agencies (such as the National Registry of Microbiologists) that certify one particular type of laboratory worker, and agencies that certify a variety of laboratory personnel.

Four agencies in the latter category certify most of the clinical laboratory personnel in the U.S.: the Board of Registry; the National Certification Agency for Medical Laboratory Personnel; American Medical Technologists; and the Credentialing Commission. The agencies are highly competitive. They differ on entry level standards for the various occupations and they use different designations for those they certify.

Board of Registry. The American Society of Clinical Pathologists established the first national certification program for clinical laboratory personnel in 1928. This program is now administered by the Board of Registry, which certifies managers, specialists, technologists, medical laboratory technicians, and histologic technicians (persons who study the organization of tissues). Nearly 280,000 laboratory workers are certified by the board.[5]

National Certification Agency for Medical Laboratory Personnel. In 1977, laboratory technologists established this agency, which certifies directors, supervisors, specialists, scientists (technologists), technicians, and phlebotomists (persons who draw blood from patients). The agency's standards are similar to Board of Registry standards but it uses different qualifying examinations. It has certified more than 60,000 laboratory workers.[6]

American Medical Technologists. This organization was established by laboratory workers in 1939. It certifies technologists, technicians, and assistants, following guidelines established by the National Commission for Health Certifying Agencies. More than 17,000 laboratory workers are now certified by the organization.[7]

Credentialing Commission. The commission was established in 1962 by a group representing laboratory technologists and technicians. It certifies medical technologists and laboratory technicians.

Professional organizations. Many national organizations promote the interests of clinical laboratory personnel. The two major ones are the American Society for Medical Technology (ASMT) and American Medical Technologists.

The two organizations are comparable in membership size but differ in their approach to regulation for clinical laboratory personnel. The ASMT is aggressively campaigning for state licensure of clinical laboratory personnel. It has adopted a scope of practice for "clinical laboratory sciences," a sophisticated campaign strategy, and a model state licensing law.[8] The American Medical Technologists, however, strongly objects to state licensing programs for clinical laboratory personnel.[9]

State regulation of clinical laboratory personnel. Five states (California, Florida, Hawaii, Nevada, and Tennessee) license clinical laboratory directors and technical personnel. In 1989, North Dakota and West Virginia enacted new licensing laws for clinical laboratory personnel. Both states are now planning their licensing programs and have not issued regulations.

There is no uniformity in the licensing programs, and each state regulates different types of personnel. For example, California licenses technologists, limited technologists, special clinical laboratory technologists, and trainees. Florida licenses supervisors, technologists, blood gas analysts, and technicians. The North Dakota program only covers specialists, technologists, and technicians.

Varying forms of regulation are found in other states. Some license laboratory directors and set standards for technical personnel working in licensed laboratories. Others certify laboratory directors or merely set standards for directors working in licensed facilities.

History of regulation in Hawaii. In 1937, Act 122 authorized the Board of Health to regulate laboratories as part of a modernization program recommended by a national public health expert. Four years later, the board was authorized to regulate laboratory technicians to safeguard the public's health. In 1945, it was authorized to regulate laboratory directors.

The first administrative rules governing laboratory personnel, issued in 1958, covered environmental and veterinary laboratory personnel as well as clinical laboratory personnel. They required nonphysician directors and technicians to be licensed and set standards for apprentices.

The rules were substantially revised in 1974 to focus only on clinical laboratory personnel. They added physician directors, supervisors, specialists, cytotechnologists, and technologists to the licensing program; required assistants and trainees to be registered; and eliminated the apprenticeship program.

Current Regulation of Clinical Laboratory Personnel in Hawaii

Scope of regulation. The licensing program is administered by the department's Laboratories Branch. It licenses clinical laboratory directors, supervisors, specialists, cytotechnologists, technologists, and technicians. Clinical laboratory assistants and trainees must be registered.

Licensed and registered personnel may collect blood, remove stomach contents, and collect material for smears and culture under the direction of, or upon the written request of, a licensed physician.

Directors may administer the technical and scientific operations of a laboratory, supervise testing procedures, and supervise the reporting of results. They are responsible for seeing that tests are done properly and for employing licensed personnel.

Supervisors may perform tests requiring special scientific skills and supervise personnel working in designated specialty fields. They work under the general supervision of a licensed director.

Specialists, cytotechnologists, and technologists may perform tests requiring independent judgment and responsibility in specialty fields designated on their licenses. They may also supervise technicians, assistants, and trainees. They work under minimal supervision by a licensed supervisor or director.

Technologists may also perform tests requiring limited technical skill and responsibility in specialty fields not included on their licenses if they work under direct supervision.

Technicians may perform testing procedures in specialty fields for which they are qualified. They are supervised by licensed technologists, specialists, supervisors, or directors.

Assistants and trainees may only perform procedures requiring limited responsibility and technical skill and a minimal exercise of independent judgment in specialty fields for which they are qualified. They work under the direct and personal supervision of a licensed technologist, specialist, supervisor, or director.

Licensing and registration standards. Clinical laboratory personnel must meet education and experience requirements in order to qualify for licensure or registration. These requirements are summarized in the exhibit.

Applicants for a director's license must be either Hawaii-licensed physicians or have academic degrees, professional credentials, or experience satisfactory to the department. Nonphysician applicants must also pass examinations covering general laboratory science and the specific areas of testing for which licensure is sought.

Applicants for other licenses must meet academic and experience requirements and pass examinations in one or more specialty fields. The department may waive the examination requirement for applicants who have unusual backgrounds or proven ability on the recommendation of an advisory committee.

Disciplinary program. The department may revoke or suspend a license for a number of reasons, such as making false statements on documents required by the department, permitting unauthorized persons to perform technical procedures, or making consistent errors in test results. The director of health must suspend a license--or the authority of a person to perform, supervise, or direct testing--when erroneous test results endanger health and life.

Individuals who are subject to disciplinary action must be given due notice and an opportunity to be heard and to present evidence in their own defense. All disciplinary actions must comply with the Administrative Procedure Act (Chapter 91, HRS). Anyone who violates the rules may be fined no more than $500, imprisoned for no more than one year, or both.

Chapter 3

EVALUATION OF THE REGULATION OF CLINICAL LABORATORY PERSONNEL

This chapter evaluates the need to regulate clinical laboratory practice and the adequacy of the current regulatory program.

Summary of Findings

1. *Clinical laboratory practice can endanger the public's health, safety, and welfare. However, it is not necessary or desirable to license clinical laboratory personnel. The best way to protect the public is to license clinical laboratories and to set standards for key technical personnel working in these facilities.*

2. *The licensing program is administered arbitrarily and improperly. The main reasons are:*

   - *inadequate statutes;*
   - *obsolete and poorly written rules;*
   - *poor organization and improper implementation of the licensing program.*

The Need for Regulation

There is a potential for harm to the public in clinical laboratory practice. Clinical laboratories develop scientific information used by physicians in diagnosing and treating medical conditions. Inaccurate or unreliable information can cause physicians to overlook serious medical conditions or to prescribe unnecessary treatment. Death, disability, physical and emotional distress, or financial ruin may result for patients and their families.

Patients have been harmed by inaccurate and unreliable laboratory tests. A Pulitzer Prize-winning series in *The Wall Street Journal* documented numerous cases where laboratory testing resulted in death, disability, or unnecessary surgery.[1] For example, several women died when laboratory tests failed to detect their cervical cancer in time for effective treatment. A child developed mental retardation when a laboratory failed to detect a genetic condition requiring special care. And a woman submitted to unnecessary surgery after a laboratory erroneously reported that she was pregnant.

It has been reported that some clinical laboratories produce inaccurate or unreliable scientific information by fraudulently reporting on specimens that are not tested ("sink-testing") and by requiring personnel to use malfunctioning equipment.

Clinical laboratory *practice* should be regulated because of the potential for harm. However, it is unnecessary and undesirable to license clinical laboratory *personnel*. The public can be adequately protected by licensing clinical laboratories and setting standards for key technical personnel working in licensed facilities.

It is preferable to license clinical laboratories because (1) licensing laboratory personnel is ineffective and unenforceable, (2) personnel licensing may increase health care costs, and (3) federal licensing of clinical laboratories provides added protection.

Personnel licensing is ineffective and unenforceable. Clinical laboratory personnel represent many occupations. The difficulty of defining their scopes of practice and developing valid minimum licensing standards for the different clinical laboratory occupations has led most states and the federal government to license clinical laboratories rather than clinical laboratory personnel.

Difficulty in defining scopes of practice. The definition problem is illustrated by the the two largest groups working in clinical laboratories--medical technologists and medical technicians. Medical technologists are usually trained at the baccalaureate level while medical technicians are usually trained in junior colleges or trade and technical schools. Both groups enter practice as generalists, although they may decide later to specialize.

The scopes of practice for entry level technologists and technicians are distinguished by the complexity of tests they perform. Medical technologists perform complex tests and specialized procedures while medical technicians perform routine tests. The decision on which tests must be performed by a medical technologist is often subjective, and laboratory managers may use technicians interchangeably with technologists. The Institute of Medicine recently reported that "there is sometimes little or no differentiation in the way technologists and technicians are used."[2]

Licensing is difficult to enforce when there are no clear boundaries between regulated occupations. One report on clinical laboratory practice found that "it is very difficult to restrict the kind of tasks performed by technicians once they are allowed to work in laboratories. As a result, personnel with the official title of technician may actually perform tasks legally limited to technologists and supervisors."[3]

Lack of clearcut licensing standards. It is difficult to develop valid and reliable licensing standards for clinical laboratory personnel because of the many different pathways to practice; the lack of consensus on the education, training, and experience needed for some jobs; and the scarcity of formal training programs for some occupations.

The U.S. Center for Educational Statistics lists twelve categories of instructional programs for allied health personnel working in clinical laboratories.[4] These include programs for laboratory assistants, blood bank technologists (persons who prepare blood for transfusions), cytotechnologists (persons who study body cells), hematologists (persons who study blood cells), histologists (persons who study body tissues), medical technologists, and others. In addition, physicians and scientists trained in a wide range of specialty fields--such as anatomic pathology, chemistry, and microbiology--work for clinical laboratories.

Entry level standards for medical technologists are hotly disputed by national certifying agencies and professional associations. Standards for smaller specialty groups, such as cytotechnologists, are more uniform, but laboratories must rely on in-house training programs because there are not enough formal training programs.

There is little clearcut data on the amount of education, training, and/or experience needed to ensure testing accuracy and reliability. One medical journal reported that "the education and experience of laboratory personnel and the percentage of specialized supervisors in large clinical laboratories" correlate with successful proficiency testing in only two specialty fields (bacteriology and parasitology) but do not correlate with successful testing in other fields such as clinical chemistry.[5] The federal government plans to issue a report on the correlation between personnel standards and the accuracy and reliability of test results in May 1990.

Laboratories perform thousands of tests in different specialty fields. There are nearly 900 tests for blood alone. The current trend is to

eliminate detailed education, training, and experience standards for clinical laboratory personnel and to rely more heavily on outcome measures such as quality assurance programs. The Joint Commission on Accreditation of Healthcare Organizations and the U.S. Health Care Financing Administration have taken this approach in developing accreditation and Medicare eligibility standards for clinical laboratories.

Personnel licensing may increase costs. A personnel licensing program is likely to increase health care costs by reducing the flexibility of laboratories to respond to a changing environment and by reducing mobility.

Reduced flexibility. Clinical laboratories are changing rapidly. They now test in new settings using automation and less skilled personnel. At the same time, they need highly trained personnel to perform complex new tests. The demand for laboratory testing is expected to rise as the population ages, as concerns about communicable diseases (such as AIDS) increase, and as substance abuse testing programs become more widespread. The cost of health care is also expected to rise as the volume of laboratory testing increases and shortages develop for some clinical laboratory occupations.

Licensure, with its rigidly defined scopes of practice and entrance requirements, conflicts with the rapidly changing environment of clinical laboratory practice. Technological changes, the increasing demand for laboratory services, and rising health care costs dictate against licensing clinical laboratory personnel because employers will need maximum flexibility to meet changing needs. They will need to use personnel in the most efficient manner to keep health care costs down.

Reduced mobility. Personnel licensing programs may limit the supply of professionals in restrictive states. Delays in obtaining licensure and exclusionary licensing practices may cause qualified personnel to practice elsewhere. Employers in the five states that currently license clinical laboratory personnel may have difficulty filling positions, and wages and prices may rise.

One study of clinical laboratory personnel licensing programs observed that "the stringency of licensure was found to have significant positive effects on wages for . . . medical technologists in restrictive states . . . medical technologist wages are about 13 percent higher than in non-restrictive states."[6] Another study found that the average wage of licensed technologists practicing in California in the early 1970s was 16.45 percent higher than the average wage of technologists practicing in less heavily regulated states.[7] These costs are passed on to consumers through higher prices.

Personnel licensing programs inhibit career mobility with their narrow scopes of practice and their requirements for education, training, and examinations. Examinations are especially troublesome for scientists, such as chemists, who do not automatically take national certifying examinations upon graduation. Laboratory personnel may have to obtain additional formal education if they wish to advance. This hampers vertical career mobility and prevents employers from using qualified personnel flexibly. In addition, the lag time for processing licensing applications delays entry into practice.

Licensing clinical laboratories adequately protects the public. Clinical laboratory testing is a process that must be effective in its entirety for accurate and reliable test results. For example, records must be kept properly to avoid mixing up specimens or test results; specimens must be carefully stored and handled to avoid deterioration or loss; and equipment must be properly calibrated to yield accurate results. Errors, mistakes, and accidents at any point in the process will lead to inaccurate results.

Licensing clinical *laboratories* is the best way to protect the public against inaccurate or unreliable test results. It encompasses the entire testing process and avoids the pitfalls associated

with licensing individual laboratory workers. Since both the federal government and the DOH require clinical laboratories to be licensed, there is no need to continue licensing clinical laboratory personnel.

Federal regulation of clinical laboratories. The federal government has regulated clinical laboratories for more than 20 years. There are standards for laboratories participating in Medicare or Medicaid and for interstate laboratories. In 1988, Congress passed major new legislation requiring all U.S. clinical laboratories to be certified (licensed) by the federal government. This program will be phased in between 1989 and 1991.

Medicare and Medicaid standards. Hospital and independent clinical laboratories must already meet federal standards in order to qualify for Medicare or Medicaid payments. These standards include minimum qualifications for technical laboratory personnel.

Congress recently passed legislation requiring high volume physician office laboratories to meet federal standards in order to qualify for Medicare or Medicaid payments. In 1990, physician office laboratories performing more than 5,000 tests a year will be required to meet the same standards as independent laboratories.

Interstate laboratory licensing program. Interstate laboratories that perform tests on specimens from other states are licensed by the federal government. This program is administered by the U.S. Centers for Disease Control, which enforces regulations governing the qualifications of laboratory directors and technical personnel. These regulations are patterned after the Medicare eligibility standards for independent laboratories.

Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). This new law establishes a mandatory certification program for all clinical laboratories in the United States. The program will be administered by the U.S. Health Care Financing Administration, financed by laboratory fees, and staffed by state-level personnel. Standards for certification will be issued by the U.S. Secretary for Health and Human Services.

CLIA '88 requires clinical laboratories to meet federal standards, undergo periodic inspections, and participate in proficiency testing programs. Laboratories that perform simple tests with a very low probability of error may apply for a "certificate of waiver" exempting them from federal standards and inspections. Laboratories in states with laws that are equal to or more stringent than federal certification requirements may seek an exemption from the federal law.

By 1990, all hospital and independent laboratories will have to meet new personnel standards in order to qualify for federal certification. Physician office laboratories will be required to meet new personnel standards by 1991. CLIA '88 specifies that these standards may vary according to the type of tests performed and the risks and consequences of erroneous test results. The standards must also consider competency, training, experience, job performance, and education.

Each certified laboratory will have to maintain appropriate records, equipment, and facilities; establish quality assurance and quality control programs; and use qualified personnel for directing, supervising, and performing tests. CLIA '88 also requires national standards to be set for cytology services, including the evaluation of PAP smears.

Laboratory certificates may be suspended, revoked, or limited, and suits may be brought in federal court to enjoin activities that present a significant hazard to public health. Laboratories that do not meet federal certification standards will face civil penalties of up to $10,000 per violation and they may be required to pay for the costs of on-site monitoring.

The U.S. Secretary for Health and Human Services must assess the nature and extent of diagnostic and treatment problems caused by inaccurate test results and determine the correlation between established personnel standards and the accuracy and reliability of test results. The results are to be reported to Congress by May 1, 1990.

State licensing of clinical laboratories. In addition to licensing clinical laboratory personnel, a separate statute, Section 321-11(12), HRS, authorizes the DOH to regulate laboratories. The department has adopted administrative rules for licensing hospital and independent clinical laboratories. The licensing of clinical laboratory personnel is part of these rules.

It is unnecessary for the department to continue licensing clinical laboratory personnel since the rules for clinical laboratories can be revised to include personnel standards. Furthermore, a state licensing program that duplicates federal regulation may increase health care costs unnecessarily.

The State should eliminate the licensing requirements for laboratory personnel, and the department should revise its laboratory licensing rules along the lines proposed in CLIA '88. This will enable the department to effectively monitor laboratory performance and reduce unnecessary duplication between licensing programs. It will also result in a more efficient use of resources since the U.S. Health Care Financing Administration will most likely contract with DOH to staff the federal certification program in Hawaii.

Arbitrary and Improper Personnel Licensing Program

The licensing program faces serious problems in the inadequacy of the enabling statutes, the department's rules, and the manner in which the department is organized. The statutes provide few of the guidelines needed for a licensing program. The rules are outdated, and many of them are inappropriate. The department's program is administered in an unsystematic manner.

Inadequate statutes. The statutes are too general and vague to be the basis for a licensing program. They do not define key terms such as "laboratory technologist" and others who are to be licensed. They fail to establish the scopes of practice for licensed personnel or the standards for licensure such as requirements for education, experience, and examination. At the same time, the statutes authorize the department to consider subjective traits unrelated to competency--such as health, habits, and character--in making licensure decisions.

The statutes restrict the department's ability to operate an effective and efficient licensing program because they do not provide for temporary licensure and reciprocity with licensing programs in other states, nor do they establish grounds for disciplinary action.

Outdated and improper rules. It is not possible to implement a licensing program under the current rules. The rules were issued in December 1974 and have not been updated to reflect changes in laboratory practice or to remove unworkable provisions. For example, they refer to an accrediting agency that no longer operates (the National Commission on Accrediting) and an advisory committee that was disbanded because it had no statutory basis.

The rules include a number of provisions that are not authorized by law. They say that laboratory assistants and trainees must meet education, training, and/or experience standards in order to practice, and they require laboratory directors to register the names of their assistants and trainees with the department. They use the statutory reference to "laboratory technologist" to license not one but three categories of personnel: technologist, specialist, and cytotechnologist.

The rules contain vague and ambiguous terms that give the department broad discretion in issuing licenses. For example, the department can issue licenses to applicants who graduate from "acceptable" colleges and it can waive examination requirements for applicants with "unusual backgrounds or proven ability." Applicants who have "satisfied" the department that they have "special qualifications" may qualify for a license. There is no information on what any of these phrases mean.

The rules also fail to define key terms for regulating different licensed personnel. For example, they do not define or distinguish between "general supervision," "supervision," and "minimal supervision."

The 1974 rules are part of a larger set of rules that govern state licensure of clinical laboratories. The department has been revising the rules for many years and several *drafts* have been circulated in the laboratory community. Laboratory directors have become confused about which rules are being used. One laboratory director had never even heard of the 1974 rules and was working off a more recent draft issued by the department.

A number of problems appear to impede the development of new rules. The statutes do not provide any guidance on the nature and scope of the licensing program. The few states that license clinical laboratory personnel have vastly different standards. The new federal law to certify clinical laboratories and develop standards for technical personnel creates uncertainty about what additional state requirements will be necessary. The DOH Hospital and Medical Facilities Branch, which was recently asked to revise the rules, does not have much experience drafting rules for occupational licensing programs because its primary mission is to regulate medical facilities.

Unsystematic program administration. The department is not organized to effectively administer a personnel licensing program. It has had difficulty following its own rules and making consistent interpretations of its own licensing standards. It does not always require complete documentation of applicants' qualifications.

Organizational problems. The licensing program is administered by the DOH Laboratories Branch. Many of the inadequacies in licensing reflect organizational problems within this branch.

There is frequent turnover among personnel assigned to the licensing program, and different staff members tend to interpret the same licensing requirements differently. As an example, one applicant was denied a temporary license pending the passing of a national examination, but another applicant was granted a temporary license for the same reason. One clinical laboratory director commented on the situation by saying that the department makes very arbitrary interpretations of the rules.

The placement of the licensing program in the Laboratories Branch creates a conflict-of-interest since many branch personnel are either licensed or subject to licensure if they wish to advance in their careers. The branch is in the untenable position of licensing members of its own staff and acting on their complaints. Staff members who apply for and are denied a license cannot be assured of an objective review of their cases. Staff members who may wish to file complaints against their colleagues cannot be sure that their complaints will be handled impartially.

In addition, the licensed staff members who have administered the program for the past several years have acted on license applications filed by their colleagues and peers without any independent oversight of their activities.

Practices that do not conform with the rules. The rules require supervisors to practice in specialty fields for which they are licensed. However, the department has been issuing

unrestricted general licenses to supervisors. This permits licensed supervisors to oversee technical work for which they have no qualifications. For example, one licensed supervisor whose technical qualifications are limited to nuclear medicine has an unrestricted general license allowing him to supervise other specialty fields.

Arbitrary decisions. The rules require applicants to pass qualifying examinations but the department can waive this requirement on the recommendation of a clinical laboratory advisory committee. This committee has been disbanded but the department has been waiving the examination requirement for some applicants. For example, it does not require individuals applying for a supervisor's license to pass an examination for supervisors. And it has issued director's licenses to nonphysician applicants without requiring them to pass a qualifying examination.

The department routinely informs applicants that the examination requirement can be waived if they are certified by an acceptable national board or licensed in a state with requirements equal to or better than Hawaii's. However, it has not identified states with equivalent requirements and it does not have the authority to recognize licenses issued by other states.

The department's unsystematic approach to licensing is illustrated by a recent case in which a local clinical laboratory challenged the examination policies. In September 1987, one of the laboratory's employees applied for a technologist's license. The employee was licensed to practice in California but he was not nationally certified. The department's initial response was to deny the application because there was no advisory committee to waive the examination requirement--even though the application form says the examination can be waived.

The department subsequently wrote to the laboratory asking for additional information on the applicant's credentials. When the employee filed a new license application, the department notified his laboratory that it could not approve the application because the rules did not provide for reciprocity. This decision also conflicted with the information on the department's application form.

In December 1988, over a year after the initial application and after the laboratory contacted the Director of Health, the department granted a one-year provisional license but instructed the applicant to submit a notarized copy of his qualifying examination results when he next applies for a license. This long-standing case is still open because the license issued by the department does not expire until December 1989.

Inadequate documentation. The department does not always require applicants to document their credentials. This means that applicants could be licensed without actually meeting all the licensing requirements. For example, the department often accepts unofficial and unnotarized copies of credentials. In 1988, it issued a technologist's license to an applicant who presented no evidence of meeting the educational requirements for math and science.

Licensed clinical laboratory personnel who apply for a higher license are not always required to document their educational background. There is no assurance that they have met the educational requirements for a higher license since some individuals did not submit any documentation with their original license applications.

The department does not routinely require employers to verify the work experience listed on license application forms. Individuals may be claiming more work experience than they actually have. One clinical laboratory director was especially concerned about this problem since supervisor's licenses may be issued to individuals with insufficient work experience.

Recommendations

1. *The Legislature should remove the regulation of laboratory personnel from Sections 321-13 to 321-15, HRS.*

2. *The Department of Health should discontinue the clinical laboratory personnel licensing program and revise its clinical laboratory rules to conform with and complement the federal Clinical Laboratory Improvement Amendments of 1988.*

Exhibit
Department of Health
Education and Experience Standards
Clinical Laboratory Personnel

Alternate pathways to a director's license:

(1) Be a Hawaii-licensed physician.

(2) Be a Hawaii-licensed physician who is certified or eligible for certification by the American Board of Pathology or the American Osteopathic Board of Pathology.

(3) Have a doctoral degree in chemical science, physical science, biological science, or public health from a college or university that is recognized by the National Commission on Accrediting or otherwise acceptable to the department,

Be certified in one of the clinical laboratory specialties by the American Board of Microbiology, the American Board of Clinical Chemistry, or a national accrediting board acceptable to the department,

Have two years of pertinent experience in one or more specialties in a laboratory acceptable to the department, and

Satisfy the department of special qualifications in specific areas of testing for which licensure is sought.

(4) Have a master's degree in medical technology, microbiology, chemistry, or biology from a college or university that is recognized by the National Commission on Accrediting or otherwise acceptable to the department,

Have four years of pertinent experience in a laboratory acceptable to the department, and

Satisfy the department of special qualifications in specific areas of testing for which licensure is sought.

(5) Have a bachelor's degree in medical technology, microbiology, chemistry, or biology from a college or university that is recognized by the National Commission on Accrediting or otherwise acceptable to the department,

Have six years of pertinent experience in a laboratory acceptable to the department, and

Satisfy the department of special qualifications in specific areas of testing for which licensure is sought.

Alternate pathways to a supervisor's license:

(1) Have a doctoral degree in chemical science, physical science, biological science, or public health from a college or university that is recognized by the National Commission on Accrediting or otherwise acceptable to the department, and

Have one year of pertinent experience in one or more specialty in a laboratory acceptable to the department.

(2) Have a master's degree in medical technology, microbiology, chemistry, or biology from a college or university that is recognized by the National Commission on Accrediting or otherwise acceptable to the department, and

Have two years of pertinent experience in one or more specialty in a laboratory acceptable to the department.

(3) Have a bachelor's degree in medical technology, microbiology, chemistry, or biology from a college or university that is recognized by the National Commission on Accrediting or otherwise acceptable to the department, and

Have three years of pertinent experience in one or more specialty in a laboratory acceptable to the department.

All applicants must also satisfy the department of special qualifications in specific areas of testing for which licensure is sought.

Alternate pathways to a specialist's or a technologist's license:

(1) Have a bachelor's degree in medical technology from a college or university that is recognized by the National Commission on Accrediting or otherwise acceptable to the department, and

Complete one year as a medical technologist trainee in a program approved by the American Medical Association's Council on Medical Education.

(2) Complete three academic years of study (90 semester hours) in a program that meets the requirements for entry into an school of medical technology approved by the Council on Medical Education of the American Medical Association, and

Successfully complete a training course in a school of medical technology approved by the Council on Medical Education of the American Medical Association.

(3) Have a bachelor's degree in one of the chemical, physical, or biological sciences from a college or university that is recognized by the National Commission on Accrediting or otherwise acceptable to the department,

Complete one year of pertinent laboratory experience and/or training covering the specialty or specialties in which tests are to be performed, and

Satisfy the department of special qualifications in specific areas of testing for which licensure is sought.

(4) Complete three years (90 semester hours) of study in one of the chemical, physical, or biological sciences in a college or university that is recognized by the National Commission on Accrediting or otherwise acceptable to the department,

Complete one year of pertinent laboratory experience and/or training covering several fields of medical laboratory work that, in conjunction with college work, is equivalent to a medical technology course in a school approved by the Council on Medical Education of the American Medical Association, and

Satisfy the department of special qualifications in specific areas of testing for which licensure is sought.

Coursework completed by applicants after September 15, 1963 must include the following:

16 semester hours of chemistry (with six hours in inorganic chemistry acceptable toward a chemistry major),

16 semester hours in biology (pertinent to medical sciences and acceptable toward a major in the biological sciences), and

Three semester hours of college-level mathematics.

Alternate pathways to a cytotechnologist's license:

(1) Complete two years in an accredited college or university with at least 12 semester hours in biology courses pertinent to the medical sciences, and

Complete 12 months in a cytotechnology school approved by the Council on Medical Education of the American Medical Association.

(2) Complete two years in an accredited college or university with at least 12 semester hours in biology courses pertinent to the medical sciences,

Complete six months of formal training in a cytotechnology school approved by the Council on Medical Education of the American Medical Association, and

Complete six months of full-time experience in cytotechnology in a laboratory acceptable to the physician who directed the formal training.

(3) Applicants who were trained before January 1, 1969 must meet the following qualifications:

Be a high school graduate,

Complete six months of cytotechnology training in a laboratory directed by a pathologist or other physician recognized as a specialist in cytology, and

Complete two years of full-time experience in cytotechnology.

Alternate pathways to a technician's license:

(1) Have an associate degree from a college or university that is recognized by the National Commission on Accrediting or otherwise acceptable to the department.

(2) Complete 60 semester hours in a college or university that is recognized by the National Commission on Accrediting or otherwise acceptable to the department--including 12 semester hours in chemistry, bacteriology, or parasitology and three semester hours in college-level mathematics, and

Complete six months full-time training or experience as a technician in an acceptable laboratory, including three months within two years of the application date.

(3) Graduate from high school,

Complete one of the following:

A one year medical technician's training course approved by the Council of Medical Education and Hospitals of the American Medical Association,

A one year medical technician training course approved by the Accrediting Bureau of Medical Laboratory Schools or the International Society of Clinical Laboratory Technologist Accrediting Commission, or

A 50-week official military laboratory training course, and

Complete one year of pertinent full-time experience as a technician or trainee in an acceptable laboratory--including six months within two years of the application date.

(4) Graduate from high school,

Complete a training course as a clinical laboratory assistant,

Complete three years of progressive full-time experience as a clinical laboratory assistant in an acceptable laboratory--including one year just prior to the application date, and

Obtain a recommendation from the laboratory's director.

After January 1, 1978, applicants who qualify under the last two items (3 and 4) must pass an equivalency examination to meet the formal education requirements.

Requirements for registration as an assistant:

Graduate from high school and complete one year of pertinent full-time experience in an acceptable laboratory.

Requirements for registration as a trainee:

Be enrolled in one of the following:

A recognized training program for medical technology, clinical laboratory specialist, or cytotechnologist,

A recognized medical technician training course, or

A recognized medical laboratory assistant training course.

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NOTES

Chapter 1

1. See discussion in *51 American Jurisprudence*, 2d., "Licenses and Permits," Sec. 14.

2. *Terr. v. Fritz Kraft*, 33 Haw. 397.

Chapter 2

1. Hawaii, Department of Health, "1989 Licensed Clinical Laboratory Personnel," Honolulu, undated.

2. Institute of Medicine, *Allied Health Services, Avoiding Crises*, Washington, D.C., National Academy Press, 1989, p. 98.

3. U.S. Congress, House Subcommittee on Regulation and Business Opportunities, *Deadly Mistakes: Are Laboratory Results Reliable?*, 100th Cong., 2nd sess., March 2 and May 3, 1988, p. 66.

4. U.S., Office of Inspector General, Department of Health and Human Services, *Quality Assurance in Physician Office Laboratories*, June 1988 (draft report), p. i.

5. "February 1989 Examinations," *Laboratory Medicine*, vol. 19, no. 8, August 1988, p. 482.

6. "NCA-Ten Years of Professional Peer Review," *Clinical Laboratory Science*, vol. 1, no. 1, Jan/Feb 1988, p. 16.

7. Letter to the Office of the Auditor from Chester B. Dziekonski, Executive Director, American Medical Technologists, February 16, 1989.

8. American Society for Medical Technology, *State Licensure, A Planning Manual for ASMT Constituent Societies*, Washington, D.C., 1989.

9. "American Medical Technologists' (AMT) Position on Licensure for Medical Laboratory Personnel," undated.

Chapter 3

1. Walt Bogdanich, "The Pap Test Misses Much Cervical Cancer Through Labs' Errors," *The Wall Street Journal*, November 2, 1987; "In Oklahoma, A Different Lab To Screen Pap Tests Means Very Different Results," *The Wall Street Journal*, November 2, 1987; "Inaccuracy In Testing Cholesterol Hampers War on Heart Disease," *The Wall Street Journal*, February 3, 1987; "Medical Labs, Trusted as Largely Error-Free, Are Far From Infallible," *The Wall Street Journal*, February 2, 1987.

2. Institute of Medicine, *Allied Health Services, Avoiding Crises*, p. 105.

3. William D. White, *Public Health and Private Gain: The Economics of Licensing Clinical Laboratory Personnel*, Chicago, Illinois, Maaroufa Press, 1979, p. 82.

4. Institute of Medicine, *Allied Health Services, Avoiding Crises*, pp. 293-294.

5. Miriam Bloch, George Cembrowski, and George Lembesis, "Longitudinal Study of Error Prevalence in Pennsylvania Physicians' Office Laboratories," *JAMA*, vol. 260, no. 2, July 8, 1988, p. 234.

6. Gary Gaumer, "Regulating Health Professionals: A Review of the Empirical Literature," *Milbank Memorial Fund Quarterly/Health and Society*, vol. 62, no. 3, 1984, p. 387.

7. William D. White, *Public Health and Private Gain: The Economics of Licensing Clinical Laboratory Personnel*, p. 116.

APPENDIXES

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APPENDIX A

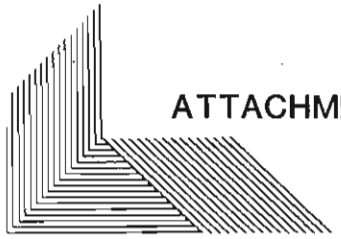
COMMENTS ON AGENCY RESPONSE

We transmitted a preliminary draft of this report to the Department of Health on October 12, 1989. A copy of the transmittal letter to the department is included as Attachment 1 of this Appendix. The response from the department is included as Attachment 2.

The Department of Health disagrees with the recommendation to discontinue licensing clinical laboratory personnel. It says that regulation is needed to prevent unqualified persons from practicing. Our report points out--and we continue to maintain--that licensing individual laboratory personnel is ineffective and unenforceable and that the public can best be protected by federal and state licensing of clinical *laboratories*.

The department acknowledges the limitations in the current regulatory program and plans to remedy the situation by adopting new rules and studying the introduction of a bill to establish a licensing board. We do not believe that these approaches are sufficient since (1) the statutory basis for the licensing program is inadequate, (2) the new draft rules continue to be vague and ambiguous in setting licensing standards, and (3) a licensing board would not alleviate many of the operational problems which affect the department's administration of the program.

THE OFFICE OF THE AUDITOR
STATE OF HAWAII
465 S. KING STREET, RM. 500
HONOLULU, HAWAII 96813



ATTACHMENT 1

C O P Y

October 12, 1989

The Honorable John C. Lewin, M.D.
Director of Health
Department of Health
1250 Punchbowl Street
Honolulu, Hawaii 96813

Dear Dr. Lewin:

Enclosed are three preliminary copies, numbered 4 through 6 of our *Sunset Evaluation Report, Regulation of Clinical Laboratory Personnel.*

The report contains our recommendations relating to the regulation of the three occupations. If you have any comments on our recommendations, we would appreciate receiving them by November 13, 1989. Any comments we receive will be included as part of the final report which will be submitted to the Legislature.

Since the report is not in final form and changes may possibly be made to it, we request that you limit access to the report to those officials whom you wish to call upon for assistance in your response. Please do not reproduce the report. Should you require additional copies, please contact our office. Public release of the report will be made solely by our office and only after the report is published in its final form.

We appreciate the assistance and cooperation extended to us.

Sincerely,

Newton Sue
Acting Auditor

Enclosures

ATTACHMENT 2

JOHN WAIHEE
GOVERNOR OF HAWAII

JOHN C. LEWIN, M.D.
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
P. O. BOX 3378
HONOLULU, HAWAII 96801

In reply, please refer to:
File:

November 17, 1989

Mr. Newton Sue
Acting Auditor
The Office of the Auditor
465 S. King Street, Rm. 500
Honolulu, HI 96813

Dear Mr. Sue:

Thank you for the opportunity to comment on your office's draft report relating to the licensing of clinical laboratory personnel. We have two major comments to make with respect to this report.

First, the department acknowledges the limitations in the current program outlined in the report. Because of our laboratory's current responsibilities cross a diversity of fields, inadequate attention has been given to the licensure of clinical laboratory personnel. We are remedying this deficiency by completely reworking Chapter 104, "Licensing of Clinical Laboratory Personnel" and by studying the introduction of a bill to provide our laboratory with the support of a licensing board. Such a board, composed of clinical laboratory specialists, would enable the department to more completely carry out its licensing responsibilities.

Second, we disagree with the draft report findings that there is no need to license clinical laboratory personnel. We believe that the regulation and licensing of clinical laboratory personnel by the state is indeed very necessary to protect public health and safety. Non-regulation would allow unqualified persons to practice and that would pose a direct threat to the quality of clinical laboratory determinations which are used as a basis for providing treatment. This could very well result in serious injury to, or even death of members of the consuming public, particularly if such things as blood gas, chemistry, or blood transfusions are involved.

The report states on page 9 that it is preferable to license laboratories rather than personnel because "licensing laboratory personnel is ineffective." We feel that it is not only preferable but necessary to license both if the quality of care is to be assured.

The report suggests that the facility (for employer) will be responsible for determining the qualifications and confidence of laboratory personnel. In a majority of settings in Hawaii, these decisions are being made by lay persons based on certification or licensure by professional bodies in the State; such certification or licensure implies that "standards" have been met. Both laboratories and the public expect the application of state standards through licensure to assure a basic level of professional skill. With no such verification, competency could be expected to vary from lab to lab.

No one really knows or can appreciate the enormity of CLIA '88's impact. While it is true that the accreditation and regulatory agencies are adopting more outcome-oriented measures, they also require that the facility (clinical laboratory) have a sufficient number of qualified personnel to accurately perform the tests. It is the state's responsibility to determine what are "qualified personnel."

Licensing of laboratory personnel is the only way of assuring that the people performing the tests are qualified to do so, as the licensing body not only assess the credential and qualifications of the licensee, but its processes assure continued competence in the licensee's category or specialty. Certification by the ASCP Board of Registry, National Certification Agency, and other credentialing agencies is not sufficient by itself and these agencies do not purport to be comprehensive in the regulation of laboratory personnel. They only reflect a basic level of training received, not current competency.

It should be pointed out that the Department of Health's obsolete Clinical Laboratory Administrative Rules were totally revised this year. They reflect current standards and practices and are organized so that considerations for certification and licensure of laboratory personnel are a separate subchapter. These are currently in the process of adoption. A copy is attached for your information.

We appreciate the opportunity to provide input on this report and hope that the report will, in the light of this new information, be revised to eliminate the recommendation to sunset licensure of clinical laboratory personnel.

Very truly yours,

JOHN C. LEWIN, M.D.
Director of Health

Attachment

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APPENDIX B

G0184

DIGEST: RELATING TO LABORATORIES

Repeals regulation of clinical laboratory personnel as recommended by the legislative auditor's sunset report.

HOUSE OF REPRESENTATIVES
FIFTEENTH LEGISLATURE, 1990
STATE OF HAWAII

H.B. NO.

A BILL FOR AN ACT

RELATING TO LABORATORIES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. The purpose of this Act is to implement the findings and recommendations of the legislative auditor in the auditor's "Sunset Evaluation Report Regulation of Clinical Laboratory Personnel" reviewing state laws which authorize the licensing of laboratory directors, laboratory technologists, laboratory supervisors, and laboratory technicians by the department of health. The legislature agrees with the auditor's findings that licensing of clinical personnel should be repealed, because these concerns can be handled more efficiently and just as effectively under the department's existing authority to license the clinical laboratories themselves.

SECTION 2. Section 26H-4, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(a) The following chapter and sections are hereby repealed effective December 31, 1990:

(1) Chapter 466J (Board of Radiologic Technology)

(2) Sections 321-13 to 321-15 (midwives, [laboratory directors, laboratory technologists, laboratory supervisors, laboratory technicians,] tattoo artists,

electrologists, and sanitarians)"

SECTION 3. Section 321-13, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(a) The department of health, with the approval of the governor, may prescribe such rules as it deems necessary for the public health or safety respecting:

(1) The occupations or practices of midwives, [laboratory directors, laboratory technologists, laboratory supervisors, laboratory technicians,] tattoo artists, electrologists, sanitarians, asbestos inspectors, asbestos management planners, and asbestos abatement project designers;

(2) The health, education, training, experience, habits, qualifications, or character of persons to whom certificates of registration or permits for [such] those occupations or practices may be issued;

(3) The health, habits, character, practices, standards, or conduct of persons holding [such] those certificates or permits; or

(4) The grounds or causes for revoking or suspending [such] those certificates or permits.

[Such] The rules shall have the force and effect of law."

SECTION 4. Statutory material to be repealed is bracketed. New statutory material is underscored.

SECTION 5. This Act shall take effect upon its approval.

INTRODUCED BY: _____