PROGRAM REVIEW

MICROBIOLOGY LABORATORY DIVISION

MONTANA STATE DEPARTMENT OF HEALTH

MARCH 1970

REVIEW TEAM:

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PROGRAM REVIEW OUTLINE

I. INTRODUCTION

Purpose and Scope of Study

In a letter dated January 8, 1970, Dr. John S. Anderson, Executive Officer, Montana State Department of Health, requested a program review of the Microbiology Laboratory Division, with emphasis to be placed on exploration of the need for a Laboratory Improvement Program in the State of Montana.

The on-site portion of the requested review was conducted during the period March 16-20, 1970. In the initial stages of this review, the study team met with Dr. Anderson, Dr. David Lackman, Director of the Microbiology Laboratory Division, and Mr. Ralph Barnes, NCDC Representative, of the Denver DHEW Regional Office, to discuss the scope of the proposed review.

It was agreed that many aspects of the need for laboratory improvement at the State level have been well established and need not be redocumented in this study. Rather, this study will reiterate those points which have been well established, discuss them briefly, and then relate them to needs in the State of Montana.

It was also agreed that the report of the study team must be communicative to a relatively broad audience, not all of whom are familiar with the operations of a State Public Health Laboratory. For this reason, some background data concerning broad aspects of laboratory practice are included.

Study Design

After the receipt of the aforementioned letter from Dr. Anderson and prior to the on-site portion of this review, a number of telephone discussions and exchanges of correspondence were entered into with Dr. Lackman in order to establish frames of reference and to accumulate as much germane data as possible for analysis prior to conducting the on-site portion of the review. An exceptional quantity of germane data - approximately one cubic foot - was provided to the study team during the overall course of the review. A bibliography of significant documents is included as Attachment No. 1, page 22. A great deal of relatively unstructured data such as newsletters, correspondence files, procedure manuals, newspaper clippings, planning documents, draft legislation, and budget reports were also provided. These items proved extremely helpful to the study team.

During the week of March 16, 1970, the study team conducted a number of interviews with users of existing laboratory services concerning the quality and availability of these services. In addition, potential users of new services were interviewed in terms of the type and quantity of services they feel are needed now and in the near future. Contact was also made with representatives of planning groups and with representatives of other public health programs which have an interest in laboratory improvement in the State of Montana.

Attachment No. 2, page 24, contains a listing of all contacts made during this survey and is arranged by date of first contact, name, organization, and location. Depending upon the nature and content of subsequent informational inputs, some interviewees were contacted several times during the week of the survey.

II. THE PUBLIC HEALTH LABORATORY FUNCTION

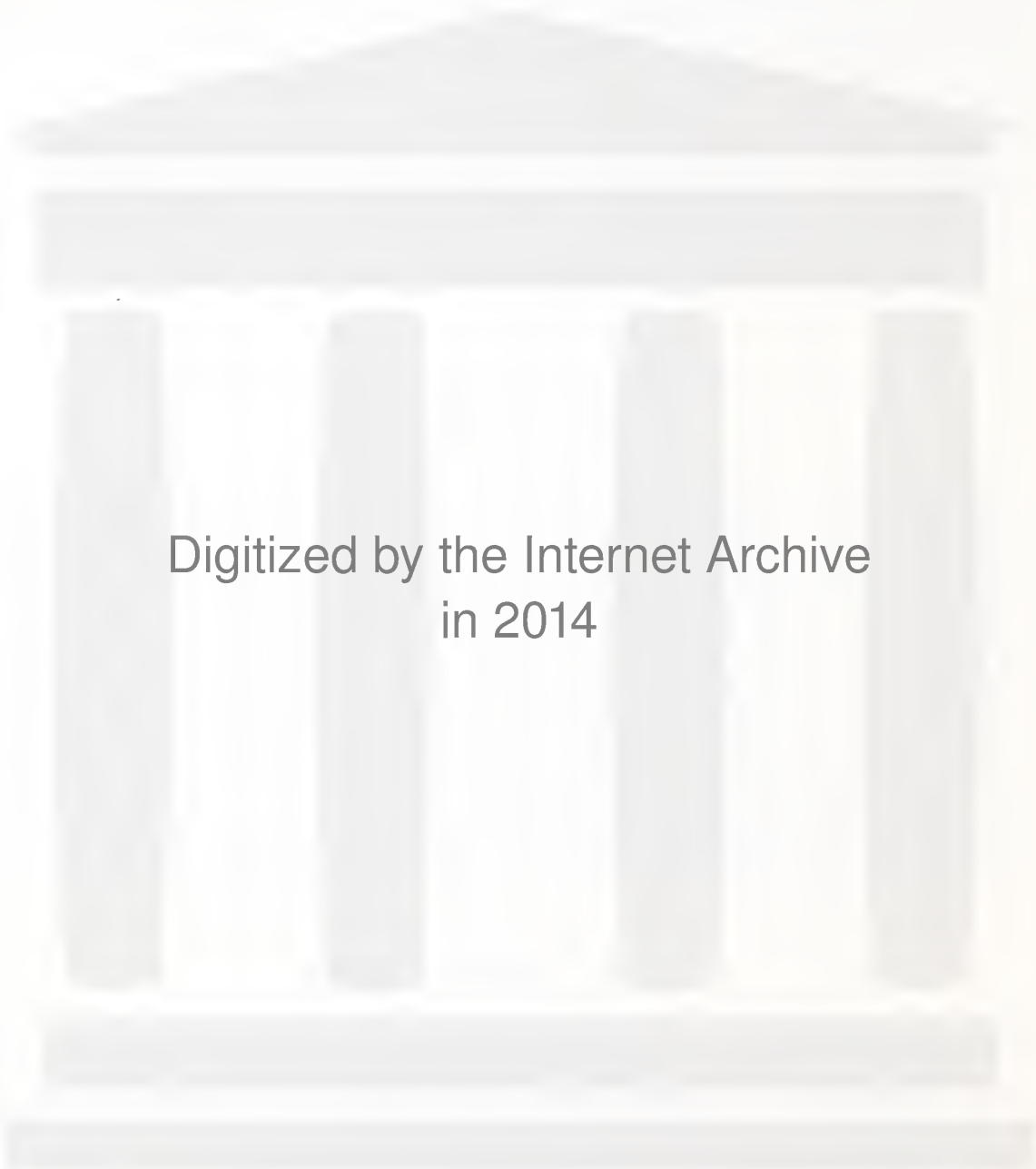
Historical Background

Public health laboratories (hereafter referred to as PHL's) had their genesis in the latter part of the nineteenth century and rapidly became a basic instrument for the control of infectious diseases, for epidemiologic studies of such diseases and for environmental sanitation. Over time, however, an increasing number of public health programs have availed themselves of the services of the laboratory so that now the services of the PHL cut across almost all health program lines. In practically all States the laboratory has achieved division status in the Health Department organizational structure. In addition, the historical supportive service role of the laboratory is being complemented with various program roles. In large measure this report deals with an active program role for the Montana PHL concerning Statewide laboratory improvement efforts.

Organizational Patterns

Generally speaking, there is no single organizational pattern for PHL's, yet a number of features they hold in common can be discussed. All States have a central PHL; practically all of these centralized laboratories are under the organizational aegis of the State health department; and more than half of the State health departments maintain branch laboratories in various parts of their State.

Within a given State or local health department, three organizational arrangements have been identified. These arrangements are listed in descending order of preference. First, there can be a designation of a single central division, or bureau, of laboratory services which



provides all laboratory services to all operating programs of the health department. Secondly, there can be a designation of a central laboratory with some of the operating programs maintaining their own laboratory services. The third possibility, which is the least desirable and the least common, is for each operating program to maintain their own specialty laboratories. The study team knows of no State PHL (hereafter SPHL) in which this latter organizational arrangement is used.

Staffing Patterns

In order to provide a complete range of public health laboratory services, a considerable variety of scientific knowledge and skills must be represented among the personnel of the laboratory. Various levels of laboratory workers are employed, ranging from trainees to technologists, with some specialists trained at the graduate and postgraduate level.

Depending upon the scientific field involved, services are divided into various branches or specialties. A given laboratory worker, especially at the technologist level and above, will have training and experience qualifying them as highly skilled in one or more of the following specialties:

Microbiology	Chemistry and Physics
Bacteriology	Clinical Chemistry
Virology	Sanitary Chemistry
Parasitology	Toxicology
Mycology	Radiochemistry
Serology	Radiophysics
Immunology	

Pathology	Entomology	Animal Care
Cytology		

Each of the aforementioned broad fields can be extensively divided into further subgroupings. For example, in the bacteriology specialty area alone there are six subspecialty groupings. Within these six subspecialty areas there are approximately 5,000 separately identifiable organisms. The identification of all these organisms would require operational familiarity with approximately 32 separate tests or procedures.

Personnel working in the above mentioned specialty areas receive technical and administrative supervision from a Director and Deputy Director of the Laboratory. Professional and technical personnel receive assistance from a number of individuals in administrative, clerical, maintenance, or other supportive service positions.

The total number of positions in a given SPHL varies remarkably. The largest SPHL had, during fiscal year 1968, 642 budgeted positions, while the smallest SPHL had 7 budgeted positions. The median number of positions is 70, while the average number of positions is 99.

Services and Programs

The typical SPHL receives many thousands of specimens annually for laboratory examinations. Specimens received are primarily from the human body (urine, blood, cellular smears, and other specimens) and from the environment. Environmental specimens are taken from various water sources, air samples, milk and dairy products, foods, drugs, liquors, narcotics, toxicological substances, sewage, shellfish, and industrial wastes. Many of these specimens are also examined to determine the levels and sources of ionizing radiation.

Functionally speaking, these examinations are conducted to aid in the diagnosis, prevention, control, and treatment of communicable diseases, chronic diseases, metabolic disorders, and any impairments, or threatened impairments, in the health of man for which the results of a laboratory examination would prove helpful in a diagnostic or remedial way.

From a service point of view, the foregoing specimens and examinations are generated primarily by private physicians, various divisions of the State health department, and from various hospital and private laboratories who submit reference specimens for confirmation of their own test results.

From a program point of view, a SPHL conducts a number of activities on its own initiative. These activities include proficiency testing programs*; training and consultation programs in a wide variety of laboratory specialties; and various screening efforts to identify the existence of disease or metabolic disorder. Research is conducted in a number of areas, with special emphasis on new and improved methods of diagnosis, prevention, and control of disease and on the applied aspects of laboratory methodology.

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*Generally speaking, proficiency testing programs consist of distributing various types of unknown specimens, at various time intervals, to participating laboratories. The receiving laboratory is requested to process the specimen for purposes of identifying organisms present, or to determine the type and level of chemical constituents present. The findings are then reported to the distributing laboratory for a comparison with the findings of reference and referee laboratories. Through analyses of reported findings, the laboratory conducting the program can identify deficient performance as well as trends toward deficient performance. These analyses of course guide the development of programs of training and consultation which are tailored to correct deficiencies identified.

Montana State Public Health Laboratory

Most of the aforementioned services and programs are offered by the Montana SPHL, or are otherwise available within the Department of Health. From a quantification point of view, Attachment No. 3, page 26, enumerates thirty program topics relating to Montana and compares Montana with five other nearby States for these same topics. It is emphasized, however, that these items should be considered as relative indicators only.

The Montana SPHL has excellent plant facilities and equipment with adequate room for needed program expansion. Services offered include diagnostic bacteriology, parasitology, virology, serology, mycology, sanitary bacteriology, sanitary chemistry, air pollution, and forensic toxicology. Attachment No. 4, page 27, indicates the specialty areas in which tests are offered, the number of specimens received, and the number of examinations conducted during Fiscal Years 1967, 1968, and 1969.

Organizationally, the Montana SPHL is classified as one of the major divisions of the State Department of Health, with the Director of the Laboratory reporting directly to the Executive Officer. The existing organizational placement of the SPHL and its vertical and lateral lines of communication are considered ideal. In subsequent sections of this report, recommendations will be made for various expansions in the SPHL Program. It is felt that the existing excellent communications and ideal organizational placement of the SPHL will be most helpful for purposes of implementing a Statewide laboratory improvement program. A current organization chart for the Montana State Department of Health is shown in Attachment No. 5, page 28.

Internally, the Microbiology Laboratory Division is organized into four Sections. These are the Microbiology Section, Laboratory Improvement Section, Services Section, and Office Section. This organizational structure appears to meet the present needs of this Division. It is not anticipated that incorporation of a Statewide laboratory improvement program will necessitate organizational realignments in the Montana SPHL at this time. The current internal organizational structure of the Montana SPHL is shown in Attachment No. 6, page 29.

The present leadership and direction of the Montana Microbiology Laboratory Division can only be termed as outstanding. This factor in addition to the other favorable characteristics mentioned above strongly indicate that this SPHL should optimize its potential in every way possible to the benefit of the citizenry of the State of Montana.

Insofar as internal administration is concerned, the study team reviewed generally the Division's planning and budgeting systems, office procedures, records maintenance, supply systems, personnel administration, reporting requirements, and preventive maintenance procedures.

For the most part, all administrative systems were functioning effectively. Program expansions recommended in the subsequent section can be adequately incorporated within existing administrative systems at little or no additional cost. As reflected in Section V, following, there will be a moderate increase in program costs.

Recommendations of the study team concerning relatively minor modifications of the aforementioned administrative systems are included in the letter transmitting this report to the Executive Officer of the Montana State Health Department, since such recommendations do not come within the scope of this report.

III. LABORATORY RRACTICE IN THE UNITED STATES

The Need for Laboratory Services

Thus far this report has been almost entirely concerned with describing missions, organization structure, and services of public health laboratories and of the Montana SPHL in particular. This may have given the reader an impression that laboratory work is almost exclusively the responsibility of SPHL's whereas these laboratories do only a small portion of the total examinations performed on specimens from the human body. Before identifying providers of laboratory services and discussing their workload volumes, a brief discussion of why laboratory services are needed is in order.

Most medical laboratory examinations are done to aid physicians in identifying the cause or causes of ill health of patients and changes in the health status of patients who are under treatment, including those who are hospitalized. Increasingly, laboratory examinations are used in screening programs aimed at early detection of infections and other health hazards to the population including those individuals believed to be well. Objectives of such preventive screening programs are improved health and increased longevity at lowered total costs for health care services.

Physicians tend to place increasing reliance on laboratory examinations as an aid to diagnosis and to determination of changes in health status. Additional and more reliable examinations are constantly being made available for such purposes. These reasons in combination with the rapid rates of increase in population and programs bringing health care services to a wider segment of the population have resulted in a rapid rate of growth in laboratory examinations in the United States. Under the next two headings of this report, we will show that several categories of laboratories are engaged in providing needed services and that the public health category, including State laboratories, provides only a

very small portion of total medical laboratory services. However, it should be a matter of primary concern that the State Department of Health, through the SPHL, have a continuing responsibility for the quality of laboratory services provided throughout a State.

Providers of Laboratory Services

Laboratory services are provided by a variety of laboratories that can be placed in five groupings or categories. State, local, and federal public health laboratories form the public health category. A second category is hospital laboratories including those operated by various agencies of government and private individuals and groups of individuals. The third category is independent clinical laboratories, which are laboratories that accept specimens from all authorized sources, perform examinations on these specimens and report back the results for a fee. The fourth category consists of laboratories operated by one or more physicians to examine specimens from their own patients. A fifth category is industrial laboratories which are laboratories operated by business firms to perform examinations on specimens from their employees.

Generally, laboratories have not been required to secure a license, register, or take any other mandatory action that indicates their existence. Therefore, comprehensive and accurate statistical data are not available concerning the number and location of independent clinical laboratories, laboratories in private physician's offices, and industrial laboratories.

Statistical data and other information indicating the name and location of public health laboratories and the examination workload they handle are generally available. Most of these laboratories prepare annual reports. The name and location of most hospital laboratories are available from at least two sources: (1) the Annual Guide Issue published by the American Hospital Association and records kept by the State health department or other agency in each State responsible for licensing or at least registering hospitals. We are not aware of any publication that contains statistical data on the number and types of examinations performed by hospital laboratories as a group. However, there are published reports of studies involving a large sampling of hospital laboratories. Projections of laboratory workload volume can be made from these studies.

About 2,600 independent clinical laboratories provide services to patients under Medicare and receive reimbursement for these services. Data which have been collected since 1964 indicate that the number of independent clinical laboratories decreased from about 6,500 at the end of 1964 to 4,600 by mid-1968. The principal reason for this decrease

is apparently through consolidation of existing laboratories as a result of purchases by individuals and organizations forming chains of private independent clinical laboratories.

Little is known about laboratories operated by physicians to aid in diagnosing the ills of their own patients. Estimates of the numbers of these laboratories vary from 13,000 to 40,000.

Sources of Laboratory Services, Volume, and Cost

In the absence of more exact data, annual examination workload volume for all laboratories in the United States for Calendar Year 1969 is estimated as follows:

Category of Laboratory	Annual Workload Volume	% of Total
State Public Health	35,000,000	2.4
Local Public Health	13,000,000	.9
Hospital	800,000,000	55.2
Independent Clinical	250,000,000	17.3
Private Physician Operated	350,000,000	24.2
Total	1,448,000,000	100

Since comprehensive and reliable data on laboratory workload volume has not been available in the past and is not now available, projections of increases are strictly estimates. These estimates of increase run at the rate of 10 to 15 percent annually. Most of the increase is projected to occur in the clinical chemistry field.

Although data have been accumulated concerning the cost of laboratory examinations, it is insufficient for use in making meaningful cost computations that apply to totals for various specific tests performed or for a particular discipline such as clinical chemistry, mycology, or virology. However, sufficient cost data have been collected to warrant using an average cost of $5 per examination as a good "ball park" estimate. On the basis of $5 per examination, the total cost of laboratory examinations in 1969 was approximately 7.2 billion dollars.

Increasing automation of laboratory testing, particularly of clinical chemistry examinations which represent the fastest growing area, should tend to lower the average cost per examination. However, the effects of inflation tend to counter this trend somewhat with increased salary, equipment, and supply costs. After considering all known factors, it is concluded that the annual total cost of laboratory examinations will continue to rise, but at a rate somewhat lower than the rate of increase in number of examinations.

Problems in the Provisions of Laboratory Services

Adequate laboratory services are not always available for medical diagnostic or public health purposes. In some instances the desired services are simply not available. In other instances the services are available but test results provided are not sufficiently reliable. While various studies have shown that desired quality standards are frequently not met and have revealed a number of causes of erroneous testing, they have done little to pinpoint the extent to which each of these causes is a contributor to deficient laboratory performance. These causes will be named and discussed briefly in Section IV of this report.

Laboratory Practice in Montana

Definitive data are not available concerning the full scope of laboratory practice in the State of Montana as this practice relates to services provided by hospital laboratories, independent clinical laboratories, and the laboratory facilities located in private physician's offices.

The study team sought to secure such data as was available concerning these areas of laboratory practice. In Attachment No. 7, page 30, the ratios of population/physicians/hospitals/laboratories/and geographic space are shown for each county and for each Comprehensive Health Planning District. In Attachment No. 8, page 32, most of the same data are entered on a stylized map for ready reference.

The data in these attachments was compared in a number of ways, but no statistically valid conclusions could be drawn because (1) the range of services provided in each laboratory was unknown, (2) workload data by specialty testing area was unavailable, (3) the geographic area served by each laboratory varies considerably, (4) the number of laboratorians employed in each laboratory was not known for all laboratories, and (5) data are incomplete concerning the educational and experience backgrounds for Montana laboratorians.

The study team wishes to make a point of enumerating the foregoing lack of data for the simple reason that the quality of laboratory practice is a matter of concern from a public health point of view. This vitally needed data can be acquired through the mechanism discussed in Section V of this report.

While no specific conclusions are offered from analysis of the data in Attachments Nos. 7 and 8, the study team does offer that there are several significant reasons for non-availability of adequate laboratory services at the time and place they are needed.

Many areas with small populations do not have laboratories located in the area - but as will be indicated elsewhere in this report, this may be a positive factor where logistics permit access to a laboratory providing services known to be reliable. It appears that Montana has an unusually large number of relatively small hospitals providing a limited range of hospital services. The basis for this premise is found in Attachment No. 9, page 33, which reflects the ratio of clinical and hospital laboratories to population served. Particular reference is made to Column F of this attachment which indicates that Montana has 9.7 hospital laboratories per 100,000 population which is more than twice the median figure of 4.0 and the highest of any State shown in the tabulation, except for Wyoming. Generally similar analogies can be derived from Columns E and G, except that data in these columns are somewhat qualified in that the data in Column A, for Montana, includes some laboratories located in private physician's offices and therefore does not provide a sufficiently accurate basis for comparison.

Since many of these relatively small hospitals of necessity provide a limited range of hospital services, it follows that their laboratories also provide a limited range of services with a corresponding limited volume of testing. It is well known that low volume is oftentimes a correlate of deficient laboratory performance. Lastly, and somewhat subjectively, it appears that there are not sufficient numbers of adequately trained laboratorians employed in some of the geographic areas which do in fact offer laboratory services.

IV. THE NATIONWIDE NEED FOR LABORATORY IMPROVEMENT

Problems Identified

Deficiencies in medical laboratory services have been verified and brought to public attention at various times over a period of years. Perhaps the one person who has wielded the greatest influence in this area is Dr. Morris Schaffer, Director of the City of New York Public Health Laboratory. Some of his findings were given national exposure by a television network. The Laboratory Division of the Center for Disease Control (formerly the National Communicable Disease Center) has a basic mission of improving laboratory practice on a national scale. In June 1967, the Communicable Disease Center published "A Report on Laboratory Performance and Methods for Improvement." This document contained a listing of problem areas and proposed a program for improvement to be carried on as a joint effort by the CDC, State public health laboratories, and professional associations.

Major problems contributing to substandard laboratory performance listed and discussed in the document are:

Lack of Information on Laboratory Operations
Shortage of Educated, Trained, and Experienced Personnel
Obsolescence of Laboratory Personnel (failure to keep current in training)

Need to Educate Clinicians to Evaluate Laboratories Critically and Use Them Properly
Use of Poorly Controlled Technical Methods
Lack of Standardized Procedures
Lack of Standardized Reagents
Absence of Established Standards of Performance
Insufficient Performance Evaluation
Lack of Regulation of Laboratories
Failure of Laboratories to Recognize Limitations
Inadequate Facilities
Overtly Dishonest Laboratory Operation
Lack of Funds for Laboratory Improvement

A number of individuals took exception to portions of the report, particularly those sections of the report which gave statistical data concerning the extent of deficient laboratory performance. However, studies made subsequent to publication of the report indicate that noted deficiencies were in fact generally understated rather than overstated.

Solutions to each of the major problems were proposed in the document. Although these solutions call for the CDC, professional associations, and educational institutions to carry out important responsibilities, the report correctly noted that the key organization in the improvement program is the State public health laboratory.

Statewide Laboratory Improvement Programs

Practically all States conduct laboratory improvement programs of one type or another. There is a considerable variation in the type of program conducted depending on whether participation is voluntary or mandatory. An additional variation arises in the mandatory programs, depending on whether laboratories only are licensed (or registered or certified) or whether both laboratories and the personnel employed in them are licensed. The third source of variation depends upon the scope and depth of the State program used to identify deficient performance and the comprehensiveness and effectiveness of remedial services offered such as training and consultation.

While data describing the laboratory improvement programs in each State are not available, Attachment No.10, page 34, shows the status of legislation which authorizes such programs, the types of laboratories covered, and the educational and experience requirements for laboratory personnel.

Components of Laboratory Improvement Programs

The following elements are common to most Statewide programs although terminology may differ from one program to another.

- Legislative authority to regulate the quality of laboratory performance.
- Provision of adequate funding support.
- Collection of baseline data.
- Operation of proficiency testing programs to distribute "unknown" specimens to participating laboratories to assess their ability to test for the presence and identity of organisms or the presence and level of certain chemical elements.
- Provision of training and consultative services which are responsive to the problems identified in the proficiency testing program.
- Provision of reference diagnostic services to assist requesting laboratories to confirm their own test results.
- Provision of recommendations concerning standardized procedures.

States having adequate laboratory and personnel licensing authority, have appropriate means to require participation in proficiency testing and evaluation programs. Some leaders in the field, at the State level, have noted that "there must be a legal authority available either to enforce the correction of errors detected in such (proficiency) testing or to prevent such laboratories from providing services to the public. Proficiency testing without enforcement is inadequate, serving only to collect disquieting data." In the absence of an adequate licensure law, the laboratory improvement program is on a voluntary basis and slow and uneven improvement can be expected.

The Clinical Laboratory Improvement Act of 1967

Concern of the United States Congress over the quality of laboratory services available to patients enrolled in the Medicare program resulted in the passage of legislation requiring accreditation of laboratories providing services. This law established standards for the operation of clinical laboratories providing services to Medicare recipients; required these laboratories to be certified; and set personnel standards for directors and other laboratory personnel.

When the Congress realized that a number of laboratories participating in interstate commerce were not subject to licensure, it passed the Clinical Laboratory Improvement Act of 1967, which provided for licensure of laboratories engaged in interstate commerce. Licensure is based upon the meeting of standards relating to maintenance of an adequate quality control program; maintenance of appropriate records, equipment and facilities; qualifications of the director and other supervisory personnel and satisfactory participation in a mandatory proficiency testing program.

The Secretary, Department of Health, Education, and Welfare, was authorized to implement this Act and he, in turn, delegated this

authority to the National Communicable Disease Center (now Center for Disease Control) where the Licensure and Development Branch of the Laboratory Division has been made immediately responsible for implementation and administration of the Act.

It should be noted that in a State which has a duly authorized laboratory improvement program with applied standards which equal or exceed the Federal standards, the Secretary may exempt clinical laboratories in that State from compliance with certain portions of the Act.

Laboratory Improvement in Montana

The laboratory improvement program in Montana consists of training provided by the State Public Health Laboratory, certification of non-doctoral directed laboratories in the Medicare program on the basis of on-site inspections performed by the Laboratory Director, and inspection of non-JCAH accredited hospital laboratories by a representative of the State Health Departments' Division of Hospital and Medical Facilities. The State laboratory furnishes information and advice through such means as a periodic newsletter, a manual of services and a substantial number of personal contacts between the Director and staff of the State laboratory and personnel of laboratories located in the State.

The aforementioned efforts are rendered in the face of severe budgetary and staffing constraints. While these efforts should be commended, they fall far short of needed services which will be discussed in a subsequent sub-section entitled Recommended Responsive Role.

V. RECOMMENDED ROLE FOR THE MONTANA STATE PUBLIC HEALTH LABORATORY

Summarization of Need

In previous Sections of this report and in referenced collateral data, the premise is offered that the need for an ongoing laboratory improvement program exists in every State. A secondary premise of this report is that IN THE STATE OF MONTANA THERE IS A GREATER THAN AVERAGE POTENTIAL FOR PROBLEMS IN THE DELIVERY OF LABORATORY SERVICES IN TERMS OF PROVISION OF AN ADEQUATE SPECTRUM OF SERVICES, MAINTENANCE OF THE QUALITY OF THESE SERVICES, AND MAINTENANCE OF THE REQUISITE QUALITY OF INTERNAL SUPERVISION AND EXTERNAL QUALITY CONTROL. Thus, inductively, one may reason that the State of Montana has a greater than average need for an ongoing laboratory improvement program.

The scope of this study is such that we do not have performance data on individual laboratories. However, several interviewees did indicate that, in their opinion, half or more of the laboratories in the State

had correctable deficiencies which could affect the quality of their performance. The foregoing statement is not offered as a blanket indictment of laboratory practice in Montana but rather in support of the idea that the aforementioned deficiencies can be identified, corrected, and in most cases, prevented from occurring in the future through programs of continuing education.

It has been shown numerous times that there is a direct relationship between the volume of specimens tested in a given laboratory specialty and the proficiency of the laboratory or laboratorian conducting the test. In the State of Montana there are a number of laboratories which, potentially, do not receive sufficient specimens to maintain their proficiency in all of the specialty areas in which they offer specimen examination.

This problem derives of course from the relative sparseness of population distribution and the fact that many of the independent laboratories, hospital laboratories, and laboratories in private physician's offices do not serve populations that are large enough to generate a sufficient volume of specimens for maintenance of proficiency.

In addition to limited specimen volume, there are other contributing factors which can lead to deficient performance. These include lack of adherence to recognized and accepted methodology; use of inappropriate or out-of-date reagents, improper maintenance or improper calibration of equipment; failure to use control specimens where indicated; failure to adhere to ongoing internal quality control procedures; and failure to schedule appropriate continuing education for all technical and professional personnel.

Recommended Responsive Role

In previous Sections of this report certain problems and needs concerning the provision of adequate laboratory services of acceptable quality for the State of Montana have been discussed and defined. With a view toward the development of remedial services which are responsive to the problems and needs discussed, IT IS RECOMMENDED THAT THE MONTANA STATE DEPARTMENT OF HEALTH INITIATE A COMPREHENSIVE PROGRAM OF LABORATORY IMPROVEMENT. It is suggested that the implementation of this program can be approached in five stages. These are:

(1) Establish Performance and Resource Baselines. In order to insure adequate information for program design and to establish a point from which program progress can be measured, data should be obtained from all laboratories in Montana through a definitive survey which will identify, for each laboratory, (a) the scope of services offered,

(b) tests performed, (c) the extent of referral service provided, (d) type and number of personnel employed, (e) volume of workload for each test performed, and (f) a description of plant and equipment facilities. Depending on authorizing legislation, data on the educational and experience qualifications of specified laboratory personnel may also be sought.

(2) Establish and Conduct a Proficiency Testing Program. This sub-program will consist of sending split specimens, in a number of specialty testing areas, to participating laboratories. This approach will assess their ability to identify pathogenic organisms; to perform serologic tests, tests in clinical chemistry, hematology, and immunohematology; and will provide a measure of the precision reproducibility of a given method or procedure in an individual laboratory. This sub-program is of utmost importance in identifying existing and emerging problems in the quality of laboratory performance. It is intended that identified deficient performance be upgraded through the provision of services discussed in (4) below.

(3) Establish Internal Quality Control Systems. Participating laboratories should be assisted in establishing their own internal systems of quality control by insuring the availability of printed procedures for each diagnostic test offered, the adequacy of equipment and facilities, appropriate calibration of equipment, adequate control reagents, and insuring their ability to correctly use these systems and interpret the results thereof. This assistance for the most part can be provided through printed monographs covering test procedures offered and through on-site training and consultation when circumstances dictate.

(4) Establish Training and Consultative Services. In the survey mentioned in (1) above, a number of general problem areas can be identified. More specific problem areas will be identified through the proficiency testing program mentioned in (2) above. Depending upon the nature, location, and criticality of the problems identified, training courses and consultative services should be designed so as to be optimally responsive, on a continuing basis, to emerging problems in laboratory practice as they are identified. (See additional comments on Regional Training Centers in Section V following.)

(5) Establish a Program Evaluation System. In order that the overall program can be both efficient, effective, and flexible on a continuing basis, it is recommended that relevant, quantifiable evaluative factors be tabulated and analyzed in order

that emerging problem areas can be readily identified and so that program services can be directed toward identified problems.

Assessment of Existing Staffing and Budgetary Resources

It is the opinion of the study team that existing staff and budgetary resources of the Montana SPHL border on the marginal in relation to the type and level of services currently being provided.

If the expanded program services described in this report are to be provided, then additional staff and budgetary resources must also be provided. There seems to be no possibility of "absorbing" any portion of this new program effort because existing services are essential and certainly should not be reduced in any way.

It is recommended that the following staffing and budgetary adjustments be provided for as soon as possible:

ESTIMATED COST FOR IMPLEMENTATION OF
MONTANA LABORATORY IMPROVEMENT PROGRAM

	1st Year	2nd Year	Ongoing Costs Per Year
Personnel			
Director, Microbiology Lab. Div.(Pro rata)	2,400	2,500	2,500
Med. Tech. II (Lab Surveyor)	10,320	10,500	11,000
Lab. & Field Tech. II	7,440	7,500	7,650
Clerk Typist I	4,755	4,800	5,000
Equipment IBM Typewriter IBM Dictating System	2,000	1,000	250
Travel	5,000	7,500	6,000
Supplies (specimen tubes and styrofoam mailing containers)	3,000	2,000	2,000
Total	34,915	35,800	34,400

The foregoing budgetary data reflects an extremely lean, efficient, and substantive program. To the extent that less funds are provided, there will, of necessity, be less services available.

In Attachment No. 12, page 40, annual budget increases of the Montana SPHL and SHD are compared. Over the nine year period indicated, the SHD has received an increase in budget of 155% for an annual average

increase of 17%. The SPHL has received an increase in budget of 53% for an annual average increase of 5.9%. This latter figure can hardly be said to represent an increase since it barely keeps pace with the rate of inflation.

Adequacy of Legal and Regulatory Base

In the literature which compares the merits of a voluntary laboratory improvement program with a mandatory laboratory improvement program, the point is made that those laboratories that most need improvement are the ones most reluctant to expose their deficiencies and thus, they tend to refrain from participation in voluntary programs. In order that the existing quality of laboratory performance can be professionally evaluated; and so that trends leading toward future deficient performance can be identified for purposes of designing and offering corrective training and consultation; IT IS STRONGLY RECOMMENDED THAT A MANDATORY REQUIREMENT FOR PARTICIPATION IN A PROFICIENCY TESTING PROGRAM BE AN INTEGRAL PART OF THE MONTANA LABORATORY IMPROVEMENT PROGRAM.

However, the State of Montana does not have a legislative and regulatory base which would authorize the implementation of a Statewide laboratory improvement program requiring mandatory participation in a proficiency testing program.

It should be affirmed at this point that it is the impression of the study team that no interviewee was interested in a regulatory function per se, or in closing down any laboratory where deficient performance can be adequately upgraded. It is believed that the approach proposed herein represents the quickest and most effective way of identifying deficient laboratory performance so that training and consultation which will upgrade the laboratory involved can also be quickly made available.

If, however, after the provision of remedial assistance, the laboratory in question still cannot raise the quality of its performance above minimum standards, then, in the public interest it should not be permitted to operate further in the particular area in which it is deficient until it can demonstrate satisfactory performance.

To facilitate and authorize the administration of the program described herein, and to insure that the health expectations of Montana citizens are met, It is recommended that State enabling legislation be sought which would provide for the licensure of clinical laboratories and their personnel.

Licensure of personnel only is considered inadequate because there are factors relating to quality of performance apart from the availability of qualified personnel. With the licensure of laboratories, in addition to the licensure of personnel, a mechanism is made available whereby the owner of a laboratory can be required to provide the qualified laboratorian with facilities, equipment, supplies, and reagents which meet or exceed standards set by the State Department of Health. In the absence of adequate facilities, functioning and properly calibrated equipment, clean and adequate supply stocks, and in-date reagents, maintenance of quality laboratory performance overtime would be very difficult regardless of the technical ability of the laboratorian.

The aforementioned legislation should authorize the State Department of Health to set standards relating to participation in a mandatory proficiency testing program, qualifications of director and personnel, internal quality control programs, facilities, records, and equipment.

The Council of State Governments has issued a draft of a model bill entitled "Regulation of Clinical Laboratories and Their Personnel." The study team commends this model bill and recommends that it be followed as closely as possible although minor redrafting may prove necessary to meet Montana requirements. A copy of the aforementioned draft is included as Attachment No. 11, page 39.

Regional Training Centers

If this study can be said to have a primary focus, then that focus is directed toward insuring that the quality of performance and reliability of operation of clinical laboratories in the State of Montana meet or exceed minimum standards.

Passage of the aforementioned legislation would authorize the promulgation of regulations which would in turn define program parameters and methods for identifying laboratory performance deficiencies and trends leading toward deficiencies. A considerable portion of the interview time of the study team dealt with eliciting ideas and opinions from interviewees on logistically feasible methods for providing training and consultation in the State of Montana.

A number of problems in the delivery of training services were identified by interviewees. These problems included the fact that when previous training services have been established at a central point many prospective trainees were unable to attend because travel time and costs were sometimes prohibitive and no one was available to cover their jobs during the training period.

One interviewee described a training approach which would seem to answer the aforementioned problems to the extent they can be answered in Montana. This approach involves establishing "sub-centers of excellence."

That is, establish seven or eight training centers throughout the State, taking into account the distribution of health personnel, the availability of training space and resources, and transportation accessibility.

Such Centers would be ideal points from which to deliver training and consultation leading toward the improvement of laboratory performance. The program described in previous sections could easily identify those laboratory performance problems common to a particular geographic area and specifically remedial training courses could be designed accordingly and made available in those areas.

The utilization of these Centers would greatly reduce travel time and cost for attendees and in many instances these courses could be scheduled for the evening hours. These Centers would be quite useful, from a continuing education point of view, for personnel across the entire spectrum of health services. Physicians, Nurses, Laboratorians, X-ray Technicians, Dentists, Hospital Administrators, and Representatives from Indian Health Agencies, as well as Industrial Health, should find them of high utility for course and seminar presentations.

Liaison with Professional Associations, Planning Groups and Academic Institutions

The implementation of a Statewide Laboratory Improvement Program impinges upon the professional and academic interests of a number of medical and paramedical groups engaged in the delivery of health services in that State. Inasmuch as implementation of such a program can, over time, have a highly substantive impact upon health care delivery systems throughout a State, appropriate health planning groups should be included from the outset in implementation efforts to insure optimal effectiveness and efficiency.

Existing liaison between the Montana PHL and the aforementioned groups can only be described as exemplary. However, it is recommended that additional liaison efforts be made in carrying out the aforementioned recommendations concerning legislation.

Specifically it is recommended that all professional associations, planning groups, and academic institutions having operational or advisory interests relating to the quality of performance of clinical laboratories be apprised of the constructive intent of the legislation and the ensuing program.

VI. SUMMARY

In the previously referenced document entitled A Report on Laboratory Performance and Methods for Improvement (NCDC-June 1967) a number of studies are mentioned which concern the existence of serious deficiencies in the Nation's clinical laboratories. These data were obtained from laboratories participating in performance evaluation programs. The point is made that the results reported by these laboratories may represent the best they can do rather than routine performance.

A synthesis of these studies reflects that erroneous results were obtained in more than 25% of all tests analyzed. For reasons previously indicated, the State of Montana has a greater than average potential for problems in the maintenance of an adequate spectrum of laboratory services; in the maintenance of quality of services provided; and in maintaining the quality of supervision required. Because of somewhat fewer physicians and problems of distribution and distance, it is essential that paramedical supportive services, such as those rendered in clinical laboratories, meet or exceed minimum quality standards.

The study team submits that the need for a Statewide Laboratory Improvement Program in Montana is clear cut. There may be public health problems of greater scope and magnitude, but most of these problems will require a great deal more effort, time, and resources before they can be dealt with effectively. THE PROBLEM AND PROPOSED SOLUTION DEALT WITH HEREIN CAN BE IMPLEMENTED WITH MINIMUM RESOURCES IN VIEW OF THE EXCELLENT PERFORMANCE BASE WHICH ALREADY EXISTS IN THE STATE PUBLIC HEALTH LABORATORY; THE PROPOSED STEPS TOWARD IMPLEMENTATION CAN BEGIN IMMEDIATELY; AND SUCH IMPLEMENTATION WILL IN NO WAY PRODUCE A FRAGMENTED EFFORT, BUT RATHER SHOULD CLEARLY ACHIEVE A SYNERGISTIC EFFECT IN A NUMBER OF AREAS.

ALL ESSENTIAL INGREDIENTS FOR PRODUCTIVE IMPLEMENTATION ARE PRESENT WITH THE EXCEPTION OF AN APPROPRIATE LEGISLATIVE BASE AND THE APPROPRIATION OF ADEQUATE FUNDS.

It is hoped that this study will provide helpful information for the various levels of decision-makers who will form judgments concerning the establishment and implementation of this program. The study team expresses its thanks to all interviewees who were without fail cooperative and candid in responding to numerous questions posed.

LISTING OF ATTACHMENTS

ATTACHMENT NO. 1

BIBLIOGRAPHY

A Listing of Major Documents Reviewed During Program Review for Microbiology Laboratory Division, Montana State Department of Health.

1. Consolidated Annual Report on State and Territorial Public Health Laboratories - Fiscal Year 1968. Published by U.S. Department of Health, Education, and Welfare, PHS-HSMHA-NCDC, Laboratory Division and the Association of State and Territorial Public Health Laboratory Directors.

2. A Guide for Establishing an IntraState Proficiency Testing Program - August 1967. Published by U.S. Department of Health, Education, and Welfare, PHS-BDPEC-NCDC.

3. A Report on Laboratory Performance and Methods for Improvement - June 1967. Published by U.S. Department of Health, Education, and Welfare, PHS-BDPEC-NCDC.

4. Montana County Profiles - November 1969. Published by State Department of Health, Division of Comprehensive Health Planning.

5. Annual Statistical Supplement - 1968. Published by Montana State Department of Health, State Registrar's Office.

6. Public Health Services to Montana Families - 34th Biennial Report, July 1, 1966 - June 30, 1968, Montana State Department of Health.

7. Report of a Survey of Consumers of Health Care - May 1969. Mountain States Regional Medical Program, Western Interstate Commission for Higher Education, Boulder, Colorado.

8. Report of a Survey in Continuing Education Needs for Health Professionals - June 1969. Mountain States Regional Medical Program, Western Interstate Commission for Higher Education, Boulder, Colorado.

9. Initial Analysis of Health Professional Survey - September 1968. Mountain States Regional Medical Program, Western Interstate Commission for Higher Education, Boulder, Colorado.

10. Montana Medical Technologists Survey - February 1969. Mountain States Regional Medical Program, Western Interstate Commission for Higher Education, Montana Division, Boulder, Colorado.

11. Health Profile - Montana - July 1969. Montana Division - WICHE - Mountain States Regional Medical Program, Great Falls, Montana.

12. Revised Codes of Montana 1947 - Titles 48 and 69.

13. Regulations - Montana State Board of Health.

14. Montana Licensing Law and Standards for Hospitals and Related Institutions.

15. Conditions for Coverage of Services of Independent Laboratories (Medicare) - Code of Federal Regulations, Title 20, Chapter III, part 405.

16. The Clinical Laboratory Improvement Act of 1967, Public Law 90-174, 42 USC 263a.

17. Regulations Under the Clinical Laboratories Improvement Act of 1967. Code of Federal Regulations, Title 42, Chapter I, Subchapter F, part 74, Section 353 of the Public Health Service Act.

ATTACHMENT NO. 2

Listing of contacts made during program review for Microbiology Laboratory Division, Montana State Department of Health, by date, name, organization, and location.

DATE	NAME	ORGANIZATION OR PROGRAM AREA	LOCATION
3-16-70	Dr. John S. Anderson	Executive Officer, State Department of Health	Montana SDH
3-16-70	Dr. David B. Lackman and Staff	Director, Microbiology Laboratory Division	Montana SDH
3-16-70	Mr. Keith Colbo	State Budget Director	Office of the Governor
3-16-70	Mr. Ben Johns	State Budget Bureau	Office of the Governor
3-16-70	Mr. Robert James	Budget Officer	Montana SDH
3-17-70	Mr. M. C. Mitchke and Staff	Assistant Postmaster	U.S. Post Office Helena, Montana
3-17-70	Mr. David DePew	Assistant Director, Div. of Comprehensive Health Planning	Montana SDH
3-17-70	Dr. Mary E. Soules	Director, Division of Disease Control and Assistant Executive Officer, SDH	Montana SDH
3-18-70	Dr. Martin Skinner	State Epidemiologist, Acting	Montana SDH
3-18-70	Mr. Vernon Sloulin	Chief Sanitarian, Div. of Environmental Sanitation	Montana SDH
3-18-70	Mr. Donald Willems	Acting Director, Div. of Water Pollution Control	Montana SDH
3-18-70	Dr. Sidney C. Pratt	Director, Montana Division Mountain States Regional Medical Program	Great Falls, Montana
3-18-70	Mr. Edward H. Gatzemeier	Division of Air Pollution and Industrial Hygiene	Montana SDH

DATE	NAME	ORGANIZATION OR PROGRAM AREA	LOCATION
3-18-70	Mr. Larry L. Lloyd	Radiological Health, Div. of A.P. and Ind. Health	Montana SDH
3-19-70	Mr. M. E. Lindbergh	Division of Hospital and Medical Facilities	Montana SDH
3-19-70	Miss Judy Schulze	Laboratory Surveyor, Medicare Non-JCAH Hospitals, Division of Hospital and Medical Facilities	Montana SDH
3-19-70	Dr. Al Fiscus	Associate Professor of Microbiology, Clinical Microbiology and Virology	Montana State University, Bozeman, Montana

ATTACHMENT NO. 3

Comparisons between State Public Health Laboratories
For Fiscal Year 1968, For the Following Program Topics

No.		MONTANA	IDAHO	WYOMING	UTAH	COLORADO	NORTH DAKOTA
1.	Population of area served	701,000	699,000	315,000	1,024,000	1,975,000	639,000
2.	Population density per sq. mile	4.6	8.1	3.4	10.8	16.9	9.1
3.	Total Budgeted Employees	18	35	7	44	39	24
4.	Professional and Tech. Positions	8	24	3	28	22	14
5.	Admin. and Clerical Positions	5	6	2	9	5	6
6.	Supportive Svcs. and Maintenance pos.	5	5	2	7	12	4
7.	Ratio, prof. personnel/population	1:100,143	1:29,125	1:105,000	1:37,926	1:89,773	1:45,643
8.	Ratio, total personnel/population	1:41,235	1:20,559	1:45,000	1:23,814	1:50,641	1:26,625
9.	Percent employee turnover, all pos.	16.7	2.9	-	22.7	20.5	33.3
10.	Total mandays attending tech. trng.	26	31	20	44	50	5
11.	Avg. # mandays in trng. per P&T emp.	3.71	1.29	6.67	1.63	2.27	0.36
12.	Training offered by student days	112	228	-	606	416	251
13.	Total specimens examined	67,065	100,265	80,402	183,983	386,750	129,484
14.	Total examinations performed	89,221	159,772	88,279	288,255	481,290	249,842
15.	Ratio, specimens to exams	1:1.3	1:1.6	1:1.1	1:1.6	1:1.2	1:1.9
16.	Ratio, exams to population	1:7.9	1:4.4	1:3.6	1:3.6	1:4.1	1:2.6
17.	Ratio, prof. personnel to exams	1:11,153	1:6,657	1:29,426	1:10,295	1:21,877	1:17,846
18.	Ratio, total personnel to exams	1:4,957	1:4,565	1:12,611	1:6,551	1:12,341	1:10,410
19.	Total annual expenditures	135,867	272,394	74,382	260,933	382,900	174,421
20.	Expenditures per capita	0.194	0.394	0.236	0.255	0.194	0.273
21.	% of lab expenditures for salaries	77.7	73.6	49.9	73.7	65.1	75.0
22.	% of lab expenditures for pers. benefits	7.0	7.8	3.6	6.7	3.9	0.8
23.	% lab expenditures for supplies	7.9	11.8	4.5	10.6	28.6	13.2
24.	% lab expenditures for equipment	1.7	1.0	40.4	5.9	1.4	1.5
25.	% lab expenditures of health dept. expen.	7.0	9.6	23.7	8.3	3.5	14.3
26.	Lab space in net sq. ft.	6,613	15,619	1,550	6,479	12,820	-
27.	Space for prof. & tech. personnel	1,593	7,011	745	4,001	8,700	-
28.	Space for supportive services pers.	3,237	2,387	366	1,685	3,120	-
29.	Space for administrative personnel	1,783	6,221	439	793	1,000	-
30.	Expenditures/examinations, for cost range per examination	1.52	1.74	0.85	0.90	0.79	0.70

ATTACHMENT NO. 4

This attachment reflects the specialty areas in which tests are offered, the number of specimens received, and the number of examinations conducted during Fiscal Years 1967, 1968, and 1969.

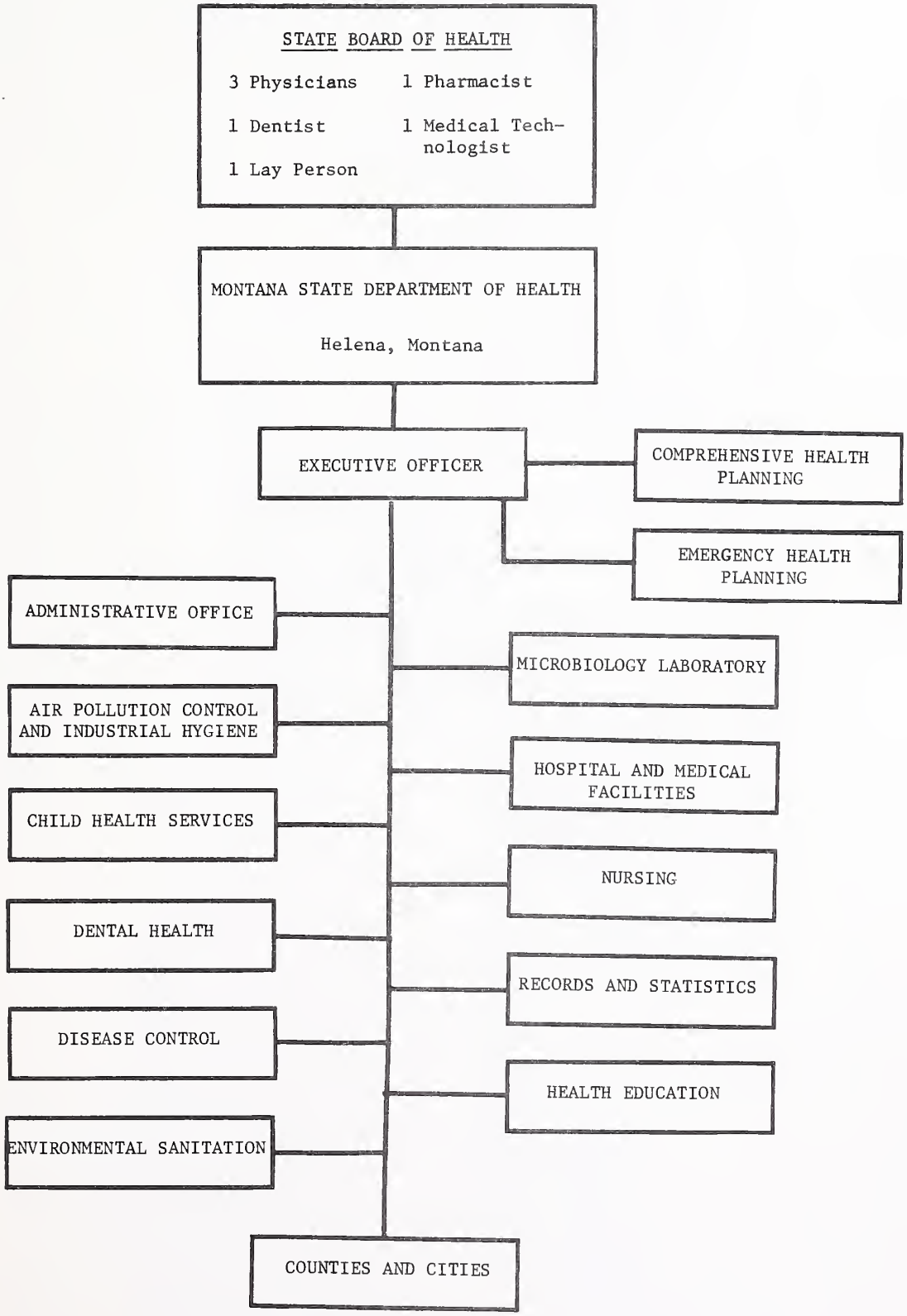
	1967		1968		1969	
SPECIALTY AREAS	Spec.	Exams	Spec.	Exams	Spec.	Exams
Diagnostic Bacteriology	n.a.	13,923	5,606	14,081	5,313	11,911
Parasitology	n.a.	74	71	68	78	78
Virology	n.a.	397	238	339	343	343
Mycology	n.a.	170	127	264	72	288
Serology	n.a.	40,872	34,774	41,527	32,562	32,885
Sanitary Bacteriology	n.a.	16,441	11,715	18,180	12,391	17,960
Clinical Chemistry	n.a.	9,351	9,974	9,849	11,849	11,849
Sanitary Chemistry	n.a.	6,855	n.a.	n.a.	1,094	1,094
Air Pollution	---	---	n.a.	n.a.	1,159	1,159
Occupational Health	---	4,700	n.a.	n.a.	30	30
Forensic Toxicology	---	---	n.a.	n.a.	735	735
TOTAL SPECIMENS RECEIVED	65,000		67,065		65,626	
TOTAL EXAMS CONDUCTED		92,783		89,221		78,332

ATTACHMENT NO. 5

ORGANIZATION CHART

MONTANA STATE BOARD OF HEALTH

MONTANA STATE DEPARTMENT OF HEALTH

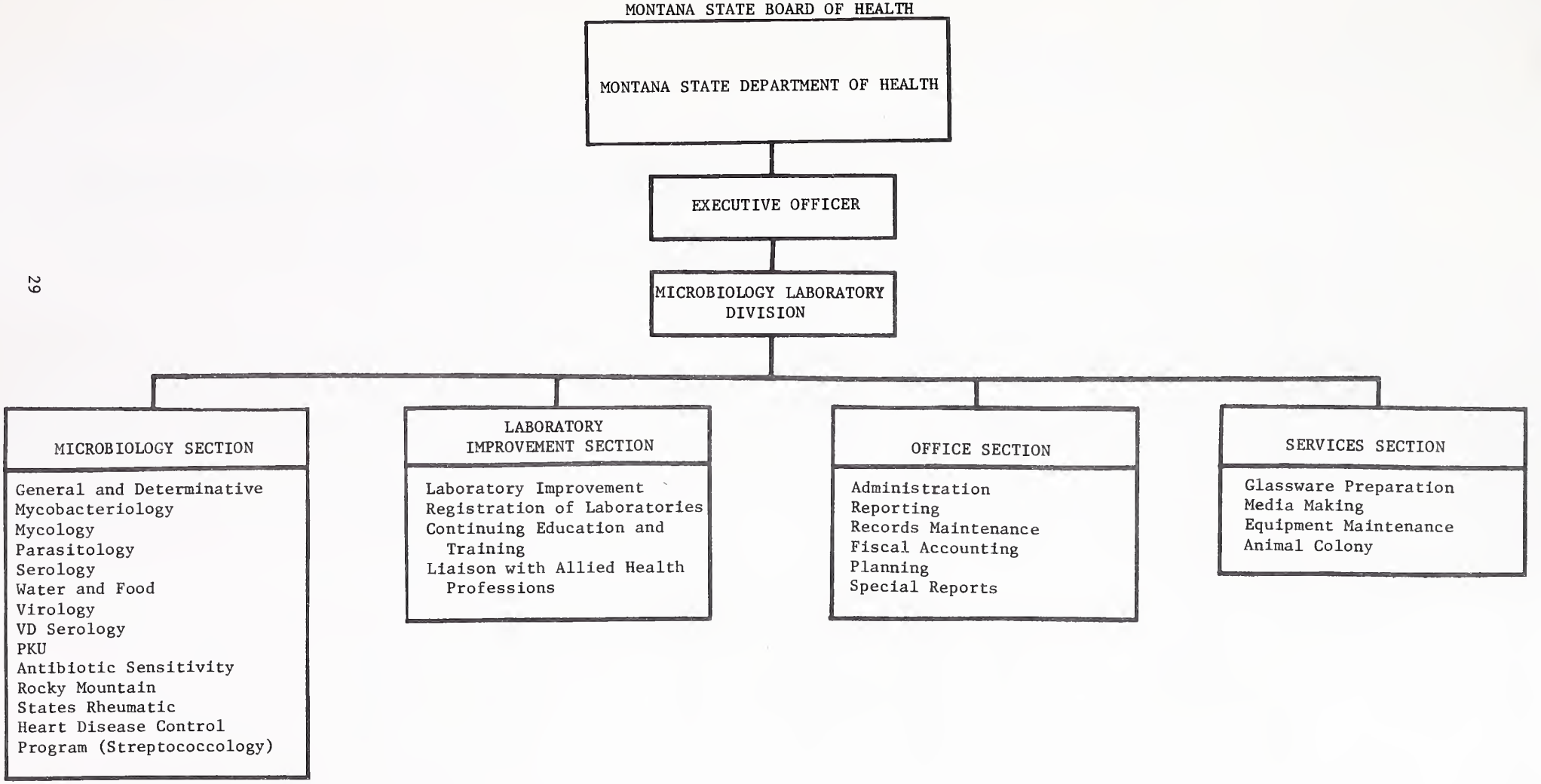


ATTACHMENT NO. 6

ORGANIZATION CHART AND ABBREVIATED FUNCTIONS

MICROBIOLOGY LABORATORY DIVISION

MONTANA STATE BOARD OF HEALTH



ATTACHMENT NO. 7

This attachment is intended to reflect generally the ratios of population/physician/hospitals/ laboratories/geographical space, by county and by Comprehensive Health Planning District. In Attachment No. 8, the following data are shown on a stylized map.

CHP District 1

County	1970 Pop. Est.	Square Miles	Est. Pop. Dens. Per Sq. Mi.	Nr. Gen. Hosps.	Total Hosp. Beds	Nr. Physicians Gen. Pract.	Spec.	Nr. Hosp. LABS	Nr. Ind. LABS
Flathead	35,000	5,140	6.8	3	116	19	17	3	1
Granite	3,100	1,733	1.8	1	14	1		1	
Lake	11,800	1,500	7.9	3	95	9	1	3	
Lincoln	16,500	3,715	4.4	1	34	6	2	1	
Mineral	4,500	1,223	3.7	1	9	1		1	
Missoula	51,000	2,613	20.0	3	367	14	81	3	6
Ravalli	13,000	2,384	5.4	1	32	7	2	1	1
Sanders	6,400	2,799	2.2	1	21	1	3	1	
AREA	141,300	21,107	6.7	14	688			14	8

CHP District 2

County	1970 Pop. Est.	Square Miles	Est. Pop. Dens. Per Sq. Mi.	Nr. Gen. Hosps.	Total Hosp. Beds	Nr. Physicians Gen. Pract.	Spec.	Nr. Hosp. LABS	Nr. Ind. LABS
Blaine	7,200	4,267	1.7	1	32	6		1	1
Cascade	93,400	2,659	35.0	3	400	19	72	3	5
Chouteau	7,000	3,920	1.8	2	55	3		2	
Fergus	13,300	4,244	3.1	1	75	9		1	
Glacier	13,200	2,974	4.4	2	86	8	3	2	1
Hill	22,500	2,926	7.7	1	160	5	8	1	2
Judith Basin	2,800	1,880	1.4			1			
Liberty	2,900	1,439	2.0	1	11	1		1	
Petroleum	800	1,650	0.4						
Pondera	8,100	1,643	5.0	1	47	3		1	
Teton	6,900	2,294	3.0	1	27	1	1	1	
Toole	8,200	1,950	4.0	1	30	1	3	1	
AREA	186,300	31,846	6.0	14	1,023			14	9

CHP District 3

County	1970 Pop. Est.	Square Miles	Est. Pop. Dens. Per Sq. Mi.	Nr. Gen. Hosps.	Total Hosp. Beds	Nr. Physicians Gen. Pract.	Spec.	Nr. Hosp. LABS	Nr. Ind. LABS
Carter	2,100	3,313	0.7	1	16	1		1	
Custer	13,000	3,765	3.4	2	232	5	15	2	3
Daniels	3,200	1,443	2.2	1	20	2		1	
Dawson	15,300	2,358	6.0	1	43	3	3	1	1
Fallon	4,200	1,633	3.0	1	25	2		1	
Garfield	1,700	4,595	0.3	1	21	1		1	
McCone	3,100	2,594	1.1	1	20	1		1	
Phillips	5,400	5,228	1.0	1	32	2		1	
Powder River	2,200	3,285	0.7						
Prairie	2,000	1,727	1.2	1	13	1		1	
Richland	9,900	2,065	4.8	1	61	4	2	1	
Roosevelt	12,900	2,385	5.4	3	93	8	1	3	
Rosebud	5,600	5,032	1.1	1	20	3	2	1	
Sheridan	5,600	1,700	3.3	1	35	2		1	

CHP District 3 (cont'd.)

County	1970 Pop. Est.	Square Miles	Est. Pop. Dens. Per Sq. Mi.	Nr. Gen. Hosps.	Total Hosp. Beds	Nr. Physicians Gen. Pract.	Nr. Physicians Spec.	Nr. Hosp. LABS	Nr. Ind. LABS
Valley	22,700	4,961	4.6	1	58	9	8	1	2
Wibaux	1,400	889	1.6						
AREA	110,300	46,973	2.3	17	689			17	6

CHP District 4

County	1970 Pop. Est.	Square Miles	Est. Pop. Dens. Per Sq. Mi.	Nr. Gen. Hosps.	Total Hosp. Beds	Nr. Physicians Gen. Pract.	Nr. Physicians Spec.	Nr. Hosp. LABS	Nr. Ind. LABS
Beaverhead	7,900	5,556	1.4	1	18	5		1	
Broadwater	2,600	1,198	2.2	1	23	2		1	
Deer Lodge	19,500	738	26.4	1	60	6	17	1	
Gallatin	31,000	2,517	12.3	1	102	21	17	1	2
Jefferson	4,500	1,651	2.7	1	91	2		1	
Lewis & Clark	32,000	3,466	9.2	2	193	12	42	2	5
Madison	4,200	3,530	1.2	2	30	4	1	2	
Meagher	3,300	2,354	1.4	1	8	1		1	
Park	13,800	2,627	5.3	1	58	7	2	1	1
Powell	7,700	2,337	3.3	2	195	3		2	
Silver Bow	42,000	716	58.7	2	342	12	28	2	3
AREA	168,000	26,690	6.3	15	1,120			15	11

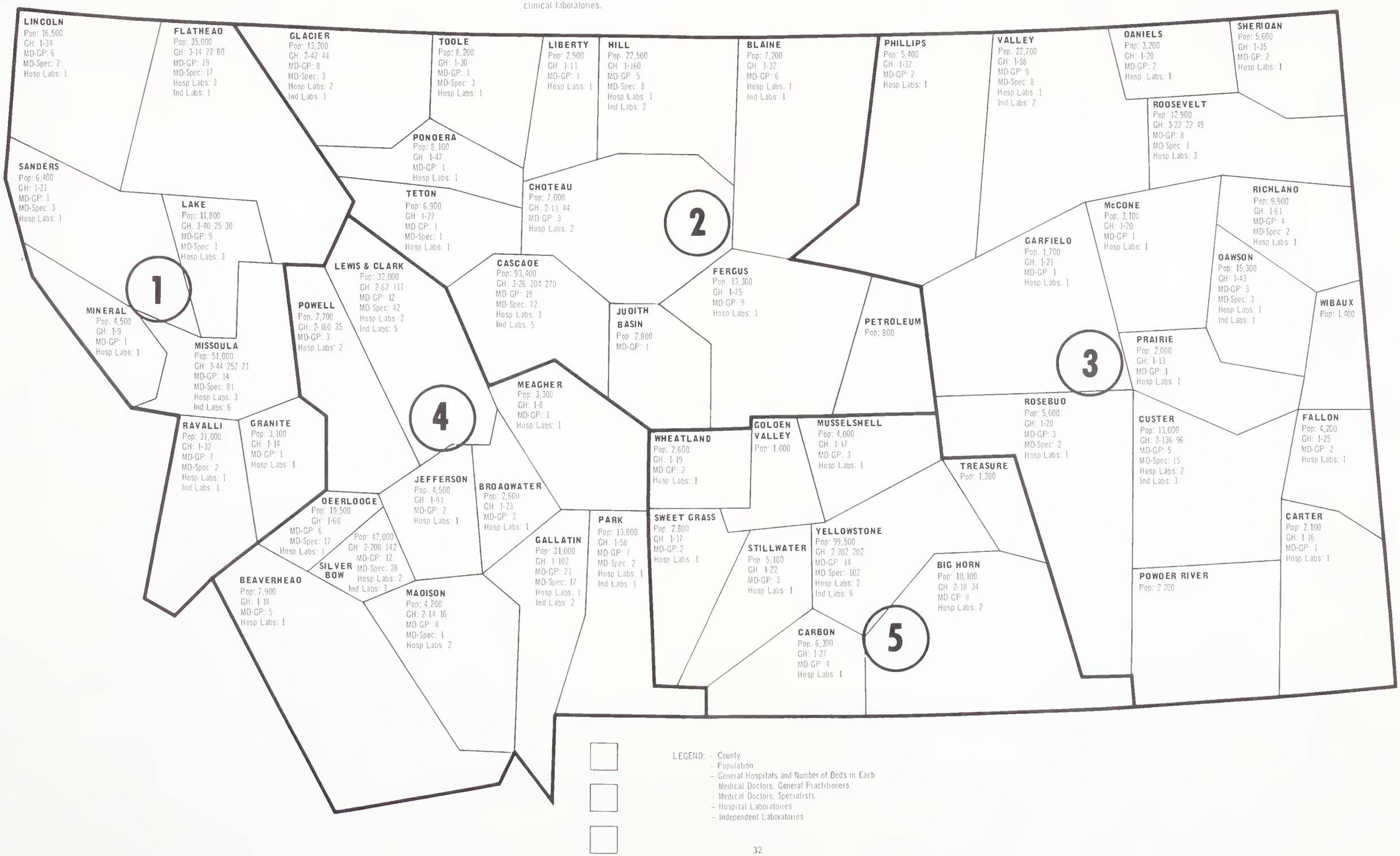
CHP District 5

County	1970 Pop. Est.	Square Miles	Est. Pop. Dens. Per Sq. Mi.	Nr. Gen. Hosps.	Total Hosp. Beds	Nr. Physicians Gen. Pract.	Nr. Physicians Spec.	Nr. Hosp. LABS	Nr. Ind. LABS
Big Horn	10,100	5,033	2.0	2	52	8		2	
Carbon	6,300	2,070	3.0	1	27	4		1	
Golden Valley	1,000	1,178	0.8						
Musselshell	4,000	1,886	2.1	1	17	3		1	
Stillwater	5,100	1,797	2.8	1	22	3		1	
Sweetgrass	2,800	1,846	1.5	1	17	2		1	
Treasure	1,200	984	1.2						
Wheatland	2,600	1,422	1.8	1	19	2		1	
Yellowstone	99,500	2,635	37.8	2	404	14	102	2	6
AREA	132,600	18,851	7.0	9	558			9	6

MONTANA	739,047			69	4,078	265	438	69	40

ATTACHMENT NO. 8

This attachment reflects, by County and by Comprehensive Health Planning District, population, the number of general hospitals and the number of beds in each, the number of medical doctors in general practice and in specialty practice, and the number of hospital laboratories and independent clinical laboratories.



LEGEND: - County
- Population
- General Hospitals and Number of Beds in Each
- Medical Doctors, General Practitioners
- Medical Doctors, Specialists
- Hospital Laboratories
- Independent Laboratories

ATTACHMENT NO. 9

This attachment reflects the ratio of clinical and hospital laboratories to population served.

	Estimated Number of Labs			Estimated	Labs per 100,000 Population		
	Indep. Clin.	Hospital	Total	Population	Indep. Clin.	Hospital	Total
	A	B	C	D	E	F	G
Ala.	15	135	150	3,540,000	0.4	3.8	4.2
Alaska	2	13	15	272,000	0.7	4.8	5.5
Ariz.	*	50	*	1,634,000	*	3.1	*
Ark.	113	12	125	1,968,000	5.7	0.6	6.3
Cal.	940 (a)	565	1,505	19,153,000	4.9	3.0	7.9
Colo.	40	93	133	1,975,000	2.0	4.7	6.7
Conn.	*	*	*	2,925,000	*	*	*
Del.	7	5	12	523,000	1.3	1.0	2.3
D. C.	*	*	*	809,000	*	*	*
Fla.	240	194	434	5,995,000	4.0	3.2	7.2
Ga.	20	150	170	4,509,000	0.4	3.3	3.7
Hawaii	25	30	55	739,000	3.4	4.1	7.5
Ida.	18	49	67	699,000	2.6	7.0	9.6
Ill.	330	368	698	10,893,000	3.0	3.4	6.4
Ind.	100	130	230	5,000,000	2.0	2.6	4.6
Ia.	15	145	160	2,753,000	0.5	5.3	5.8
Kans.	29 (b)	168	197	2,275,000	1.3	7.4	8.7
Ky.	103	97	200	3,189,000	3.2	3.0	6.2
La.	*	*	*	(c)3,662,000	*	*	*
Me.	2	61	63	973,000	0.2	6.3	6.5
Md.	68	49	117	3,682,000	1.8	1.3	3.1
Mass.	98	*	*	5,421,000	1.8	*	*
Mich.	178	271	449	8,584,000	2.1	3.2	5.3
Minn.	12	184	196	3,582,000	0.3	5.1	5.4
Miss.	15	125	140	2,348,000	0.6	5.3	5.9
Mo.	100	166	266	4,603,000	2.2	3.6	5.8
Mont.	36 (d)	68	104	701,000	5.1	9.7	14.8
Nebr.	15	85	100	1,435,000	1.0	5.9	6.9
Nev.	*	*	*	444,000	*	*	*
N. H.	1	28	29	686,000	0.1	4.1	4.2
N. J.	160	140	300	7,003,000	2.3	2.0	4.3
N. M.	9	56	65	1,003,000	0.9	5.6	6.5
N. Y.	192	237	429	18,336,000	1.0	1.3	2.3
N. C.	*	150	*	5,029,000	*	3.0	*
N. D.	*	*	*	639,000	*	*	*
Ohio	145	305	450	10,458,000	1.4	2.9	4.3
Okla.	*	*	*	2,495,000	*	*	*
Ore.	115	85	200	1,999,000	5.8	4.3	10.1
Pa.	160	400	560	11,629,000	1.4	3.4	4.8
R. I.	30	23	53	900,000	3.3	2.6	5.9
S. C.	11	75	86	2,599,000	0.4	2.9	3.3
S. D.	*	*	*	674,000	*	*	*
Tenn.	38	194	232	3,892,000	1.0	5.0	6.0
Tex.	180	*	*	10,869,000	1.7	*	*
Utah	24	41	65	1,024,000	2.3	4.0	6.3
Vt.	5	25	30	417,000	1.2	6.0	7.2
Va.	*	*	*	4,536,000	*	*	*
Wash.	167 (e)	124	291	3,087,000	5.4	4.0	9.4
W. Va.	45	85	130	1,798,000	2.5	4.7	7.2
Wisc.	20	234	254	4,189,000	0.5	5.6	6.1
Wyo.	3	40	43	315,000	1.0	12.7	13.7
P. R.	108	45	153	2,697,000	4.0	1.7	5.7
V. I.	*	*	*	56,000	*	*	*

ATTACHMENT NO. 10

STATUS OF STATE LABORATORY LEGISLATION IN THE U.S.

PRESENT REQUIREMENTS FOR LABORATORIES					REQUIREMENTS FOR LABORATORY PERSONNEL	PERMIT		LABORATORY LEGISLATION		
	Labs Covered		Mandatory Supervision by Physician	Performance Evaluation	Education and Training	License, Permit or Certificate	Examination	States Introducing Lab Legislation in 1970	States Where Lab Legislation Has Failed (1970)	States Adopting Lab Legislation in '67, '68, '69, or '70
	Independent	Hospital								
Ala.	X				TECHNICIAN: h/s or equivalent and 1 yr of college chemistry, bacteriology and biology and 1 yr in accredited medical technology school.	X	X			
AK.								X		X(1970)
Ariz.	X	(1)			DIRECTOR: Above B.A. with paramedical, chemical, or biological science major.	X	X	X	X	X(1969)
Cal.	X	X		X	DIRECTOR: M.D. or Bioanalyst (Master's + 4 yrs experience) TECHNOLOGIST: Bachelor's and 1 yr training in approved lab. TRAINEE: Bachelor's mandatory before certification for training.	X	X	X		
Conn.	X	(1)			DIRECTOR: Pathologist with Boards in Clinical Pathology exempt from exam. Other M.D. or Sc.D. or Ph.D. in chemical, physical or biological sciences eligible after examination Others specially qualified may be directors after examination. Regulations include qualifications for lab director and "other personnel".	X	X			
Del.	X		X		DIRECTOR: Must be licensed physician.					
D.C.	X	X	X		None					
Fla.	X	X		X	DIRECTOR: M.A. in chemical, physical or biological science + 6 yrs experience. SUPERVISOR: 2 yrs academic study, 10 yrs experience. TECHNOLOGIST: 2 yrs academic study, 2 yrs experience. TECHNICIAN: h/s and 2 yrs experience.	X	X			X(1967)

(1) Covered under separate law
(2) Died in House
(3) Died in Senate

Revised 6/29/70
DHEW, PHS, HSMHA, NCDC, LAB

STATUS OF STATE LABORATORY LEGISLATION IN THE U.S.

PRESENT REQUIREMENTS FOR LABORATORIES					REQUIREMENTS FOR LABORATORY PERSONNEL	PERMIT		LABORATORY LEGISLATION		
	Labs Covered		Mandatory Supervision by Physician	Performance Evaluation	Education and Training	License, Permit or Certificate	Examination	States Introducing Lab Legislation in 1970	States Where Lab Legislation Has Failed (1970)	States Adopting Lab Legislation in '67, '68, '69, or '70
	Independent	Hospital								
Ga.	X	X		X	DIRECTOR: M.D. However, Board may authorize Ph.D.'s. SUPERVISOR: minimum qualifications established by Board.	X		X		X(1970)
Hawaii					DIRECTOR: M.D. or 5 yrs experience in lab or teaching basic medical sciences (M.S. counts as 2 yrs, D.V.M. as 4 yrs, M.D. counts as full 5 yrs). TECHNOLOGIST: B.S., B.A. or equivalent degree.	X	X			
Ill.	X	(1)		X	DIRECTOR: Degree above baccalaureate level with major in chemical or biological sciences. SUPERVISING TECHNOLOGIST: 2 yrs of college and 1 yr supervised training in approved lab with 2 yrs additional lab work. TECHNICIAN: Received adequate training.	X	X			
Iowa								X		
Kansas								X	X	
Ky.	X	(1)		X	DIRECTOR: M.D. in medicine; Ph.D. with chemical, physical, or biological science major + 2 yrs in medical lab specialty (minimum qualifications for personnel prescribed by Department of Health).	X				X(1968)
La.	X		X		None					
Me.	X	(1)	X	X	DIRECTOR: M.D.	X				X(1967)

STATUS OF STATE LABORATORY LEGISLATION IN THE U.S.

	PRESENT REQUIREMENTS FOR LABORATORIES				REQUIREMENTS FOR LABORATORY PERSONNEL	PERMIT		LABORATORY LEGISLATION		
	Labs Covered		Mandatory Supervision by Physician	Performance Evaluation	Education and Training	License, Permit or Certificate	Examination	States Introducing Lab Legislation in 1970	States Where Lab Legislation Has Failed (1970)	States Adopting Lab Legislation in '67, '68, '69, or '70
	Independent	Hospital								
Md.	X	X		X	DIRECTOR: M.D. or Ph.D. in biological or chemical science with 2 yrs experience in approved lab. SUPERVISORY TECHNOLOGIST: Bachelor's in biological or chemical science and 1 yr experience in approved laboratory.	X		X		
Mass.	X	(1)		X	"Submit evidence of satisfactory training and experience."			X		
Mich.	X	X		X	DIRECTOR: Physician certified in all fields for which he applies; doctoral degree in medicine, microbiology, chemistry or biological science and 3 yrs experience; M.A. degree with 5 yrs experience and, depending on specialty, at least 6 mos to 2 yrs experience acquiring proficiency in a specialty. ASSISTANT TO DIRECTOR: Meets educational requirements for director and 1 yr experience; combination of 7 yrs education, training & experience and passes examination; or meets requirements for technologist and 3 yrs academic study & and 12 mos training and 3 yrs experience.	X		X		X(1968)
Nev.	X	X		X	DIRECTOR: B.S. in biological sciences and 5 yrs experience. TECHNOLOGIST: 3 yrs college + experience training. ASSISTANT TECHNOLOGIST: 2 yrs experience under direction of person at doctorate level. MEDICAL TECHNICIAN: h/s graduate + 2 yrs experience as technician trainee or completed 50 wks med lab procedures course. LAB ASSISTANT: h/s and 1 yr training by certified lab director. LAB TRAINEE: Enrolled in approved formal education program.	X				X(1967)

STATUS OF STATE LABORATORY LEGISLATION IN THE U.S.

	PRESENT REQUIREMENTS FOR LABORATORIES				REQUIREMENTS FOR LABORATORY PERSONNEL	PERMIT		LABORATORY LEGISLATION		
	Labs Covered		Mandatory Supervision by Physician	Performance Evaluation	Education and Training	License, Permit or Certificate	Examination	States Introducing Lab Legislation in 1970	States Where Lab Legislation Has Failed (1970)	States Adopting Lab Legislation in '67, '68, '69, or '70
	Independent	Hospital								
N.H.	X	X	X		None					
N.J.	X				DIRECTOR: M.D. or Ph.D. to bachelor's (with experience on ascending scale).	X	X	X	X*	
N.Y.	X	X		X	DIRECTOR: M.D. or Ph.D. with board certification in pathology, clinical chemistry or microbiology; or licensed M.D. with "sufficient" experience; or M.D., D.V.M. or D.D.S. with long lab experience. No requirements for personnel below this level.	X		X	X	X(1970)**
N.Y.C.	X	X		X	DIRECTOR: Pathologist, or M.D., D.V.M. or D.D.S. with sufficient experience or PhD. board certified in 1 or more lab disciplines. SUPERVISOR: M.D. to bachelor's (with experience on ascending scale). TECHNOLOGIST: Bachelor's + board certification. TRAINEE: 60 semester hours of college credits in science + 1 yr training.	X	X			
Ohio								X		
Okla.								X	X	
Ore.	X	X			DIRECTOR: Sc.D. or Ph.D. with major in chemical, physical, or biological science and special qualifications.	X				X(1969)

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STATUS OF STATE LABORATORY LEGISLATION IN THE U.S.

PRESENT REQUIREMENTS FOR LABORATORIES					REQUIREMENTS FOR LABORATORY PERSONNEL	PERMIT		LABORATORY LEGISLATION		
	Labs Covered									
	Independent	Hospital	Mandatory Supervision by Physician	Performance Evaluation	Education and Training	License, Permit or Certificate	Examination	States Introducing Lab Legislation in 1970	States Where Lab Legislation Has Failed (1970)	States Adopting Lab Legislation in '67, '68, '69, or '70
Penn.	X			X	DIRECTOR & SUPERVISOR: M.D. to bachelor (with experience on ascending scale). TECHNOLOGIST: Bachelor's + 1 yr experience or training. TECHNICIAN: 2 yrs of college, 1 yr of training + 2 yrs in lab.	X	X	X		
R.I.	X			X	ADMINISTRATOR: 10 years of lab experience.	X				
S.C.								X	X	
Tenn.	X	X		X	DIRECTOR: Ph.D. in chemical, physical, or biological science + 4 yrs experience. SUPERVISOR: B.S. + 6 yrs experience. TECHNOLOGIST: B.S. + 2 yrs experience. TECHNICIAN: h/s + 1 yr training.	X	X	X	X	X(1967)
Tex.	X	X	X		None					
Wis.								X	X	
P.R.	X	X		X	DIRECTOR: M.D. to bachelor's (with lab experience on ascending scale). TECHNOLOGIST: Bachelor's + 1 yr in accredited school of medical technology and 5 yrs of experience.	X	X			

REGULATION OF

CLINICAL LABORATORIES

AND THEIR PERSONNEL

1969

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REGULATION OF CLINICAL LABORATORIES AND THEIR PERSONNEL

In recent years the public has become aware of the desirability of regulating clinical laboratories and their personnel. Various studies have indicated that a substantial number of laboratory tests may be performed or reported incorrectly.

The following draft is the product of extended consultation with an advisory group composed of leaders in the professions dealing with clinical laboratories and, hopefully, represents the most enlightened professional thinking on an approach to the problem of regulation.

The Act would apply to all laboratories except those operated by the United States Government, those operated exclusively for teaching and research, and small laboratories used by physicians in connection with their private practice.

Licensing procedures are provided for both clinical laboratories and personnel. The licensing program and standards would be established by the appropriate State department and licenses could be suspended or revoked for specified offenses. The draft also includes a prohibition against fee-splitting and solicitation of business, and provides a penalty section for violations. In general, the suggested Act parallels standards found in federal legislation and regulations.

Sugested Legislation

[Title should conform to State requirements. The following is a suggestion: "An Act to provide for the regulation of clinical laboratories and their personnel and for related purposes."]

(Be it enacted, etc.)

Section 1. Purposes and Findings.

The legislature finds that clinical laboratories provide essential services to the medical practitioner and, through him, for the patient by furnishing vital information for the diagnosis, prevention, or treatment of any disease, or impairment of, or the assessment of the health of, man. Consequently, the regulation of clinical laboratories and the prescribing of qualifications for professional and technical personnel employed thereby is necessary in the public interest in order to reduce the hazards of improper performance.

Section 2. Exemptions.

(a) This Act shall not apply to clinical laboratories:

(1) Operated by the United States Government.

(2) Operated jointly by not more than two duly licensed physicians exclusively in connection with the diagnosis and treatment of their own patients.

(3) Operated and maintained exclusively for research and teaching purposes, involving no patient or public health services.

(b) Notwithstanding anything in this Act to the contrary, the provisions of Section 7 (b) shall apply to clinical laboratories described in item (a) (2) of this Section.

Section 3. Definitions.

As used in this Act:

(1) "Person" means any individual, firm, partnership, association, corporation, the State, or any municipality or other subdivision thereof, or any other entity whether organized for profit or not.

(2) "Department" means the [State Department of Public Health, including the State Board of Health where applicable.]

(3) "Board" means the [State Board of Public Health.]

(4) "Clinical laboratory" means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, man.

(5) "Director" means an individual in overall charge of the technical and scientific operations of the laboratory including the reporting of findings of laboratory tests.

(6) "Supervisor" means an individual, other than the director, who may supervise technical personnel, perform tests requiring special scientific skills, and is held responsible for the proper performance of all clinical laboratory procedures within his area of special competence and the reporting of results.

(7) "Technologist" means an individual who performs tests which require the exercise of independent judgment and responsibility, with minimal supervision by the director or supervisor, in only those specialties or subspecialties in which he is qualified by education, training, and experience.

(8) "Personnel" means the director, supervisor, and technologist.

Section 4. Powers of the Department.

In addition to powers conferred elsewhere in this Act, the Department may:

(1) Issue, amend, and repeal rules and regulations for the implementation of this Act, after consultation with one or more advisory committees authorized in Section 9.

(2) Establish and enforce standards governing the construction, renovation, maintenance, safety, and sanitary requirements pertaining

to clinical laboratories to the extent that they are not otherwise subject to requirements imposed by law or municipal ordinance.

(3) Prescribe qualifications for any one or more categories of clinical laboratory personnel, including microbiology, serology, chemistry, hematology, immuno-hematology, biophysics, cytology, pathology, or other specialties. To the extent feasible such qualifications shall take into consideration standards formulated by appropriate professional associations.

(4) Formulate and administer or contract with appropriate professional organizations for such formulation and administration of, written, oral, and practical examinations to determine the qualifications of clinical laboratory personnel for the purpose of licensure.

Section 5. Licenses.

(a) No clinical laboratory shall be operated without a license issued and in force pursuant to this Act unless it is a function of a hospital licensed by the State.

(b) No individual shall function as a director, supervisor, or technologist unless he is the holder of a license issued and in force pursuant to this Act, or he is a licensed practitioner of [the healing arts] who possesses additional qualifications in clinical laboratory science specified by the Department.

(c) Applications for licenses shall be made to the Department on forms prescribed by it. The application shall indicate the procedures or categories of procedures to be performed and shall contain such additional information as the Department may require. Each application shall be accompanied by the fee prescribed by the Department, and no such fee shall be returnable, whether or not the license applied for is issued.

(d) The license applied for shall be issued, if the Department finds that all requirements therefor are met, or, in the case of a new clinical laboratory not yet in operation, that the owner is in a position to meet them. A license shall authorize the performance of one or more procedures or categories of procedures and shall be valid for [one year] from the date of issue, unless sooner canceled, suspended, or revoked.

(e) A clinical laboratory license may be denied, revoked, suspended, limited, or renewal thereof denied for knowingly:

(1) Making false statements of material information on an application for clinical laboratory license or any other documents required by the Department;

(2) Permitting unauthorized persons to perform technical procedures or to issue or sign reports;

(3) Demonstrating incompetence in the performance or reporting of clinical laboratory examinations and procedures;

(4) Performing a test for or rendering a report to a person not authorized by law to receive such services;

(5) Referring a specimen for examination to a clinical laboratory in this State which has not been licensed under this Act;

(6) Making a report on clinical laboratory work actually performed in another clinical laboratory without designating the name of the director and the name and address of the clinical laboratory in which the test was performed;

(7) Lending the use of the name of the licensed clinical laboratory or its personnel to an unlicensed clinical laboratory;

(8) Violating or aiding and abetting in the violation of any provision of this Act or the rules or regulations promulgated hereunder; or

(9) Violating any other provisions of law applicable to the proper operation of a clinical laboratory.

(f) A clinical laboratory personnel license may be denied, revoked, suspended, limited, or renewal thereof denied for knowingly:

(1) Making a false statement of material information on an application for a license or any other document required by the Department;

(2) Performing or attempting to perform or representing himself as entitled to perform any clinical laboratory procedure or category of procedures not authorized in his license;

(3) Demonstrating incompetence in the performance or reporting of clinical laboratory examinations or procedures;

(4) Performing a test for or making a report thereon to a person not authorized by law to receive such reports;

(5) Violating or aiding and abetting in the violation of any provision of this Act or the rules or regulations promulgated hereunder; or

(6) Violating any other provisions of law applicable to the proper operation of a clinical laboratory.

(g) A license shall be valid only in the hands of the person or persons to whom it is issued and shall not be the subject of sale, assignment, or transfer, voluntary or involuntary, nor shall a license be valid for any premises other than those for which issued until the new premises are approved by the Department.

(h) Each clinical laboratory shall have a licensed director. Unless specifically authorized by the Department, an individual shall not be permitted to direct more than three clinical laboratories.

(i) A clinical laboratory license shall specify on the face thereof the names of the owner and director, and procedures or categories of procedures authorized, the period for which it is valid, and the location at which such procedures must be performed. The license shall be displayed at all times in a prominent place where it may be viewed by the public.

(j) If a clinical laboratory carries on one or more of its functions at one or more separate locations, a license shall be required for each such location.

(k) Licenses issued pursuant to this Act shall be subject to renewal in accordance with rules and regulations of the Department.

(l) The Department shall fix and publish, and from time to time revise, a schedule of fees for applications and renewals. Such fees for

clinical laboratory licenses shall be in amounts calculated to defray the costs of necessary inspections, evaluations, and investigations related thereto, but no fee for application or renewal of a personnel license shall be in excess of [$25].

(m) Any person who knowingly or with reasonable cause to know makes a false or misleading statement of a material fact in connection with any application for a license or renewal thereof pursuant to this Act, in addition to any other penalty or remedy, is guilty of perjury.

Section 6. Acceptance, Collection, Identification, and Examination of Specimens.

(a) A clinical laboratory shall examine human specimens only at the request of a licensed physician, dentist, or other person authorized by law to use the findings of laboratory examinations.

(b) The results of a test shall be reported only to or as directed by the licensed physician, dentist, or other authorized person who requested it. Such reports shall include the name of the director and the name and address of the clinical laboratory in which the test was actually performed.

(c) All specimens accepted by a clinical laboratory shall be tested on the premises, unless forwarded to another properly licensed clinical laboratory.

(d) Only a licensed physician or a person authorized by law shall manipulate a person for the collection of specimens, except that duly licensed clinical laboratory personnel may, upon the written request or confirmation of a licensed physician, dentist, or other person authorized by law, or in connection with the taking of specimens for a purpose covered by subsection (i) hereof, collect human blood or materials for smears or cultures.

(e) No person shall represent, or maintain an office or specimen collection station or other facility for the representation of any clinical laboratory situated in this State or any other State which makes examinations in connection with the diagnosis and control of diseases unless the clinical laboratory so represented shall meet or exceed the minimal standards issued by the Department pursuant to this Act and the regulations issued hereunder.

(f) The Department may require laboratories to show evidence that specimens shipped through the mails and accepted by them for analysis are sufficiently stable for the determinations requested.

(g) Records involving clinical laboratory services and copies of reports of laboratory tests shall be kept for the period of time and in a manner prescribed by the Department.

(h) Each clinical laboratory shall establish its own quality control program acceptable to the Department including use of, where applicable, reference or control reagents, standards, serums or other biological or chemical samples, concurrent calibration standards, and control chart recordings.

(i) Subsections (a), (b), and (c) hereof shall not apply to the

taking, examination, or testing of specimens by a clinical laboratory or its personnel solely in order to test the accuracy or sufficiency of its procedures, or equipment or in order to make improvements in the same.

Section 7. Reporting.

(a) The Department may require reporting by clinical laboratories of evidence of such infectious diseases as the Department may prescribe. The Department may furnish or approve forms for such reporting. The reports shall not be construed as constituting a diagnosis nor shall any clinical laboratory making reports be held liable for having violated a trust or confidential relationship. The reports submitted shall be deemed confidential and not subject to public inspection.

(b) Every director of a clinical laboratory shall report to the Department such information regarding the operation of the clinical laboratory as may be requested by the Department or required by the rules and regulations of the Department in order to aid in the proper administration of this Act.

Section 8. Inspection and Evaluation.

(a) The Department shall make periodic inspections of every clinical laboratory, at its discretion, but in no case less often than [once in each year]. For the purposes of this subsection, the employees or agents of the Department shall have the right of entry into the premises of the laboratory during the hours of operation.

(b) The Department shall operate a clinical laboratory evaluation program and shall prescribe standards of performance in the examination of specimens. As part of the clinical laboratory evaluation program, the Department may require the clinical laboratory to analyze test samples submitted or authorized by the Department and report on the results of such analyses.

Section 9. Advisory Committees.

The Department shall appoint one or more multidisciplinary committees to assist it in the administration of this Act.

Section 10. Hearings and Judicial Review.

(a) No license issued pursuant to this Act may be suspended, revoked, or denied without a hearing, if requested by the holder of or applicant for the license on due notice. If a hearing is requested, the Department shall make written findings of facts and conclusions on which its action is based.

(b) Any action of the Department taken pursuant to or under the color of this Act shall be reviewable as provided in the [State administrative procedure act]. [If there is no State administrative

procedure act, or if a special review procedure is desired, make appropriate provisions.]

Section 11. Substitution of Qualifications.

In determining the qualifications of an applicant, the Department may accept training and experience acquired prior to the effective date of this Act in lieu of education.

Section 12. Effect of Act.

Nothing in this Act shall authorize any person to practice medicine or to furnish the services of physicians for the practice of medicine. This Act does not repeal or in any manner affect any provisions of the laws of this State relating to the practice of medicine.

Section 13. Prohibitions, Penalties, and Enforcement.

(a) No person shall:

(1) Solicit referral of specimens to his or any other clinical laboratory or contract to perform clinical laboratory examinations of specimens in a manner which offers or implies an offer of rebate, fee-splitting inducements or arrangements, or other remuneration.

(2) Violate or aid or abet the violation of any provision of this Act, or the rules or regulations in force pursuant hereto.

(b) Any act or omission prohibited by subsection (a) hereof shall be punishable as a misdemeanor.

(c) Whether or not there is a prosecution pursuant to subsection (b) hereof, any act, omission or course of conduct prohibited by subsection (a) hereof may be prevented, corrected, or penalized by injunction or any other remedy. Suit shall be [by the Department] [by the Attorney General on referral of the Department].

(d) Nothing in this Act shall prevent or limit any private cause of action or the recovery thereon.

Section 14. Effective Date.

[Insert effective date.]

[If a State desires to include detailed qualifications for the director of a clinical laboratory, it may refer to definitions contained in Title 20, Section 405.1312 (b), Code of Federal Regulations.]

ATTACHMENT NO. 11

ATTACHMENT NO. 12

This attachment compares the annual budget increases of the SPHL and the SHD, with the percentage increase over the prior year shown in parenthesis to the right. Also shown in the far right column is the ratios of lab. expenditures to Department of Health expenditures.

Fiscal Year	Microbiology Laboratory Division Expenditures	Percentage Increase from prior Year	Department of Health Expenditures	Percentage Increase from prior Year	Percentage of Lab. expenditures to Health Dept. Expenditures
1961	91,306		969,122		9.4
1962	92,582	(1.3)	989,568	(2.1)	9.3
1963	98,957	(6.8)	1,023,597	(3.4)	9.7
1964	92,220	(-6.8)	1,089,645	(6.4)	8.5
1965	99,599	(8.0)	1,238,247	(13.7)	8.0
1966	105,045	(5.4)	1,470,776	(18.6)	7.1
1967	120,005	(14.2)	1,867,947	(27.0)	6.4
1968	135,867	(13.2)	1,949,372	(4.3)	6.9
1969	139,996	(3.0)	2,470,618	(26.7)	5.6