FEASIBILITY OF AN EPA CERTIFICATION PROGRAM

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FEASIBILITY
OF AN
EPA CERTIFICATION PROGRAM

By

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Contract No. 68-03-2012
Program Element No.

Project Officer

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Prepared for
OFFICE OF RESEARCH AND DEVELOPMENT
U. S. ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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EXECUTIVE SUMMARY

This study, which was sponsored by the Methods Development and Quality Assurance Research Laboratory of the U.S. Environmental Protection Agency, explored the possible certification of environmental monitoring laboratories as a means for assuring that the quality and reliability of data generated by them would meet at least minimum levels of acceptability. A clear distinction is made between the formal and administrative aspects of the certification process and the technical evaluatory procedures through which laboratory eligibility would be established. It is recommended that laboratory evaluation be conducted by EPA's Quality Assurance organization. It is believed that the current QA Inter-laboratory Program, if appropriately expanded and provided with sufficient resources, could, in conjunction with the NERCs, adequately fulfill the evaluatory function. It is also recommended that responsibility for program formalities, including certification decision making, be vested in a new EPA element which would be organizationally separate from the QA organization.

During the early phases of the study, various on-going laboratory certification programs were examined. These programs, operated by Federal, State and private organizations, related to various types of laboratory activity (clinical, milk, water, etc.). In virtually all cases, however, the same elements were found to occur as the bases for laboratory certification or accreditation. These elements are:

- Laboratory facility evaluation, based on direct inspection.
- Assessment of personnel credentials in terms of established criteria for training and experience.
- Evaluation of laboratory performance through proficiency testing. (Results of analyses of test samples are compared with target values.)

The principal objective of the certification program survey, which included on-site visits to accrediting organizations and to laboratories approved under their programs, was to elicit factual information and viewpoints which might be helpful in the development of a plan for EPA consideration. A key finding was that, in most instances, certification programs were strongly influential in upgrading the quality and reliability of laboratory data. The proficiency testing component of

these programs was usually cited as the prime factor because it enables the laboratories to pinpoint specific areas of deficiency and institute remedial action.

The study also included an analysis of various important issues relating to structural and procedural aspects of an EPA certification program. The principal conclusions are:

- EPA should operate a certification program directly, rather than as a contracted service.
- Responsibility for procedural aspects of the formal certification process should be vested in a central EPA entity established for this purpose.
- Responsibility for all standard setting, evaluatory and other technical support functions should be assumed by the Quality Assurance program staff.
- Certification should be conducted on an integrated (cross-programmatic) basis, rather than implemented by separate certifying entities for the different EPA programs (air, water, pesticides, etc.).
- EPA should certify only to the State level, with State agencies assuming responsibility for approving intra-state laboratories.
- EPA should not attempt to institute laboratory certification in all programs simultaneously, but should first address water analysis laboratories (the need is judged to be greatest in this area), then air laboratories, then radiation laboratories and ultimately, possibly, pesticide laboratories.
- EPA should schedule State laboratory certification on a progressive basis, beginning with a small number of States already operating water laboratory licensing or approval programs in addition to one State in which such a program does not now exist.

An outline of a preferred certification program plan was formulated, reflecting the above conclusions as well as several more detailed recommendations.

The direct cost to EPA of establishing and operating a State laboratory certification program is believed to be moderate. On the other hand, it appears certain that many State agencies will require substantial funding support in order to establish and maintain effective environmental laboratory certification programs.

EPA-

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ABSTRACT

Certification or licensing of environmental monitoring laboratories by EPA was examined as a mechanism for assuring data conformity with minimum acceptable standards of quality and reliability. Various on-going laboratory certification programs conducted by Federal, State and private organizations were reviewed in a preliminary survey. A recommended program was developed for EPA's consideration under which the Agency would certify or license State environmental laboratories, with the States then certifying intrastate laboratories, using Federally established criteria. Legislative authorization for this program is considered a pre-requisite. EPA's direct role in the certification process which would operate as an adjunct to its current Quality Assurance interlaboratory program, is not believed to entail excessive costs. Many States, however, would require substantial supplementary funding support for establishing and operating their programs.

ACKNOWLEDGEMENTS

The authors wish to acknowledge the cooperation received from the many officials associated with Federal, State and private organizations who provided information during the performance of this study. Specific thanks are extended to the following for their help:

Environmental Protection Agency

Paul Britton, National Environmental Research Center, Cincinnati, Ohio
Thomas W. Stanley, Quality Assurance Division, Washington, D.C.
Headquarter and Regional Office Staffs

Officials associated with the laboratory certification programs reviewed in this study and staffs of the laboratories operating under these programs.

The authors also wish to express their appreciation of the contributions of Ira Blei and Arnold Greenberg to this study in providing guidance and advice and in performing reviews of some of the certification programs discussed in this report.

I CONCLUSIONS

- Surveys of several existing analytical and testing laboratory certification programs conducted by Federal, State and private organizations showed an essentially similar structure, regardless of the areas of technical involvement. Typically this structure includes the following key elements: facility inspection and evaluation, personnel qualification based on experience and/or training and laboratory performance assessment by proficiency testing.

- Most certifying organizations and the laboratories operating under their programs agreed that the laboratory qualification process, based on defined standards and criteria, substantially improved the quality and reliability of the data produced.

- The principal benefit to EPA of an environmental monitoring laboratory certification program is that it would provide the agency with a legal basis for refusing to accept data of uncertain quality and reliability as might originate from uncertified facilities. Conversely, a laboratory certification program would greatly enhance the probability that data generated by approved facilities would satisfy the Agency's minimum reliability requirements.

- A laboratory certification program operated by EPA should be based on legislative authority and should directly license only State laboratories, with the responsibility for the certification of intra-state laboratories borne by State agencies. Further, while it would be desirable to certify all States simultaneously in all programmatic areas (air, water, etc.),it may prove more feasible to initiate certification in one program area and extend State coverage progressively until all are included because of cost and other considerations. One possible approach is to initiate certification with selected States on a voluntary, cooperative basis and subsequently to make it mandatory for all States.

- The cost of EPA program operations could approximate $750,000 annually for the certification of State water laboratories. The total annual costs of State certification programs would be considerably higher and the requirement for Federal support of these programs through grants is viewed as inevitable.

II RECOMMENDATIONS

- EPA should examine both the strength of current legislative authority and the prospects for obtaining explicit authority for requiring environmental monitoring laboratory certification prior to initiating a regulatory program. It is also recommended that the Agency consider the merits of an interim voluntary program conducted on a cooperative basis with selected States, even though this program would lack regulatory force.

- The formal and administrative components of a laboratory certification program should be regarded as separate from technical evaluatory activities directed to determing the potential capability and actual performance of a candidate laboratory. It is recommended that responsibility for these activities, as well as the initial setting of criteria and standards for laboratory qualification, reside with Quality Assurance components of the Regional Offices and the NERCs. It is also recommended that a distinct administrative EPA element be established for implementing the purely formal functions of the certification program and that this entity be independent of the Agency's Quality Assurance organization.

- EPA should preferably certify State laboratories only, with the States certifying intra-state laboratories. EPA certification of intra-state laboratories should occur only in event of default by the State.

- The program should be addressed initially to water laboratories, then to air laboratories and then to radiation and, possibly, to pesticide laboratories.

- The term "certification" is not recommended for several reasons. It is suggested that State and other governmental laboratories be "accredited" or "qualified" and that private laboratories be "licensed."

- Laboratories should be qualified or approved only for those specific test or analytical categories within which their ability to satisfy the program standards and criteria has been established.

III INTRODUCTION

The certification of environmental monitoring laboratories has been proposed as a possible mechanism for supporting the efforts of the U.S. Environmental Protection Agency's data Quality Assurance (QA) Program. The importance of this Program is difficult to overstate because the information derived from environmental monitoring activities addressed to air quality, water quality radiation and pesticide surveillance is pivotal to most of EPA's decision making processes, to its assessments of progress and trends in pollution abatement and to the implementation of its emission and effluent discharge control responsibilities. The Agency's performance is thus critically dependent on the quality (i.e., the accuracy and reliability) of the environmental data which constitute its operating information base. It is therefore in no way incorrect to regard QA as coequal in importance with monitoring itself, rather than as a supplement to this function.

An underlying data quality problem faced by EPA arises from the fact that environmental monitoring, on the national scale, is not wholly performed by a single Federal agency controlling uniformly organized surveillence operations. In reality, a substantial proportion of monitoring functions is delegated to State environmental agencies and disseminated to local government and privately operated laboratories. The range and variety of the latter is quite broad. For example, some private laboratories engaged in water analysis are large, well equipped and well staffed establishments. Others are little more than one- or two-man operations with severely limited facilities and resources. This is not to imply that data generated by smaller laboratories are necessarily less reliable than those developed by larger organizations. However, it is clear that the large number (in the thousands) and diversity of environmental monitoring laboratories dictate the need for a centrally administered and comprehensive QA program in order to ensure that, to the degree practicable, environmental data received and evaluated by EPA, regardless of their source, will meet defined reliability criteria. During the last few years the Agency has been developing a QA program specifically designed to accomplish this objective. While initially addressed to the establishment of uniform quality assurance standards and procedures through all EPA laboratories, it is now being extended to State environmental monitoring agencies and should ultimately include all participating analytical laboratories, both publicly and privately operated.

Although the preceding discussion stressed the importance of the QA role in relation to analytical laboratory operations, it must be appreciated that its application to other aspects of environmental sampling is no less important. These include sample acquisition techniques (particularly insofar as these may affect sample "representativeness") and also methods for sample preservation which are designed to assure that its chemical and physical parameters have changed only minimally during the interval between collection and subsequent analyses.

This study, whose broad purpose was the evaluation of environmental monitoring laboratory certification in terms of its feasibility and its potential contribution to the support and advancement of EPA's QA interests, was primarily oriented to policy considerations and the examination of possible modes of implementation as opposed to essentially technical factors. Specific project objectives included an assessment of the probable benefits and costs of certification as well as the formulation of various certification program options. During the course of the study, certain potential problems were identified which could present obstacles to program establishment or could impair the effectiveness of its implementation. Such problems are discussed later in this report. The study was performed in successive phases as follows:

Phase I: Preliminary Survey

Several on-going certification programs administered by Federal, State and private organizations were examined in terms of processes, criteria and other major characteristics. These programs specifically related to the certification of laboratories (as opposed to products, educational institutions, etc.) in several areas of activity, such as clinical, drinking water testing, and so forth. In addition, numerous interviews were conducted with EPA personnel, including those representing programmatic interests (air and water pollution abatement) and those directly associated with QA activities.

Phase II: In-Depth Program Studies

Selected certification programs were examined in detail through visits with officials responsible for their administration and through on-site discussions at laboratories certified under these programs. The purpose of this phase of the study was to gain information and elicit opinions regarding the nature of any problems these programs had encountered, operating cost experience and benefits achieved.

Phase III: Program Option Identification and Assessment

Various environmental monitoring laboratory certification program options were identified and reviewed in terms of their advantages and disadvantages from EPA's standpoint. The overall certification process was initially separated into various major administrative and procedural elements and alternative approaches for each of these were then formulated.

Phase IV: Development of Preferred Option

Using the analysis performed in Phase III as a basis, a preferred certification program option was developed for EPA's consideration. This study Phase included preparation of various procedural recommendations for program establishment and implementation, as well as an identification of prospective benefits of the program to the Agency.

The following discussion, which deals with certain conceptual aspects of laboratory certification, is intended to provide a background orientation

which may be found particularly helpful to those with little direct association with the process.

In principle, the certification of an analytical or testing laboratory, regardless of its specific functions, is the formal recognition by a qualified evaluatory organization that the laboratory in question has satisfied a set of established criteria relating to its capability and performance. Accordingly, the data generated by a "certified" laboratory are presumed to be more likely to meet defined standards of reliability and accuracy than might be the case for an uncertified facility. This consideration is, in itself, the basis of EPA's interest in examining the certfication of environmental monitoring laboratories as a mechanism which could contribute to the attainment of its data quality objectives.

Virtually all laboratory certification processes are based on three categorical evaluatory elements whose specific details differ from program to program, but whose fundamental character is invariant. Of those, two relate to the assessment of the inherent capability of the laboratory being appraised. The third concerns actual laboratory performance. In summary, these elements are:

a) Facility Assessment

Through on-site visits and, in many cases, through information previously submitted by the applicant laboratory, the certifying organization performs an evaluation of the candidate's facility in terms of both physical and functional parameters. The former usually include such factors as adequacy of laboratory space, general layout, equipment and the like. Functional parameters may include not only the test and analytic methods routinely employed but also internal quality control procedures, such as details of sample handling and identification, instrument calibration frequency and the maintenance of an adequate and reliable set of reference standards.

b) Personnel Assessment

Professional and technical staff credentials often required as prerequisites to laboratory certification, are usually specifically identified by the certifying organization. These credentials typically reflect both education and experience and, under some programs, provide a basis for certifying a laboratory with respect to only certain categories of analysis and testing within its possible range of capability.

It is important to recognize that a laboratory which has met the criteria of a certifying body with respect to the above assessment categories has, at that point, established only that it is potentially capable of acceptable performance. Whether actual performance demonstrates this capability must still be determined. For this reason, certification processes necessarily include, as a third categorical element, some form of laboratory performance evaluation.

c) Performance Testing

The laboratory under evaluation is provided with test samples which it then analyzes, usually employing procedures which are either formally "approved" by the certifying organization or otherwise acceptable to it. The differences between the results submitted by the laboratory and the "target" figures provide a measure of performance. Although similar in basic purpose and principle, performance testing procedures conducted under different certification programs vary considerably with respect to such details as the frequency of post-certification testing, the identification or non-identification of test samples as "unknowns", acceptability criteria and the degree to which the laboratory under review is informed of its performance with respect to other laboratories.

Most certifying organizations require recertification (or renewal of certification) of an approved laboratory either after some predetermined time interval or after some major alteration in the laboratory condition (such as removal to a new location or a significant change in staff) has occurred. Typically, certification programs also provide for facility re-examination and assessment as well as for repeated performance testing on a scheduled basis during the period certification is in effect.

A central thesis of this study is the establishment of a clearcut division of the overall certification process into two distinct categories as follows:

a) Technical

This category includes all technical program elements and actions involved in or directly related to the evaluation of an applicant laboratory in terms of the adequacy of the facility, its apparent capabilities and its demonstrated performance. It also includes the setting of standards and criteria on which qualifications for certification are to be based as well as functions ancillary to evaluation such as the provision of reference samples.

b) Formal

This category includes all administrative, legal and regulatory program elements and actions involved in or directly related to the formal implementation of the certification process. Examples of such actions include: processing laboratory certification applications; assessing data and information derived from laboratory facility and performance evaluation in terms of applicable standards and criteria; determining laboratory eligibility or no-eligibility for certification on the basis of this assessment; and implementing the formal certification of laboratories judged to be qualified.

The considerations underlying this distinction, which is not commonly stressed within most laboratory certification programs, are discussed later in the report. In general, they are based on the fact that EPA's QA activities already include the operation of an Inter-laboratory Quality Assurance Program which, although still in the early stages of its development, could in the future provide all of the evaluative and other technical functions appropriate to the technical category (a) above. Further, for reasons which are presented later, it is recommended that, while the responsibility for all technical actions related to the certification process (standard setting, facility evaluation, etc.) remains within EPA's Quality Assurance operation, responsibility for formal and administrative procedures (such as identified in (b) above) be vested in a new EPA organizational component which would be independent of the QA structure.

Although the term "certification" is used throughout this report as a matter of convenience, there are certain reservations about its appropriateness as the official descriptor of an actual program, should one be implemented by EPA. A major reservation is that "certification" of a laboratory could be construed as meaning or implying that the "certifying" entity (EPA, in this case) in effect guaranteed the accuracy and reliability of data produced by that laboratory. Because of this, it would appear advisable to use some other term, such as "accreditation," "approval," "licensure," or "qualification." (In California, for example, water analysis laboratories are "approved" by the responsible State agency). The designation of a laboratory as "qualified," "accredited," or "approved" would, in itself, express the fact that it had satisfied acceptability criteria, but would be far less subject to the interpretation that EPA assumed responsibility for the validity of the data generated by the laboratory. It is considered, however, that in view of the regulatory implications of laboratory certification, which would provide EPA with a legal basis for the rejection of data originating from unqualified sources, that the use of a stronger term would be more appropriate.

This study was oriented primarily to policy related aspects of laboratory certification, as seen from EPA's vantage point, rather than to specific technical considerations. Thus, much of the ensuing discussion relates to certification as a formal process rather than to its technical details. However, under a coordinated program EPA's Methods Development and Quality Assurance Research Laboratory, National Environmental Research Center, Cincinnati, Ohio, is sponsoring several studies, in addition to this one, which are specifically technically oriented and which should prove directly contributary to both the attainment of the Agency's QA objectives and to the implementation of a laboratory certification program. The projects which are specifically pertinent to the latter are:

- Development of a System for Conducting Inter-laboratory Tests for Water Quality and Effluent Measurements (This project is being conducted by FMC, Inc.)

  It is expected that this study will result in the design of detailed proficiency testing and similar procedures which,

although addressed to water analysis laboratories, will include guideline principles applicable to laboratories engaged in developing environmental data relating to other media (air, pesticides, etc.)

- Protocol for Laboratory Inspection (This project is being conducted by Tracor, Jitco, Inc.)

  It is expected that this project will result in the development of laboratory inspection and assessment procedures and criteria which will include considerations of general applicability as well as those specifically related to analytic operations oriented to specific media (air, water, pesticides, etc.).

IV STUDY FINDINGS

This Section provides a report on the investigative aspects of the study and discusses certification program options developed during the formulation of a preferred approach for EPA's consideration. These options are treated in terms of their pros and cons and the recommended plan is assessed from a benefit/cost standpoint. The following discussions are organized on the basis of the study phases previously identified in the Introduction.

Phase I: Preliminary Survey

Certification Program Reviews: Methodology

As part of this study phase a survey was made of existing certification programs operated by Federal, State and private entities and was conducted largely through telephone interviews and through the examination and analysis of available descriptive materials supplied by the certifying organization. In performing the survey, emphasis was placed on those programs which relate to analytical and testing laboratories. Other certification programs which are concerned mainly with product approval or with the accreditation of educational institutions were not reviewed because their purposes and goals are not germane to the objectives of this project.

Over twenty organizations were identified as either directly conducting certification programs or as influencing such operations. All of these were examined and fourteen were selected for further analysis. This selection was based on the following criteria:

- The organization currently conducts or is preparing to conduct a laboratory certification program.
- The program involves laboratories whose operations are either related to environmental monitoring directly or are addressed to analagous analytical or testing activities.
- Availability of sufficient information to permit a reasonably complete description of the certification process and requirements.

Certification programs and qualification criteria administered or established by the following organizations were examined, but not selected for analysis are as follows:

- Department of Defense, Defense Electronic Supply Center
- American Dental Association

- Law Enforcement Assistance Administration
- The National Committee for Careers in the Medical Laboratory
- American Chemical Society
- American National Standards Institute
- American Council of Independent Laboratories
- American Society for Testing and Materials
- National Bureau of Standards

The programs selected for further study are the following:

Federally Operated

- Food and Drug Administration (HEW, PHS), Bureau of Foods
  Approves State milk testing laboratories
- U.S. Department of Agriculture, Animal and Plant Health Inspection Service
  Certifies private meat inspection laboratories
- Center for Disease Control (HEW, PHS) Laboratory Licensure Section
  Licenses clinical laboratories
- Occupational Safety and Health Administration (Department of Labor, Division of Safety Standards
  This Agency contemplates accreditation of laboratories engaged in the evaluation of safety of products, materials, installations, etc.
- Social Security Administration (HEW), Bureau of Health Insurance
  Qualifies independent clinical laboratories for eligibility for reimbursement for services performed under the medicare program.
- Office of Water and Hazardous Materials (EPA), Water Supply Division
  Certifies State laboratories analyzing potable water on interstate carriers.

State Operated

- New York State Department of Public Health, Division of Laboratories and Research
  Approves laboratories for testing public water supply samples.

- Oklahoma Department of Health, Syphilis Serology Proficiency Testing Program
  Certifies clinical laboratories for serological testing

- Oklahoma Water Resources Board*
  Licenses water analysis laboratories.

- Connecticut State Department of Public Health
  Approves private and municipal water laboratories.

- California State Department of Public Health
  Approves laboratories engaged in water quality testing.

- California State Department of Public Health*
  Licenses clinical laboratories

Privately Operated

- American Industrial Hygiene Association
  Accredits laboratories performing analyses of air samples (from the working area) and biological specimens whose examination is dictated by work related considerations.

- College of American Pathologists, American Society of Clinical Pathologists
  CAP accredits clinical laboratories. ASCAP certifies laboratory personnel.

It should be noted that certain institutions, such as the American Council of Independent Laboratories and the American Society for Testing and Materials have developed standards and criteria for laboratory performance which have contributed to the evolution of laboratory approval procedures. These organizations, however, do not operate formal certification programs and, for this reason, are not included in the above list.

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* The synopsis of this program was developed during Phase II of the study.

The analyses of the fourteen selected programs are presented in Appendix I as synopses which are based on a more or less uniform format structure. This structure which was designed to emphasize the major program features and elements specifically relating to EPA's own certification interests, employs the following topical headings:

I Background

A. Nature of Program

The key functions of the program are briefly described together with other available general information.

B. Authority

In the case of Federal and State programs, the authorizing or enabling legislation is identified.

C. Objective

The essential purpose of the program is defined.

II The Certification Process

A. Scope

The principle elements of the certification process are identified, as well as the size of the program in terms of the number of laboratories approved or qualified under it.

B. Laboratory Elements Evaluated

All factors relating to laboratory capability and operation which are examined and evaluated during the certification process are identified. These factors or elements typically include the basic facility, equipment, procedures, personnel and record keeping practices.

C. Procedure

The procedure through which a laboratory becomes certified is summarized. Procedures employed for recertification or for the maintenance of certification are also identified.

III Identified Problem Areas

Any problems described under this heading are those which were identified by certifying organization personnel (as opposed to personnel of certified laboratories).

IV Program Administration and Evaluation

Information provided here deals primarily with the basic organization of the certifying entity and also identifies any methods used by this entity for assessing the effectiveness of its operation.

V Cost and Level of Effort Estimates

Where estimates of program operating dollar costs, or equivalent data, were available, such information is included.

VI Comments

Any general useful information relating to the program which is not appropriate to the other headings is noted here. This includes, for example, information regarding any interrelationships which may exist between the certifying organization described and other certifying entities.

As had been initially supposed and as confirmed by the Phase I study, practically all laboratory certification programs are based on the same key elements which include the facility itself, the personnel and operating procedures. The actual certification process is, as stated earlier, usually implemented through facility and personnel evaluation based on site visits and on the analysis of information supplied by the applicant and through performance for proficiency testing. Programs differ primarily with respect to the degree of importance or emphasis placed on the above elements, rather than in terms of essential principle or approach. Table I on page 14 presents a summary of the program synopses in a manner which permits ready comparison of the key elements of a given program with the corresponding elements of another. The differences among these programs with respect to stress placed on different laboratory elements can easily be noted.

In performing this survey, it was usually possible to obtain considerable information about the certification programs and their important features through telephone interviews. A consistent problem, however, was the difficulty of eliciting data regarding program costs, either as a whole or on a per laboratory basis. This difficulty did not appear to reflect any unwillingness or reticence on the part of the interviewees, but rather a surprising dearth of available information. The problem was more severe in the case of Federal and State agencies than in that of private organizations.

Within the context of the total project, the certification program studies conducted under Phase I served two key purposes: One of these was to provide information useful in selecting case example programs to be examined in greater detail in Phase II. The other was to clarify the definition of the major elements common to most laboratory qualification programs and to detect any specific features of these which could be

TABLE I
ANALYSES OF CURRENT LABORATORY CERTIFICATION PROGRAMS

NATURE OF PROGRAM	STATE PROGRAMS						FEDERAL PROGRAMS						PRIVATE ORGS.	
	CAL.		CONN.	N.Y.	OKLA.		HEW, CDC	EPA, WSD	HEW, BUR. OF FOODS	USDA, APHIS	HEW SOC. SEC.	LABOR, OSHA	CAP	AIHA
Type of Laboratory Certified														
Commercial														
Environmental	X		X		X			X						
Clinical		X				X	X				X		X	
Other[1]									X	X		X		X[6]
Governmental														
Environmental	X			X				X						
Clinical						X	X							
Other[1]									X					
Authority														
Not specific					X					X	X	X	NA	NA
Explicit Legislation	X	X	X	X	X		X	X	X				NA	NA
The Certification Process														
Scope														
Number of laboratories Certified	450	2000	60	100	200	37	700	50(approx)	50(approx)	166	300	NONE[3]	12,000	26[4]
State examiners certified by Federal Agency	NA	NA	NA	NA	NA	NA		X	X		X		NA	NA
Laboratory Elements Evaluated														
Facility														
Stressed as Qualification requirement			X		X	X								
Noted as Qualification Requirement	X			X			X	X	X	X	X	X	X	
Not an explicit qualification requirement														X

NATURE OF PROGRAM	CAL.		CONN.	N.Y.	OKLA.		HEW, CDC	EPA, WSD	HEW, BUR. OF FOODS	USDA, APHIS	HEW, SOC. SEC.	LABOR, OSHA	CAP.	AIHA
Personnel														
Stressed as Qualification requirement		X	X		X		X				X			
Noted as Qualification requirement	X			X		X		X	X	X		X	X[5]	X
Procedures														
Initial Certification Procedure														
Site visit is performed	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Proficiency testing	X				X	X			X	X			X	X
Certification Maintenance Procedure														
Reinspection	X	X	X	X	X		X	X	X		X	X	X	X
Proficiency testing	X		X		X	X	X		X	X	X	X	X	X

1. Programs in this category are principally concerned with food and product testing and also industrial health laboratories.
2. NA means not applicable.
3. The program has not yet been implemented.
4. 99 additional applications have been received. Final determinations concerning their accreditation will be made after the required site vists are performed.
5. The American Society of Clinical Pathologists is responsible for personnel certification.
6. These laboratories are involved in industrial health related areas such as toxicology and the evaluation of the local working environmental air samples.

useful in developing program options under Phase IV.

Certification Program Reviews: General Findings

The studies conducted under Phase I confirmed an original impression to the effect that there are, as yet, very few certification programs directed specifically to the licensing or approval of environmental monitoring laboratories. For this reason, the scope of the Phase I survey was deliberately made sufficiently broad to include programs directed to clinical and testing laboratories, since several such progams exist which are well established and documented. In principle, the basic procedural features of these programs are inherently applicable to environmental laboratories. The major differences involve underlying policy, institutional interrelationships and technical details, all of which can be readily separated from generic certification procedures and requirements.

The following discussion summarizes the general findings derived from the analysis of the programs reviewed and is organized so that topical presentations are keyed to the format described earlier.

I Background

A. Nature of Program

Of the fourteen programs presented in Appendix I, five relate to the accreditation of clinical laboratories. (The Oklahoma program approves both municipal and private laboratories, while the other four deal with private laboratories exclusively.) Five of the programs listed (of which four are State operated and one is administered by EPA's Water Supply Division) are mainly concerned with the monitoring of public water supplies, although in some instances they also oversee laboratories engaged in effluent discharge analysis and ambient water quality determinations. Of the four remaining programs, three of which are operated by Federal agencies, two deal with food testing by State and private laboratories and one with private laboratories involved in product testing and one with private industrial health laboratories.

B. Authority

Federal laboratory monitoring agencies vary with respect to the specificity of the legislative fiats under which they operate. For example, the CDC program is authorized by the Clinical Laboratories Improvement Act of 1967 which requires the licensing of laboratories accepting specimens introduced into interstate commerce. Also, HEW's Bureau of Foods' certification program applying to milk testing laboratories derives its authority from the Grade A Pasteurized Milk Ordinance which stipulates that these laboratories be "official" or "officially

designated," a status which must be achieved through inspection, evaluation and proficiency testing. On the other hand, USDA's program for approving meat testing laboratories is not specifically mandated under the 1906 Meat Inspection Act which the Agency generally cites as its authority. Actually, this Act states that meat which is to be transported across State lines must first be Federally inspected and that the cost of such inspection shall be borne by the Government. Under this program, the private laboratories which inspect the meat act as agents of the USDA and their certification by this Agency is an administrative decision rather than a legislatively authorized and mandated requirement.

Many State programs are either authorized under prevailing State health codes or are provided for under general administrative statutes. On occasion, however, statutory language may be somewhat liberally interpreted in program execution. For example, the California State Department of Public Health "approves" water laboratories under Article 2 of Group 6, Title 17, entitled "Need and Authority for Approval", specifically references "water supply". However, it appears that the "approval" mechanism is applied to laboratory operations addressed to the analysis of effluent and ambient water as well as to drinking water.

C. Objective

Various certification programs define their objectives in different ways, some of which are quite broad and loosely worded, such as "the protection of the public health, safety and welfare". In all cases, however, they are obviously addressed to the enhancement of the reliability and quality of the data relating to their area of administrative activity.

II The Certification Process

The certification program synopses presented in Appendix I are not designed to describe every detail of the criteria and processes they summarize. These descriptions were developed with the primary goal of identifying those elements which are the distinctive policy and procedural aspects of the programs examined and which EPA would consider, at least generically, should it elect to implement formal certification of environmental monitoring laboratories. Accordingly, the program descriptions emphasize key procedural mechanisms and factors rather than specific technical considerations which tend to reflect only the specific area of activity of a given laboratory category.

A. Scope

The range of program size, in terms of the number of laboratories

certified, is considerable and falls within extreme limits of 25 at the low end to 12,000 at the high end. The scope of these operations was also examined in terms of utilization of personnel in other organizations which were not a direct part of the certifying agency. It was found that three Federally operated certification programs utilize State personnel for the performance of laboratory inspection and evaluation.

B. Laboratory Elements Evaluated

Facility

Virtually all certification programs include facility evaluation which is generally performed through both on-site visits and the review of information supplied by the applicant (such information is usually submitted prior to the site visit).

Laboratory Procedures

In nearly all instances laboratory procedures are required to conform with standard methods as set forth in designated laboratory manuals or reference texts. Deviations are sometimes permitted, but usually only when the laboratory can demonstrate satisfactory methods equivalency. During the interviews, most of the certifying entities stated that internal laboratory quality control is a prerequisite for approval. However, it was found that the term "quality control" is interpreted differently by different organizations and, in many cases, means only that laboratory equipment must be periodically calibrated.

Personnel

All programs, without exception, consider personnel qualifications. Three of them lay particular stress on specific details of training and experience.

C. Procedure

Most of the certification procedures examined in Phase I include three key elements, as follows:

- Examination and assessment of information supplied by the applicant laboratory. This information is usually provided on forms provided by the certifying organization. Aside from the differences in these forms which reflect the different technical natures of the laboratory operations, there are also differences with respect to the level of detail required.

- Direct laboratory inspection and evaluation. This is accomplished through on-site visits, as mentioned earlier. These visits are usually pre-arranged. Some programs require that the inspection personnel must themselves be certified.

- Performance testing. Split sample or similar check procedures are employed by practically all certifying entities. In many cases performance testing is an integral part of the initial certification procedure. In some, performance testing is employed only in connection with certification maintenance or with recertification.

III Identified Problem Areas

The problem areas identified in the various certification programs studied necessarily represent those difficulties perceived by the program representatives with whom interviews were conducted. It therefore does not follow that these problems, as articulated, include all of those which may actually exist. In most cases, the problems mentioned reflected, in one way or another, the difficulty of operating with inadequate funding resources. Typical manifestations of severe budget limitation include inadequate proficiency testing programs, insufficient numbers of trained laboratory inspectors and a general and pervasive lack of capability for performing certification program activities at a level of effectiveness considered desirable by the responsible organizations.

IV Program Administration and Evaluation

It is not possible to generalize with respect to program administrative practices and organizational structure. For example, some of the certifying entities conduct centralized operations while others, such as the Social Security Administration, make greater use of regional and local personnel.

Most of the certifying organizations surveyed do not have formally established procedures for evaluating the effectiveness of their programs. This is considered to be, possibly, the most serious shortcoming common to these operations as a whole. In general, they depend on such haphazard and unsystematic feedback as may be forthcoming from field inspectors and from personnel in the certified laboratories.

V Cost and Level of Effort Estimates

In most instances, as has already been indicated, specific operating cost data for the programs examined was not available. Although, in some instances, the fees charged by the certifying organizations were provided, there was little reason for assuming that these bore

a meaningful relationship to actual costs. Estimates of the time required for the performance of laboratory inspections ranged from about one to two days, excluding travel and report preparation. In general, it was believed that one inspector could "cover" up to, but not more than 100 facilities per year. No useful information was obtained with respect to precise proficiency testing costs, although the supervisor of the Oklahoma Department of Health's Syphillis Serology Proficiency Testing Program estimated that one to two manhours are required to evaluate laboratory performance in a given test area. Other specific costs incident to proficiency testing such as reference sample preparation and distribution, data handling and analysis and the like do not appear to have been identified and categorized in the programs studied. Further, it did not appear that most program representatives had carefully considered the indirect or overhead costs of certification program operation.

Opinion Survey: Methodology

Numerous interviews were conducted with EPA personnel, State environmental agency officials and representatives of private environmental monitoring laboratories, prinicipally, but not exclusively, by telephone. Most of these interviews were performed during the Phase I portion of the study. It was assumed that, should EPA elect to adopt a certification program, much of the responsibility for its actual implementation would devolve on the Regional Office staffs and, for this reason, QA personnel from all ten EPA Regions were included among those interviewed. The overall objective was to sample the views and opinions of those who would be involved with conducting the program as well as those to whom it would be addressed.

Opinion Survey: General Findings

The following presentation, which summarizes the views encountered in this survey, is organized according to the entities with which the interviewees were associated. Few, if any, of those interviewed discussed the topic of enviornmental monitoring laboratory certification on a comprehensive basis. The usual tendency was to emphasize those particular aspects of the subject which related directly to the individual's specific activities or interest. The summary below does not reflect all comments elicited, but does take into account those considered to present some definitive position. It is emphasized that the opinions here represent individual viewpoints and should not be construed to reflect organizational positions. Further, any inconsistencies among the viewpoints below, which appear in association with a given entity, resulted from discussions with more than one individual affiliated with that entity.

Entity	Opinions Expressed
EPA Headquarters	
Office of General Counsel	EPA should certify all laboratories directly as opposed to certifying intrastate laboratories via State agencies because . This would avoid a drain on State resources . States cannot muster sufficient personnel to operate programs . More uniform application of certification standards will be achieved
Office of Legislation	Enabling legislation should be in effect prior to program initiation to establish authority. The term "certification" is less desirable, because of its implications, than alternative terms.
Water Planning and Standards (Monitoring and Data Support Division)	The Office of Water Planning and Standards would support certification. No HQ organizational problems are foreseen. State should certify private laboratories. EPA should collaborate with the States in the development of QA programs prior to initiating certification
EPA Regional Offices	
Region I	EPA should certify State laboratories only, with the States certifying intrastate laboratories. Although private laboratories engaged in effluent monitoring are required to observe QA practices, they are under pressure from the discharger employing their services. Certification, accompanied by suitable regulatory procedures, would promote data accuracy and objectivity.

Entity	Opinions Expressed
Region II	States should certify intrastate laboratories.
	EPA should develop uniform standards. Reference samples should be produced by NBS or commercial firms and distributed by them to State agencies.
	A certification program should be administered from EPA HQ and should be uniformly applied throughout all regions.
	The program should begin with water laboratories, possibly with those engaged mainly in effluent analysis.
Region III	States should certify private laboratories using existing trade associations.
	EPA's direct certification of intrastate laboratories could be regarded as infringement (on State prerogatives).
	EPA should retain a liaison with certifying State agencies, possibly a monitoring relationship.
	EPA should provide free training to State agency personnel.
Region IV	States should certify intrastate laboratories.
	EPA would gain no real advantage in certifying State laboratories because these are being covered under the QA program.
	EPA should provide reference samples and consistent criteria for data reliability.
	EPA should perform periodic performance testing (interlaboratory) of State certified laboratories.
	EPA should provide training for State laboratory personnel, with the States training intrastate laboratory personnel.

Entity	Opinions Expressed
Region V	EPA should initiate certification in relation to water laboratories
	Many States would require legislation to implement program.
	Private laboratories, in most instances, would welcome certification.
	EPA should provide respositories of test samples and reference standards.
Region VI	Certification should be optional with the States. Most States lack adequate manpower to conduct the program.
Region VII	Funding is a key problem; most State laboratories (in reference to Region VII) are badly equipped due to lack of resources.
	Grant support to States is essential.
	Region VII itself would require additional funding.
	There exists no current authority for unannounced laboratory inspection; this would be necessary under a certification program.
Region VIII	EPA should certify to State level only; States should certify intrastate laboratories.
	States should be permitted to provide inputs to certification program formulation to avoid possible later resistance.
Region IX	Private laboratories performing effluent analyses and stack emissions testing must attest to the accuracy of the data they report; hence, certification is superfluous.
	EPA should certify to the State level only, with the State agencies certifying intrastate laboratories.
	EPA should initiate certification with water laboratories.

Entity	Opinions Expressed
Region X	EPA should initiate certification with air laboratories because there are fewer of these (than of water laboratories) and thus the program would be easier to implement at the beginning. Because laboratories perform a variety of procedures, certification should be based on specific test and analysis capabilities (as opposed to a comprehensive certification of the laboratory as a whole).
State Laboratories (air and water)	Certification by EPA would impose no real burden since the officials interviewed considered that capabilities and performance were of sufficiently high level to ensure that their laboratories would experience no difficulties in complying with any reasonable standards and criteria EPA might establish. The concept of formal certification of intrastate laboratories by EPA directly was, in all instances, regarded as totally unacceptable and representing a violation of State prerogatives. (The State agencies interviewed were, on the whole, those recognized as conducting high quality monitoring operations; therefore, their view that State laboratory certification by EPA would not be burdensome, at least on technical grounds, should not be construed as necessarily typical of the position other States might take.)
Private Laboratories	Representatives of the independent private laboratories interviewed welcomed the idea of certification because they considered that this would remove the competition now experienced from organizations regarded as technically inferior.

Entity	Opinions Expressed
	(This opinion was elicited from a relatively small sample of laboratories generally regarded as competent. Therefore, it is not presented as necessarily typical.)

In general, many EPA Regional Office personnel interviewed independently agreed that an environmental monitoring laboratory certification program, if implemented, should:

- Provide for certification of State laboratories, with the States assuming responsibility for the certification of intrastate laboratories.
- Be initiated in connection with water laboratories, and then expand from there to encompass other programs. (The basis for this view is in part the large number and diversity of water laboratories now reporting data under the NPDES program. Most Regional Office personnel interviewed consider that effluent compliance monitoring requirements impose some of the most significant pressures they now face with respect to the administration of water programs.)
- Provide training and assistance to State agencies to facilitate program establishment and implementation.
- Provide for funding State certification programs and Regional Office support.

Phase II: In-depth Program Studies

Methodology

It had been considered that through direct on-site interviews with certification program officials and with the personnel of laboratories certified under their programs it should be possible to elicit information, viewpoints and suggestions which could be helpful to EPA in the development of its own certification operation. On the basis of the preliminary certification program survey conducted under Phase I and supplementary information, the eight programs identified below were selected for further study. In this selection process, both the appropriateness of specific programs and the representativeness of the administering entities were considered. Thus, the list includes two Federal, four State and two private operations.

Federally Operated

- Food and Drug Administration, Bureau of Foods
  Milk testing laboratories

- Public Health Service, Center for Disease Control
  Clinical laboratories

State Operated

- Connecticut Department of Health
  Water quality laboratories
- New York Department of Public Health
  Potable water quality laboratories
- Oklahoma Water Resources Board
  Water analysis laboratories
- California Department of Public Health
  Clinical laboratories

Privately Operated

- American Industrial Hygiene Association
  Industrial health laboratories
- College of American Pathologists
  Clinical laboratories

The interviews with program officials were, to the degree possible, structured to incorporate at least the following three elements:

- Review of program synopsis for updating, general accuracy of the presentation and modification or correction of details, as appropriate. (The synopses, which appear in Appendix I, reflect any changes made in consequence of these reviews.)
- Elicitation of program overview, as seen by the interviewee, and details of actual program operation.
- Elicitation of information regarding perceived problem areas, program costs and program benefits.
- Elicitation of suggestions for EPA's consideration in formulating its own certification program.

The interviews with personnel associated with the certified laboratories were designed to elicit the following:

- Estimation or opinion of program benefits to the laboratory.
- General experience with the program in terms of any difficulties associated with compliance as well as perceived problem areas.

- Program suggestions for EPA's consideration.

(Where possible, the interviews were conducted with program and laboratory directors or other key personnel and samples of printed program materials (such as descriptive information and laboratory appraisal forms) were obtained.)

General Findings

Key informational findings and opinions elicited during the Phase II portion of this study are presented below by program. Factual information and expressions of opinion are listed under separate headings for identification. In general, a considerable amount of the program information provided was already known to the interviewers and is synopsized in Appendix I. Therefore, informational elements appearing in the following presentation are largely those which do not appear in the synopses. Reference to the appropriate summaries in Appendix I will be helpful in reviewing the following presentations.

FEDERALLY OPERATED PROGRAMS

HEW, Food and Drug Administration, Bureau of Foods
Program: Approval of Milk Testing Laboratories

Certifying Entity

Factual Information

- All 50 States participate in this program on an essentially voluntary basis. Progam standards, criteria and procedures are based on the "Grade 'A' Pasteurized Milk Ordinance" and detailed in an issuance of PHS's Division of Environmental Engineering and Health Services entitled "Evaluation of Milk Laboratories".

- The Laboratory Development Section (LDS) has approved 65 State central laboratories. These in turn, have approved approximately 800 local municipal, industrial and commercial laboratories. State laboratory evaluation personnel must be themselves certified by LDS. Milk testing laboratories are approved and their analysts certified for specific procedures. Proficiency testing using split samples tends to dominate the overall qualification process.

- Of the 65 approved State central laboratories, 25 are re-evaluated each year on the basis of site visits, during which on-going laboratory procedures are observed and assessed. It was estimated that the average level of effort per laboratory inspection is 3-man days.

- The mechanism for "feed-back" of evaluatory information to the State central laboratories includes the following elements:

- The laboratories are informed of specific "deviations" which were detected during the site visit and which should be corrected.

- After completion of proficiency re-testing (at least on an annual basis) and analysis of the results, the evaluations are then transmitted to all laboratories simultaneously. Thus, each laboratory can rank its performance against that of other State central laboratories.

Opinions Expressed

- The principal program benefit is perceived as an improvement in the precision and accuracy of laboratory data.

- Favorable attitudes to people and correct interpersonal relationships (Federal/State personnel) are considered vital to effective program implementation.

- If resources were available, the program would benefit from the the following:

    - Increased frequence of proficiency testing to twice annually

    - The preparation of audio/visual tape presentations of all laboratory techniques as instructional aids for State and local laboratory personnel.

    - A more extensive seminar program.

    - The establishment of a system of regional consultants who would assist State laboratories in technical matters.

    - More frequent revision of guidance materials.

    - Evaluation of State central laboratories every two, rather than every three years.

- A central to regional to State form of program organization is preferable to the central to State type of operation which now exists.

- A "strong" central support staff is essential.

- An evaluatory Federal inspection and evaluation agency with multi-disciplinary competence (for the assessment of many types of laboratory operations) would be desirable in order to minimize the number of site visits to laboratories engaged in several categories of programs.

Certified Laboratory (City of Cincinnati Health Department Laboratory)

Factual Information

- No significant factual information beyond that already available was elicited.

Opinions Expressed

- Perceived program benefits:
  - The facility and its equipment were upgraded in consequence of deficiencies noted during evaluation.
  - Laboratory procedures became more standardized.
  - Information supplied with respect to results of proficiency testing was contributory to performance improvement.
  - An overall improvement in the quality of data generated by the laboratory.
- Criticisms of Program/Problem Areas:
  - Biennial laboratory evaluations may be redundant.
  - Because the milk sample collection system is unreliable, sample representativeness and holding times are uncertain, with possible adverse effects on data accuracy.
  - Split samples used in proficiency testing are identified as such; "blind" samples would provide a better basis for performance assessment.

HEW, Public Health Service, Center for Disease Control (CDC)
Program: Licensing of Clinical Laboratories (engaged in interstate commerce)

Certifying Entity

Factual Information

- All clinical laboratories (engaged in interstate commerce) are covered by the program. Currently, there are 700 licensed laboratories. In addition, about 1,500 "voluntary" laboratories (non-licensed) participate in proficiency testing activities. Small laboratories which process less than 100 samples per year are exempted from the requirements of the Clinical Laboratories Improvement Act under which the program is mandated.

- All Medicare laboratories will soon be included in the program and, since these number about 5,000 to 6,000, there will be an appreciable strain on the inspection capabilities of the program. The present laboratory inspection staff of nine performs about 1,000 inspections per year. CDC's Laboratory Licensure Section staff totals 67 technical, administrative and clerical personnel and receives support from the Agency's Laboratory Division whose staff is about 800.

- The program is funded at the rate of approximately $9,000,000 annually, of which a considerable amount is expended on program improvement. It was found difficult to determine the annual amount spent on laboratory licensing activities as such, but this is believed to be in the neighborhood of $2,000,000.

- Because the primary objective of the program is laboratory performance improvement considerable stress is laid on proficiency testing (which is conducted quarterly). Results are fed back to the participating laboratories on a systematic basis.

- The effectiveness of the program is reflected by the fact that laboratories new to it show an average deficiency rate of 21.4 as opposed to a rate of 9.9 for laboratories participating in the program for longer periods.

- Operation of the program is conducted either directly by CDC or through the College of American Pathologists (CAP) and through State agencies (in theory). (At present, however, the only State approved by CDC is New York.) About 10% to 20% of the laboratories qualified under the CAP and New York programs are audited by CDC.

- The present CDC program is being modified to (a) augment the objectivity of the internal QC program and on-site profile check lists and (b) strengthen the proficiency testing grading system and delisting criteria. For example, at present a laboratory must score four unsatisfactory quarters in a row before it is delisted. A moving average system which would be a more responsive indicator of poor quality work is now being considered.

Opinions Expressed

- CDC officials consider the following essential to an effective laboratory accreditation program:

    - Standards must be formulated on the basis of an objective concensus.

- Explicit standards and criteria must be stated in the regulations.
- The licensing authority must maintain control of the program.
- Facility evaluation must be based on a check list to eliminate subjectivity on the part of the inspector.
- A proficiency testing program must be maintained on a regular basis.
- The licensing authority, not the State, should delist.
- Data processing should be automated.
- If State programs exist, the State should evaluate and the Federal agency should accredit.
- Facility inspection check lists should be designed to objectivize the process to the degree possible. For example, questions should be answerable in terms of "yes", "no", "NA", or numerically.

- It is suspected that some laboratories may send their proficiency testing samples to outside analysts and then represent the results as their own.
- The CDC Administrators believe that their experience in operating the laboratory accreditation program could be effectively used by other agencies.

Certified Laboratory (Northern Virginia Pathology Laboratories)

Factual Information

- Northern Virginia Pathology Laboratories (NVPL) are accredited under the programs of both the Center for Disease Control (CDC) and the American College of Pathologists (CAP). The facility is large, with a staff of 160 to 180 and is qualified for all major categories of both programs in which they have participated since their inception.
- The laboratories are inspected by CAP every two years and perform self-inspection on alternate years. These self-inspections are conducted on an inter-departmental basis, i.e., technicians associated with some given department inspect a different department.

- NVPL employs certain internal quality control procedures which are not required under either the CAP or CDC programs. For example, in addition to running standards through analysis equipment on the basis of every tenth reading, unknowns are submitted to the operating technicians. Also, statistical records of mean values of all analyses are maintained. A drift in these means, up or down, from historic values is interpreted as a warning signal indicating the possibility of a laboratory operational problem.

Opinions and Observations Expressed

Because the laboratories are qualified under both CAP and CDC, the officials interviewed were in an excellent position to provide a comparison of the two accreditation programs as seen by a working laboratory. Their observations synopsized below therefore include references to both of these programs and also reflect comparative assessments.

- The CDC program appears more mandatory in nature. For example, although the CAP and CDC delisting procedures are quite similar, CDC letters citing deficiencies are "tougher" and more authoritative in tone. Therefore, the laboratory tends to react more strongly to unsatisfactory results reported back under the CDC program.

- Although both CDC and CAP take pride in their systems for feedback to the laboratories (of evaluations) and both organizations devote considerable effort to the completeness of statistical reporting, NVPL believes that the data sent back is needlessly complicated.

- On-site inspections conducted by CDC are considered more uniform than those performed by CAP, although the CAP checklist is more objective. This is attributed to the fact that CDC employs full-time inspectors, while CAP uses volunteer pathologists.

- It was felt that both organizations ask too many trivial questions and dwell too heavily on OSHA (Occupational Safety and Health Administration) requirements. NVPL believes that OSHA should concern itself with safety considerations and that CDC and CAP should be less occupied with the number of fire extinguishers available and more with such matters as analytical equipment and procedures that bear directly on laboratory performance.

- NVPL believes that its self-inspection may be more rigorous than the CAP inspection.

- NVPL believes that CDC should be more specific in the

formulation of its requests. For example, ambiguities sometimes result because findings are reported in different units from those desired by CDC and in these cases the results are considered incorrect, even though the analyses may have been accurate.

- Sometimes, standards suggested by CDC for use in maintaining equipment calibration could not be obtained (by them). NVPL believes that CDC should provide the participating laboratories with specific information as to where such standards are commercially available.

- The cost of accreditation (to the laboratory) was considered reasonable.

- NVPL considers that yearly on-site visits performed by full-time inspectors coupled with quarterly proficiency testing constitute the basis of an effective laboratory approval program

STATE OPERATED PROGRAMS

Connecticut State Department of Health, Laboratory Standards Section
Program: Approves Water Laboratories

Certifying Entity

Factual Information

- The State Department of Environmental Protection, which is responsible for the maintenance of Federal/State standards, does not operate its own water analysis laboratories, but depends on local laboratories which require annual approval. This requirement provides the Laboratory Standards Section with considerable control in that a laboratory found unacceptably delinquent may be declared a health hazard by the State Department of Health and immediately closed down.

- Both municipal and private laboratories are approved under the program. These include facilities performing analyses of potable water as well as sewage plant and industrial effluents.

- The initial approval process includes site inspection and evaluation, but the program as a whole, particularly annual re-approval, rests largely on proficiency testing which is highly emphasized. Test samples are sent to the laboratories by the Laboratory Standards Section and results are provided to the laboratories within approximately three weeks. The results are expressed in comparative terms, showing the laboratory's

score for a particular test vs. the mean result of all peer laboratories. It was estimated that the average annual proficiency testing cost per laboratory, for all analyses, lies between $300 and $400.

Opinions Expressed

- The agency regards the key objective of its program to be laboratory improvement, rather than laboratory approval as such. That is, Laboratory Standards Section personnel are more concerned with upgrading laboratory performance than with the maintenance of minimal standards. They appear to feel that a Federally operated program is more apt to adopt minimal standards as a working goal and this approach they find totally unacceptable.

- The Laboratory Standards Section regards its program as highly successful as judged by the responses of the laboratories they evaluate. They find the laboratories eager to receive test results quickly and very willing to receive prompt help from the Section when problems develop.

- The most serious perceived problem relates to test sample preparation. Samples have been obtained from EPA NERC/Cincinnati at no cost so far and will still be available from QALE Branch, though possibly not in the required amounts.

Certified Entity (Bridgeport Hydraulic Company Laboratory)

Factual Information

- No significant previously unknown factual information about the programs or its operation was provided.

Opinions Expressed

- The Laboratory Standards Section's program is well regarded. It has been found helpful in correcting technical problems and has provided the basis for upgrading laboratory equipment.

- The program is judged to be too lenient in eliminating laboratory operations of questionable quality and should be firmed up in this respect.

- The response of the State agency to laboratory data submission, is considered quite rapid and it was doubted that a Federal operation could respond as quickly.

- It was felt that where State agency programs are now operating effectively, they should be permitted to continue without Federal interference. However, where States have no effective certification or licensing apparatus, the introduction of a Federal program may be the only realistic solution.

- Two desirable Federal roles are seen as:

    - Establishment of uniform measurement standards which would compel laboratories to use modern equipment.

    - Provide guidance to laboratories in the cost/benefit evaluation of modern competitive analytic instrumentation.

New York State Department of Health, Division of Laboratories and Research
Program: Approves Laboratories Analyzing Potable Water

Certifying Entity

Factual Information

- Laboratories are rated as either "satisfactory" or "approved". A "satisfactory" facility is one which has passed inspection with respect to the facility, equipment and demonstrated skills of the technicians, but which has no professional staff. An "approved" laboratory is one which is both "satisfactory" and also has a professional staff. "Satisfactory" laboratories are generally those associated with municipal waterworks. "Approved" laboratories are usually independents. Directors of "approved" laboratories must hold bachelors' degrees, as a minimum.

- The agency is quite small with very limited resources. It does not have a reference sample system and, therefore, does not maintain a proficiency testing program.

Opinions Expressed

- The program is frankly regarded as inadequate because of the lack of fiscal and personnel resources.

- The lack of proficiency testing program, which should cover all relevant water pollutants, is seen as the dominating problem.

Certified Laboratory (Bender Hygienic Laboratory, Albany, New York)

Factual Information

- No significant additional factual information about the program was acquired from the laboratory personnel.

Expressions of Opinion and Observations

- Program benefits were said to include:
  - Improved working relationships with State personnel.
  - The weeding out of poorly qualified laboratory personnel (as a result of the laboratory inspection process).
  - Increased uniformity of data quality among laboratories.
  - Improvement of laboratory personnel morale.
- Program shortcomings identified were:
  - Inadequate transfer of information from the State program agency to laboratories qualified under it. In general, it was felt that the program does not keep laboratories up-to-date regarding preferred technical procedures and administrative policies, except in the cases of major issues. For example, laboratory personnel were unaware of the distinction between a "satisfactory" and an "approved" rating.
- Various general suggestions were made regarding suitable elements for incorporation within an EPA certification program, as follows:
  - EPA should certify State laboratories; the State should certify intrastate laboratories.
  - Federal funding should be made available to State programs.
  - EPA should conduct workshops and seminars for State personnel.
  - EPA's program should include a provision for checking the States' proficiency testing operations.

- EPA should encourage the State agencies to hold seminars for intrastate laboratory personnel.

- Specific suggestions with regard to proficiency testing were:

  - Initial test samples used in the EPA/State programs should be identified to "avoid hostility". These first interlaboratory tests would be thus aimed at determining achievable levels, rather than routine performance.

  - In later program steps, obviously spiked samples should then be introduced and, finally, routine "unkowns".

  - State laboratories should receive ratings for all performance tests.

  - State laboratories should have the authority to require EPA Regional Office (or other EPA proficiency testing) laboratories to analyze State prepared test samples. (It was considered that a system providing for mutual EPA/State competence checking would enhance interagency relationships.)

Oklahoma Water Resources Board
Program: Certifies Water and Wastewater Laboratories

Certifying Entity

Factual Information

- The Oklahoma Water Resources Board (OWRB) instituted its laboratory certification program about two years ago after it had determined that a significant number of reported analytical results relating to industrial effluent discharges was found inaccurate.

- Proficiency testing is accomplished through the cooperation of the United States Geological Survey's (USGS) Denver Laboratory which supplies reference samples. The USGS charge for this service is about $35.00 per sample, to which OWRB adds $5.00 for handling.

- Of about 37 laboratories now participating in the program 10 or 12 are independent commercial organizations. The balance are either municipal or industrial laboratories. In addition to sample charges to the laboratories, there is an initial application fee of $25.00 and an annual certification renewal cost which is also $25.00.

- Proficiency testing is performed once annual in order to minimize program costs. Further, neither initial nor annual site inspections are routinely conducted. However, the OWRB maintains 62 industrial discharge check points and compares its own analyses (of these effluents) with those received from laboratories operating under the program. In the event that the laboratory data does not appear to be correct or is inconsistent with that of the OWRB, State agency personnel then make on-site visit to the laboratory in question.

- Of the funds now annually received by Oklahoma from EPA, about $112,000 is allocated for the OWRB operation. The estimated cost of the certification program itself is approximately $5,000 per year.

Expressions of Opinion

- OWRB considers that routine annual on-site visits coupled with quarterly proficiency testing would be ideal.

- Because most water analysis laboratories in the State are small, it is believed that the cost (to them) of remaining in the program is a significant economic consideration.

- OWRB favors an EPA administered program, with intrastate laboratories certified by the State.

- Every certified laboratory should meet national standards and should receive reference samples from the same source.

Certified Laboratory (Oklahoma Gas and Electric Company's Water Laboratory)

Factual Information

- This laboratory is certified as AAA by the OWRB, which means that it is considered competent in all three categories of qualification (see program synopsis in Appendix I).

- Reference samples are received annually from the USGS laboratories in Denver and the analytical results are returned to them directly. USGS evaluates the test data and transmits the rating information to OWRB.

- In the case of the Oklahoma Gas and Electric Water Laboratory (OG&E), OWRB did make an initial site survey in which it examined and evaluated:

    - Personnel

- Laboratory equipment list
- Internal quality control program
- Analytical procedures

Opinions Expressed

- Pollutant concentrations in proficiency test samples are often more dilute than those typically encountered and it is considered that more realistic samples, provided on a quarterly basis, would improve the program.
- OG&E strongly supports the program and believes that OWRB requirements have enabled the laboratory to justify more and better equipment.

California Department of Health, Laboratory Field Services Program: Licenses clinical laboratories and personnel

Certifying Entity

Factual Information

- Laboratory licensing was initiated in 1937 and personnel licensing in 1938. The requirement that physicians' office laboratories, although exempt from licensing, must participate in an approved proficiency testing program, was initiated in 1972.
- Personnel licensing categories are defined and, in most cases, the license issued may be either general or limited (that is, limited to a specialty such as clinical microbiology or clinical toxicology). These categories and their requirements are:
  - Trainee: requires a bachelor's degree
  - Technologist: requires a bachelor's degree and 2 years of trainee or equivalent experience. (A "limited" trainee must have one year of experience in the designated specialty. in addition to a baccalurate.)
  - Bioanalyst: requires a master's degree and 4 years of experience as a technologist.
  - Clinical Chemist or Microbiologist: requires a master's degree and two years of experience in the designated specialty.

Qualifying written examinations are always required and oral and/or practical examinations may also be given.

- Although the agency does not itself conduct a proficiency testing program, it requires that licensed laboratories, as well as those operated by physicians in their offices, participated in such a program approved by the agency. These approved programs include those administered by the College of American Pathologists, American Association of Bioanalysts, California Society of Internal Medicine and Center for Disease Control.

- Laboratories participate in proficiency testing on a quarterly basis. The testing program provides both the data and evaluations to the State agency. In the event of two consecutive "bad" results, the laboratory is requested by the State to discontinue the provision of services in the "failure" area. Services may be resumed after two consecutive "good" results which, presumably, indicate that appropriate corrective measures have been taken.

- Except in the case of Medicare laboratories, site visits are made every five years. In the former case they are annual.

- State inspection and licensing officers have the title Examiner, Laboratory Field Services. These are licensed laboratory technologists who have received additional on-the-job training.

- The State receives Federal reimbursement for the approval of about 800 Medicare laboratories at the rate of approximately 50% of actual cost. This amounts to $500,000 annually, which implies a total program cost approximating $1,000,000.

Opinions Expressed

(Lack of adequate funding resources was cited below as the root cause of some of the problem areas identified below.)

- Ideally, each laboratory should be visited annually, as is the case with Medicare laboratories. The time required per site inspection ranges from a minimum of four up to eight hours, depending on the size of the facility. At present, visits may not be any more frequent than once every five years.

- The agency cannot satisfactorily review and maintain, on a current basis, the data that it receives from the various

approved proficiency testing programs. Aside from insufficient availability of statistical services, the agency is dependent on another unit within the Department of Health for such computer service as it can acquire and which, it considers, is grossly inadequate for its needs.

- Due to the lack of sufficient State personnel, the agency cannot enforce the requirement that physicians' office laboratories participate in proficiency testing programs. Of the estimated 8,000 such laboratories, it is believed that probably no more than 500 are actually in compliance.

Certified Laboratories (Solano Laboratories, Bio Research Laboratories)

(Note: Two laboratories, representing extremes of scale, were selected in order to ascertain differences of viewpoint reflecting facility size as such. Bio Research Laboratories is a small, independent laboratory with a staff of four or five. Though once quite profitable and a pioneer in mail order clinical laboratory services, it now appears to be well on the decline and fading. Solano Laboratories, on the other hand, is a large operation embracing eight separate licensed laboratories with a total staff of approximately 150.)

Factual Information

- No significant additional information about the California program emerged during the interviews with these laboratories.

Opinions Expressed

- Size, with the attendant economy of scale, is considered to be a critical factor in a successful operation. The small independent laboratory cannot afford automated analytical equipment and is thus at a tremendous competitive disadvantage. (Hospital clinical laboratories having hospital patients as their clients, are essentially free of such competition.)

- Many of the observations made by both laboratories related to the difficulties experienced in operating within the regulatory framework. The following specific points were made in this connection:

    - Successful laboratories tend, increasingly, to conduct mail order operations across State lines. This often requires multiple licensing by States as well as licensing by the Federal government. In consequence, there is considerable duplication of effort which, it is felt, actually provides little benefit to the public and none to the laboratory.

- California requires different licenses for different types of laboratory operation and these are administered by separate agencies within the State Department of Public Health. General clinical laboratory licensure falls under the authority of Laboratory Field Services. Licensure for radiological procedures is controlled by the Radiological Health Section. Licensure for alcohol and methadone testing falls under the Clinical Chemistry Laboratory and testing for PKU (phenylketonuria) involves the Family Health Services Section. Each of these agencies has different forms, different procedures and different personnel. In addition, the licensing processes under each program may require separate site visits and evaluations.

- Proficiency testing programs required both by the State of California and by the Federal government are found costly, in terms of both the service fees and the time required for the analyses. For a small laboratory, such as Bio Research, this cost is a significant fraction of its total operating expense. In the case of a large laboratory, such as Solano, the economic impact is relatively unimportant, but the sample frequency is objectionably high (almost weekly for Solano). Of greater concern (to Solano) is the delay which is often experienced in receiving proficiency results so that indicated deficiencies can be corrected. It was stated that such delays may extend to six months. It was also noted that, for the same proficiency testing sample, the State and Federal agencies may have different standards of acceptability.

- A major focus of criticism was the lack of adequate regulation of physicians' office laboratories. These were represented as severely requiring greater formal supervision and control. For example, about 10 to 12 percent of the total of Solano Laboratories technical operation is directed to internal quality control activities. Office laboratories, in contrast, may spend no time whatever on quality control.

- On the positive side, the interviewees at both laboratories agreed that the public is better served because of licensing requirements. While the system is regarded as far from perfect, it is believed that State regulation has considerably reduced the frequency of poor (incorrect) data. Also, from the laboratory

viewpoint, the licensing of personnel provides the facility with better qualified job applicants.

- In relation to the possibility of certification or licensure of environmental monitoring laboratories, it was suggested that any such program should avoid duplication of effort within a State, between States, and between State and Federal controls. Rather, a single State regulatory system was recommended, with reciprocity among States and operated under Federal guidance.

PRIVATELY OPERATED

American Industrial Hygiene Association
Program: Accredits Industrial Health Laboratories

Certifying Entity

Factual Information

- This program, has, since its inception, operated under the sponsorship and support of the National Institute of Occupation Safety and Health (NIOSH) which, originally directly conducted all proficiency testing in behalf of the American Industrial Hygiene Association (AIHA). Proficiency testing operations are now contracted to a private firm (Hyland Laboratories).

- The current standard for laboratory qualification under the proficiency testing portion of the program requires that results fall within $\pm$ 3 standard deviations of the target value.

- Feedback of proficiency testing results is provided to the laboratories by NIOSH.

- AIHA is responsible for facility and personnel evaluation. Prior to inspection, a "Pre-Site Questionnaire provides both for general information which is substantially independent of the particular area(s) of laboratory activity and for specifics relating to air sampling, bioassay and so forth. Academic qualifications and required experience are set forth for four categories of laboratory personnel which are:

    - Laboratory Director (preferably, a Diplomate of the American Board of Industrial Hygiene).

    - Laboratory Supervisor (Doctorate in a relevant science or an M.D. with two years experience. Lesser degrees coupled with more experience are acceptable.)

- Industrial Hygiene Technologist (baccalaurate)

- Industrial Hygiene Technician (high school graduate with two years experience, or two years in an accredited college which includes at least one course in analytical chemistry).

Opinions Expressed

- Although the program is too new to evaluate adequately, laboratory performance, based on results of proficiency testing data, collectively shows a trend toward improvement.

- Specific program benefits cited were:

  - Laboratories are now more selective in the hiring of new personnel.

  - Laboratory supervisory personnel seem more induced to take courses in environmental health sciences.

- Program modifications considered desirable were:

  - Extension of the proficiency testing program to include sample acquisition and transport procedures.

  - Inclusion of the requirement that all laboratory personnel be certified by either the American Board of Health Physics or the American Board of Industrial Hygiene.

Certified Laboratory (Maryland State Department of Health and Mental Hygiene, Occupational Health Laboratory)

Factual Information

- This interview did not elicit any previously unkown facts of significance relating to the AIHA program. The Occupational Health Laboratory is primarily in industrial hygiene and air quality procedures and performs analyses for the Maryland State Air Quality Laboratory.

Opinions Expressed

- It was stated that the Occupational Health Laboratory had been too recently accredited to permit an adequate analysis of the effects of the program on the laboratory. Nevertheless, it was believed the proficiency testing portion of the program, which is conducted every two months, has resulted in improved laboratory data quality.

- It was felt that AIHA could improve the program's usefulness through the following:
    - Preparation and updating of a master list of all commercial laboratories accredited under the program. This list would classify the laboratories on the basis of the analytic and test categories in which they are qualified.
    - Establish and maintenance of a central register of trained laboratory personnel, indicating specialty areas of competence.
    - Establishment and operation of training seminars in sample handling procedures. (This is an area which AIHA recognizes as important and highly critical.)
- The Occupational Health Laboratory has experienced considerable difficulty in maintaining a satisfactory internal quality control program because of inadequate staffing. (The annual budget is too low to permit expansion.)

College of American Pathologists
Program: Accreditation of Clinical Laboratories

Factual Information

- The College of American Pathologists (CAP), founded in 1947 and now consisting of over 6,000 Board certified pathologists, conducts a laboratory accreditation program under the authority of the Center for Disease Control (CDC). The CAP program is reevaluated each year by CDC which audits about 10% of CAP approved laboratories.
- Laboratories are initially qualified through an on-site inpection which is repeated on an annual basis. On-site visits are performed by volunteer pathologists who are reimbursed for their expenses only. These pathologists are provided with detailed check lists which are designed to aid in obtaining an objective evaluation. Approximately 1,200 to 1,300 laboratories are inspected each year.
- Three of four workshops or seminars are conducted annually in each of CAP's ten regions for the purpose of training laboratory inspectors. The subjects treated include such matters as changes in the law and field problems typically encountered. Laboratory personnel are free to attend these sessions.

- Proficiency testing is conducted on a quarterly basis, using split samples. Consecutive four quarters of unsatisfactory results by a laboratory is used as the basis for delisting in the particular analytic area in which its performance was unsatisfactory.

- CAP conducts several levels of programs as follows:

    - The "Basic" program, which is designed for the small hospital or independent laboratory, meets Medicare and most State licensure requirements. However, it is not accepted by CDC.

    - The "Comprehensive" program is consistent with the Clinical Laboratory Improvement Act of 1967 and the requirements of CDC in the areas of clinical chemistry, hematology and blood banking. It does not, however, meet the requirements for interstate licensure in the areas of mycobacteriology, parasitology, mycology and serology.

    - The "Special" program is designed to meet the above requirements in microbiology, serology and toxicology. This "Special" program is reviewed each year in a meeting between CAP and CDC administrators.

- Two major differences between the CDC and CAP programs are:

    - The CAP program uses the services of volunteer pathologists for laboratory inspection, as stated above. CDC has a full-time staff for this purpose, each member of which is an experienced clinical laboratory technician.

    - The CDC distributes its reference samples to a group (10 to 20) referee laboratories. The results of analyses performed by these laboratories are then used as the basis for arriving at the mean values of the samples. CAP, on the other hand, uses the results of the participating laboratories to determine the sample mean values.

- CAP offers a variety of services to clinical laboratories independently of its accreditation function as follows:

    - Under the Proficiency Evaluation Program (PEP), the laboratory may be assessed in terms of performance without being accredited. About 700 laboratories have enrolled in this program.

- Under the CAP Quality Assurance Service (QAS), a laboratory may submit its daily quality control data on a weekly basis. This data is reduced by CAP and a computer print-out returned to the laboratory.

- CAP publishes a variety of laboratory guides and manuals such as "Standards for Accreditation of Medical Laboratories," a "Survey Data" series which relates to PEP, "Management of Your Quality Control" and "Laboratory Instrument Maintenance and Function Verification".

- CAP operates programs for the V.A. Hospital system, Army hospitals in North America and Europe, Navy Hospital in the continental United States and for all U.S. Air Force hospitals. At present, 38 States accept CAP programs as the basis for licensure.

Opinions Expressed

- CAP considers its principal objective to be the upgrading and improvement of the clinical laboratories operating under its programs.

- Major problems have been:

  - Obtaining personnel to perform inspections. (It is estimated that the use of full-time personnel would add $400-$500 to the annual expense of each participating laboratory.

  - Inducing more laboratories to participate in the program.

- CAP is acutely aware that the CDC program is markedly less expensive (for the participating laboratories) since the latter is Federally subsidized. Thus, CAP officials consider that they are competing with the Government on an unfair basis. However, they also feel that the competition between the program is, in general, productive of better and more effective laboratory operations. They maintain, though, that CDC's fee structure should more accurately reflect its program costs.

- CAP believes that, in general, laboratory accreditation programs establish and track the level of proficiency of the laboratory categories to which they are directed. Specifically, they believe that the evidence supports their view that the CAP program has significantly upgraded the

level of performance of the average laboratory participating in it.

Certified Laboratory (Fairfax Hospital Laboratory, Fairfax County, Va.

Factual Information

- The Fairfax Hospital Laboratory (FHL) is licensed under the CAP Program and qualified in all areas. This laboratory is relatively large, well organized and has participated in the program since 1967.

- During CAP program inspections, procedure books are checked, some techniques are monitored and reagent storage and maintenance practices are examined. In addition, general housekeeping, records and safety conditions and procedures are checked.

- The proficiency testing samples, which are received quarterly, are not treated separately, but are combined with the day's regular work. Care is taken, however, to have different personnel, if possible, perform the analyses each time in order to assure that the proficiency testing evaluates a cross-section of the laboratory staff.

- FHL maintains a full-time Quality Control Section which maintains all of its records at a central location. This Section, which is primarily responsible for monitoring the performance of each laboratory department, also checks equipment to assure that it is operating within its stated parameters.

Expressions of Opinion

- Although the workload imposed by the CAP program is both considerable and expensive, the program is strongly supported by the laboratory staff. It is believed that the program has proven beneficial in two key respects:

    - Management has been made more aware of the necessity for supporting the overhead functions and equipment relating to the Quality Control Section.

    - Operating personnel are more easily motivated to perform quality work.

- Most of the deficiencies received by the laboratory involve housekeeping and safety areas and frequently involve matters considered trivial. It is felt that minor areas which do not affect the quality of performance or the basic safety of the

staff should be deemphasized during inspection in order to permit more attention to be devoted to substantive factors.

- The laboratory staff feels that no responsible laboratory can operate without a full-time Quality Control Section. It also believes that all laboratories should be licensed or accredited. They maintain that, in general, non-accredited laboratories usually lack internal quality control systems and do not display as high levels of performance (as accredited facilities).

Summary

Although an appreciable diversity of program detail and individual opinion was encountered during the Phase II portion of the study, there were clearly identifiable areas of agreement among those interviewed which were essentially independent of the character of the laboratory operations involved ((water, clinical medical, etc.). The following summarizes those findings and viewpoints which appeared to be most pervasive:

- Program deficiencies and inadequacies usually reflect, or at least seem attributable to, insufficient funding.

- Program operating cost information was usually found not to be available, especially in terms of specifics.

- Program officials consider, for the most part, that the laboratories operating under their jurisdictions exhibit improved performance and data quality.

- Program benefits most frequently identified by the personnel of laboratories operating under them include:

    - Improved operation and data accuracy. This is usually attributed to proficiency testing requirements.

    - The provision of a basis for upgrading and augmenting laboratory equipment.

    - Improved morale of laboratory personnel.

    - The exclusion (or at least the basis for exclusion) of incompetent competition.

- Program problem areas most frequently cited by the laboratory officials are:

    - Costs (in terms of both money and personnel time) expended in maintaining compliance with program

requirements. This applies particularly to proficiency testing. These costs, which can be economically quite burdensome to small laboratories, are usually easily tolerated by large organizations.

- Delays in receiving the results of proficiency testing analyses and, therefore, in the adoption of corrective measures where deficiencies have occurred.

- Inadequacy of general program information from the certifying organization to the laboratories. (This criticism by no means applies to all programs reviewed. CAP, for example, provides outstanding informational services to its participating laboratories.)

- The on-site laboratory inspection process frequently directs too much effort to details (such as housekeeping practices) which are considered extraneous to the basic laboratory operations.

Synopses of all programs studied under Phase II are presented in Appendix I. (Most of the program synopses shown were originally developed under Phase I.) Samples of the various forms used in the certification programs appear in Appendix II.

Phase III: Progam Option Identification and Assessment

Methodology

As indicated in the Introduction, the overall certification process was separated into a number of key constituent administrative and procedural elements for which alternative approaches were then identified and assessed. The selection of the particular elements examined was based on certain considerations which were determined by the objectives of this study and others which reflected various relevant features of EPA's organization and operation. Among the more important of these considerations were:

- The purpose of this study, as previously stated, was the consideration of environmental monitoring laboratory certification from a policy oriented viewpoint, rather than in terms of technical program specifics (such as laboratory evaluation criteria, for example).

- EPA's basic approach to the implementation of environmental enhancement and protection is programmatic (that is, the Agency's activities which impinge directly on the environment are organized and, to a large degree separately administered, as air programs, water programs, pesticide programs, and so forth).

- Major environmental programs (such as transportation control plans designed to ameliorate air pollution and areawide waste management plans, for example) are, for the most part, implemented through State agencies.

- As noted earlier, EPA's Quality Assurance operations already includes an Inter-laboratory Program. This program is still in its developmental phases and has, so far, directed its efforts largely to site inspection based evaluations of EPA (and, to some extent, State) laboratories as well as to cooperative inter-laboratory activities relating to the assessment of new analytic procedures and methods. It is clear, however, that with adequate support this Program could be expanded to provide the evaluatory and other technical functions required for the establishment and operation of a laboratory certification process.

In addition to the above, three basic premises, or assumptions were formulated which are believed to be realistic and which underlie much of the subsequent analysis.

The first premise is that it would be extremely difficult, if not actually impossible for EPA to provide, in a single step, all resources required for the establishment of a comprehensive laboratory certification program as well as to assure the future provision of these resources for its maintenance.

The second premise is that, over the long term, EPA's policy will favor the extension of its Quality Control and Inter-laboratory Programs to include, directly or indirectly, all laboratories generating environmental monitoring data. This assumption is based on the obvious requirement for the comprehensive (that is, on national basis) upgrading of environmental data quality. However, a very large proportion of the environmental data produced for such purposes as air and water quality status and trends analysis, as well as for compliance monitoring, is produced by county, municipal and private laboratories. A QA program which did not ultimately plan to include such facilities in its operating scope would appear to be of limited long run value to the Agency.

The third premise, which is to some extent implied by considerations inherent in the second, is that EPA will extend with the QA program independently of whether or not certification is implemented.

The above considerations and premises were important factors which played contributory roles, in many instances, not only in respect to option formulation, but also in shaping the evaluatory framework within which these options were assessed. For example, the prospective benefits and costs of certification were considered from an incremental standpoint because of the already existing QA program. Clearly, in the absence of this program as a basis, the magnitude of the effort and resources required for establishing and conducting a laboratory certifi-

cation operation would be far greater. In this connection, it should be pointed out that EPA's position is rather unique with respect to that of other organizations which have instituted laboratory certification or approval programs. In nearly all instances, it was necessary for these organizations to develop and organize the mechanisms required for implementing laboratory inspection and evaluation procedures as well as proficiency testing programs. EPA obviously enjoys a considerable advantage in that these mechanisms already exist within the Agency in operating form.

Analysis

The certification options presented below relate to various key program administrative and procedural areas which, because of the nature of the considerations involved, present themselves as issues to be resolved or as critical questions requiring answers before a recommended course of procedure can be formulated. In the presentation which follows, each such issue is identified and alternative approaches are set forth. These approaches, which constitute the program options, are then assessed in terms of their pros and cons. In this context, it is pointed out that this study was oriented to the examination of possible environmental laboratory certification by EPA from a "feasibility" standpoint. In a general sense, the accomplishment of any objective, not inherently unachievable, is "feasible", provided that sufficient resources are made available. In the context of this study, the term "feasibility" is interpreted in a relative sense in that a given method or approach can be spoken of as "more feasible" than another if it presents a smaller aggregate of expected economic costs and procedural difficulties. It follows, therefore, that equally "feasible" or "practicable" approaches to the same problem may differ among themselves, depending on the trade-offs made between economic and procedural factors. The analysis presented below was developed within an orientation in which the minimization of procedural difficulty was considered of no less importance than the minimization of funding requirements and in which the presumptive benefits of certifaction (to EPA) were not compromised.

The position taken in this study, which considers formal laboratory certification as a distinct and incremental process in relation to the evaluatory activities of the existing QA program, has already been expressed in general terms. Because of the fact that option formulation and analysis were in some instances shaped or influenced by this position, it is appropriate to examine the concept somewhat more searchingly. "Formal certification", as the expression is used in this report, relates to all accreditation or approval procedures other than those directly concerned with the actual evaluation of laboratory capability and performance. It includes such functions as application review, assessment of laboratory evaluation results in terms of

certification standards and criteria, notification of certification, notification of deficiencies and similar procedures. (This functional distinction is not as clearcut in all certification programs. However, the American Industrial Hygiene Association, for example, maintains an "accreditation committee" which makes the formal decision of whether or not to certify, based on evaluatory information received, but which is not directly involved in the acquisition of this information.) It should be noted that the EPA element administering and implementing the "formal certification" process will, almost inevitably, bear a considerable share of the liability for any adverse consequences stemming from its decisions. This consideration is the key reason underlying the stress placed on the distinction, which might otherwise appear trivial, between the "formal certification" process and the administration and performance of the evaluatory procedures on which it would be based. (Throughout this analysis, it is, of course, assumed that, regardless of the mode of implementation of the "formal certification" mechanism which is optionally presented, the responsibility of the EPA QA program for the administration and conduct of certification-related evaluatory procedures would remain unaffected.)

(Note: Wherever the terms "certification program", "certification process", or "program" appear in the following analysis, they should be understood to refer only to the formal aspects of certification as described above, unless otherwise indicated.)

Issue I Mode of Program Management

This issue concerns the question of whether EPA should manage the program itself or with support from another entity or whether it should delegate administrative and operational responsibility to another organization.

Formulated Options

Option A

EPA, under contractual agreement with a qualified entity (such as an organization now conducting a similar program) delegates responsibility for program management and operation.

Option B

EPA manages program directly with on-going contractual support which provides advisory services and/or qualified personnel for the performance of specific functions. (Note: Other possible types of support, such as the provision of microbiological reference samples which has been proposed by CDC, would relate to EPA's QA program rather than to the certification process as defined.)

Option C

EPA manages and executes the program directly, without a long-term commitment to another organization for contractual support. Such support is to be procured only when specific needs for it arise.

Option Assessment

Option A

Pro

EPA would acquire the services of already developed expertise for operating the program and would avoid the need for either acquiring additional personnel or detaching current personnel from other duties in order to staff the program. It would also eliminate the requirement for managerial involvement in program operation.

Con

Inasmuch as the program would probably be invested with legal and regulatory force and, furthermore, would almost certainly involve inter-governmental relations, the prime agency (EPA) should retain both program authority and managerial control. [In any case it is unlikely that, if (theoretically) program management were to be delegated, EPA would be substantially relieved of liability for any consequences of mismanagement by an agent].

Some EPA personnel might feel that they were being dictated to by an "outside" group or that some of their rightful functions had been, so to speak, usurped. In any case, the real possibility of inter-organizational friction cannot be dismissed.

Option B

Pro

The advantages of Option B are similar to those of Option A without the problems inherent in the delegation of program management.

Con

At the beginning of the program it will be quite difficult to foresee the nature, severity and number of problem areas EPA may encounter in the course of program

development and operation. It is entirely possible that difficulties may appear only sporadically and that a long-term commitment to contractual support could prove unjustified. Furthermore, the findings of this study strongly suggest that guidance and help from established organizations with laboratory certification experience at Federal, State and private levels would be freely available when needed.

Option C

Pro

This option offers the advantage of intra-agency program authority and control without long-term commitments to other entities.

Con

There are no significant disadvantages seen for this option. However, some staff additions would probably be required.

Conclusion

Option C is preferred.

Issue II Assignment of Intra-agency Program Responsibility

This issue, which inherently assumes the rejection of Option A, Issue I, deals with the consideration of where, within EPA, should the responsibility for program administration and performance reside. The basic question involved here is whether this responsibility with its attendant implications should be borne by the Quality Assurance staff or whether a new EPA element should be established to assume it.

Formulated Options

Option A

All administrative and procedural components of the program would be assigned to the QA program. Within the broad scope of this there are two major sub-options:

- Formal certification authority is vested in the Regional Quality Control Coordinators, or equivalent officials.

- Program management is centralized, with certification authority assigned to centrally reporting field personnel.

Option B

An independent element is established within EPA with assigned responsibility for administration and operation of the program. As in Option A, sub-option (2) above, certification authority would be vested in centrally reporting, regionally assigned field personnel.

Option Assessment

Option A

Pro

Administratively, it would appear simpler to assign an added function to an entity already existing within the Agency than to establish a new organizational element for its implementation. Further, without doubt either the necessary capability and staff expertise could be wholly supplied by existing QA organization personnel or, if necessary, could be supplemented through the acquisition of appropriately qualified individuals. In addition, the laboratory certification process is so closely linked to the procedures for establishing facility qualification that it seems "natural" to incorporate the program within the QA operating structure. Of the formulated sub-options, (2) appears preferable because centrally reporting personnel would be more immune to local pressures than a regional staff and because centralized management is inherently conducive to the establishment and maintenance of procedural uniformity.

Con

The major reservations with respect to Option A stem primarily from the fact that, in assuming direct responsibility for laboratory certification, the QA operation would, as previously mentioned, quite possibly find itself a vulnerable target in event of any unfavorable consequences of its actions under the program. There is an additional and somewhat more subtle consideration involved in this issue which concerns the relationships between EPA's QA inter-laboratory program and both current and future non-EPA participating laboratories. This program is geared, essentially, to the upgrading of laboratory capability and performance in the interests of enhancing the quality and reliability of the environmental data generated. The success of this program will in large measure depend on the establishment and maintenance of cooperative and

harmonious working relationships between EPA QA personnel and the staffs of the non-EPA participating laboratories. It is probable that this cooperation and harmony may be more effectively maintained under conditions in which the identification of the QA staff with actions having associated regulatory and legal implications is minimized to the degree possible. Another consideration which is relevant in this context is the following: Laboratory certification, as the term is used in this study, is to be interpreted as meaning no more than the formal recognition that a facility has been found to meet certain standards of capability and performance. On the other hand, the QA program, which is addressed to the more or less indefinite improvement of the laboratory operations, would not consider that a facility, merely because it had satisfied defined certification requirements, should no longer be encouraged and aided in further upgrading the quality of its performance. Accordingly, the objectives of the QA Inter-laboratory Program and those of certification are quite different in the same sense that the goal of unconstrained data quality enhancement is quite different from the goal of establishing and maintaining threshold standards for determining data acceptability. Because of this, formal certification and the Inter-laboratory Program can be regarded as wholly disparate activities and organizational separation of the former function from the QA program should in no way compromise QA's interests and actions.

Option B

Pro

This option, which in terms of the internal operation it suggests, resembles that of Option A, sub-option (2), provides the additional feature of keeping the operations of the formal certification process independent of those of the QA program. The advantages of this separation are identified in the above discussion.

Con

The organization separation of formal certification authority and responsibility from the pre-certification and certification maintenance evaluatory procedures could, in occasional instances, induce inter-department conflict.

Conclusion

It is considered that option selection in this instance would

reflect a management decision which lies outside the scope of this study. In addition, some of the reservations with respect to Option A also could be met by establishing a certification entity within the QA framework which would be administratively independent of the inter-laboratory program. This would provide the purely technologically oriented QA operations with a considerable measure of immunity to the regulatory aspects of the certification while, at the same time, permitting closer coordination between laboratory evaluative processes and the formal approval process.

Issue III Programmatic vs Unified Certification Responsibility

This issue relates to the question of whether laboratory certification should be administratively organized and implemented on a programmatic basis (implying, for example, separate certifying officers for air and water laboratories) or whether it should be conducted within an integrated entity whose staff would bear cross-programmatic responsibility.

Formulated Options

In this case the options are clearly defined in the statement of the issue as:

Option A

Organization on a programmatic basis

Option B

Organization on a comprehensive basis

Option Assessment

Option A

Pro

Fragmentation of certification responsibility along programmatic lines would permit more intensive specialization on the part of certification officers. This would be conducive to a more detailed understanding of the technical factors relevant to their responsibilities.

Con

Programmatic organization would require far more personnel and would substantially increase the cost of program operation. This system might also prove unwieldly in certain respects. For example, a given

laboratory might perform analyses of environmental samples relating to more than one program. Under this option, dual certification by different authorities of the same agency would be required in such a case. (Note: This is not the same as separately certifying a laboratory for more than one category of test or analytic procedure under a single authority).

Option B

Pro

A unified, cross-programmatic certification system is far easier and less costly to administer and to implement. This form of organization is judged to be feasible. For example, the HQ QA Division operates cross-programatically in many areas (including facility evaluation) as do various regional Quality Control Coordinators. (It is also noted that certification officers would obviously have to have only reasonable comprehensive understanding of the operations of the laboratories under their jurisdiction. The depth and scope of technical information and insight required for the satisfactory performance of their function would be substantially less than that needed for the performance of evaluatory operations.)

Con

There are no significant disadvantages seen associated with this option.

Conclusion

Option B is preferred.

Issue IV Certification Program Depth

If the certification program is to achieve its objective of ultimatley assuring that environmental data reported from all sources will meet designated reliability criteria, the program must obviously encompass all laboratories engaged in environmental monitoring activities. The issue that arises here is whether EPA should directly certify all such laboratories, or whether the Agency should certify only to the State level, with State agencies assuming responsibility for the certification of interstate laboratories (such as municipal, county, private and industrial facilities.) (Note: The latter option is not the same as Option A of Issue I under which total program responsibility would be delegated.)

Formulated Options

Option A

Under this option EPA would certify both State and intra-

state laboratories directly and would also assume responsibility for the laboratory and procedural evaluation.

Option B

EPA would evaluate and certify State laboratories directly. The State agencies would then evaluate and certify intra-state laboratories, acting either under EPA delegated authority or that conferred by State statute. Standards and criteria would be uniform for laboratories at all levels.

Option Assessment

Option A

Pro

Direct certification by EPA of all environmental laboratories would maximize the probability of attaining uniformity of standards and procedures, since all laboratory evaluations would be performed by the QA staff. The Agency would acquire a firmer control of environmental laboratory operations than would be possible through certifying intermediaries.

Con

The findings of this study show that an announced intent by EPA to directly certify intra-state laboratories would trigger a considerable amount of State objection and resistance. State agencies would seriously resent such an action because it would be seen as an invasion of their prerogatives. EPA/State relationships which may be already stressed in some instances, would be seriously damaged. (This conclusion is based on interviews conducted with a number of environmental agency officials in various States. Their views were unanimously those indicated. This sample obviously does not imply, however, that the conclusion is necessarily true of all States.)

It would be necessary for EPA to augment its QA staff by a significant amount and also to provide for a substantially larger than otherwise certification operation in order to provide adequate evaluatory and approval services to all environmental laboratories (there are thousands in the 50 States).

Option B

Pro

This option has the overall merit of being politically

far more procedurally feasible than the alternative. EPA certification program staffing requirements would be small and the laboratory evaluatory procedures should be accommodated with little additional burden on the QA inter-laboratory program resources.

Con

Many States lack the personnel and other resources necessary to conduct the facility evaluation procedures which are prerequisite to formal certification. In other cases, in which State certification programs already exist, there are likely to be differences between State standards and criteria and those which EPA would formulate. These problem areas, which are admittedly significant and are discussed later in this report.

Conclusion

Option B is preferred in spite of its attendant problems.

Option A is considered politically inadvisable.

Issue V Programmatic Timing and Range of Certification

The issue referenced here relates to the programmatic scope of laboratory certification and, perhaps more importantly, to the question of whether certification should be implemented by program successively or on a simultaneous basis. This study takes the position that it is a foregone conclusion that laboratory certification must, as a minimum, include facilities engaged in air and water analyses and probably, in the long run, those involved in certain areas of pesticide and radiation measurements as well. However, in terms of actual laboratory operations as encountered, there tends to be some degree of "programmatic" overlapping in that air and water sample analyses may be conducted by different departments of the same facility. Further, at least from the vantage point of this study, there would be some degree of artificiality in distinguishing water analyses addressed to non-pesticidal organic toxic pollutants as opposed to those which directly relate to pesticide determinations performed by the same facility, even though a "programmatic" distinction is possible on a semantic basis. In view of EPA's prospective expanded responsibility with respect to the surveillence and protection of drinking water quality, it seems appropriate to express the view of this study to the effect that, in terms of the QA program, as well as in the context of possible certification, water supply testing laboratories should not be treated separately or in a different manner from those engaged in effluent or ambient water analyses. In fact, in many cases the same facility is active in both general areas.

In spite of the above consideration that in some instances there may be a degree of blurring of inter-programmatic boundary lines in terms of monitoring and QA related operations, Issue V remains essentially valid. The position taken in this study with respect to one aspect of this issue is that the establishment and implementation of a certification plan which would address all programmatic areas simultaneously is a far less realistic option than one based on successive programmatic steps. However, a case can be made in favor of the simultaneous approach on the grounds of desirability as follows:

- It would shorten the time required for attaining certification of laboratories active in all programmatic areas.

- It would require the consideration of all program specific technical and administrative issues during the developmental stages of the certification program within the context of a single, unified planning operation and would thus possibly reduce the need for subsequent major program modifications which might otherwise be required.

The key arguments against the simulataneous approach are:

- An attempt to implement a certification system embracing all EPA programmatic monitoring areas at once would prove not only extremely costly, but because of the relative inexperience of the Agency in the certification process, an extremely complex burden for the responsible staff.

- The degrees of relative "maturity" of monitoring and QA operations are notprogrammatically uniform. Available pesticide data for some media is relatively slight compared with that developed under air, water and radiation surveillance programs.

- The pressures underlying the requirement for reliable monitoring data are different with respect to the various programs and this suggests that needs should be prioritized.

As stated at the beginning of this discussion, the certification of laboratories engaged in air and water analysis is regarded as an irreducible minimum program. Later extension to radiation and radionuclide monitoring laboratories and then to pesticide surveillance appears to be a reasonable sequence. Assuming that the certification of air and water analysis facilities only is considered realistic in terms of the not too far distant future, the issue at hand is then a matter of which of these programs should first be implemented.

Formulated Options

Option A

Air laboratories certified before water laboratories.

Option B

Water laboratories certified before air laboratories.

Option Assessment

Option A

Pro

There are far fewer air than water laboratories and also many fewer air than water pollutants for which analyses are routinely made. For these reasons, it would be considerably easier for EPA to initiate a certification program addressed to air laboratories.

Con

If ease of implementation were the only consideration involved, Option A would be favored on this basis. However, other factors, such as existing relative data quality and variety of data sources are of equal importance and do not support this conclusion.

Option B

Pro

Many of EPA's most urgent programmatic responsibilities (which include the NPDES regulatory program with its requirement for extensive, and often complex compliance monitoring as well as the Agency's recently assumed responsibility for the quality of the Nation's water supply) require reliable water quality data. Further, not only are water quality data generated by a far larger number of laboratories than is the case for air, as stated above, but these laboratories also represent a very broad spectrum of capability which potentially reflects a wide range of data reliability. In addition to this, some QA staff members believe that the necessary technical support for water laboratory evaluation (in terms of definition of standards methods, availability of reference samples and the past history of effective cooperation) is more advanced than is true in the case of other media.

Con

Admittedly, both the dollar cost and level of effort required for the implementation of this option would be considerably higher than for the execution of Option A because of the greater numbers of both laboratories and pollutants involved. However, in the case of this issue, the criteria of cost and effort are regarded as less compelling than urgency of need.

Conclusion

Option B is preferred.

Issue VI Scheduling of State Agency Certification

After analysis of the options considered under Issue IV (Certification Program Depth), it was concluded that EPA should directly certify State agencies (beginning with water analysis laboratories for reasons presented under Issue V) only, with the States then assuming responsibility for the approval of intrastate laboratories. The question that arises here is whether EPA should attempt to implement a certification program which would address all State laboratories simultaneously, or whether it should schedule the program on a progressive basis, beginning with selected States and subsequently extending the certification process until all States are included. Key factors involved in this issue are dollar costs, ease of implementation and program effectiveness as well as the consideration that EPA is relatively inexperienced in the operation of laboratory certification programs.

Formulated Options

Option A

EPA implements a plan on the basis of certification of selected State water agencies, preferably those which already operate laboratory approval programs, in addition to one or two other States in which such programs do not currently exist. (Ultimately, certification is to be extended to all States, but in a progressive manner.)

Option B

EPA implements certification programs on the basis of simultaneous certification of all State water agencies.

Option Assessment

Option A

Pro

The findings of this study indicate that EPA, in the implementation of certification with respect to State agencies already conducting laboratory approval programs, will encounter a cooperative and helpful attitude, rather than one of resistance. For this reason, EPA should gain both first hand information and guidance from experienced State agencies. This should prove contributary to the resolution of minor difficulties which may arise in the early stages of the program.

Because mechanisms for laboratory evaluation already exist within those States which now conduct certification programs, the level of additional support required from EPA should be very much lower than in the cases of States which do not now certify laboratories. Because of the considerations presented above, certification of States with currently active programs should reduce the time period required to assess and demonstrate the benefits of the program. Addressing the program in its initial stages to those States which already certify laboratories would provide, in essence, an excellent preliminary "learning process" opportunity for EPA. However, it is considered that, for an adequate test and demonstration of program benefits, the program should also be operated in at least one State in which the certification mechanism is not yet established.

Con

Extension of State certification in steps will delay realization of program benefits on a national basis.

Option B

Pro

Simultaneous certification of all State water agencies would accelerate the achievement of improved data quality and reliability from all qualifying laboratories.

Con

As indicated earlier, it must be appreciated that, although the cost of certification of State agencies by EPA may be relatively low, the cost of approval mechanisms for intra-state laboratories by the States will frequently be quite high. This is because many States do not have the equivalent of a QA apparatus for

conducting the laboratory evaluation process. In these cases, therefore, such an apparatus must be established and maintained and in many instances this will prove impossible to achieve without substantial EPA grant support. (One estimate of the magnitude of the support that might be required, as provided by an official of Region VII, was $200,000 to $300,000 annually per State, including facilities and personnel.) It is virtually a foregone conclusion that EPA cannot, at present, commit the necessary support on a national basis and this view is, in fact, one of the premises on which the option analysis is based. (It seems probable that EPA's prospects for acquiring the resources necessary for providing adequate grant supplementation ot the States on a national scale would depend to a large extent on some preliminary demonstration of the program's effectiveness. This consideration underlies the structure of Option A as formulated.)

Conclusion

Option A is preferred.

The issues identified above and discussed in terms of optional approaches to their resolution are basic in that they address general policy positions which must be unequivocally adopted before a detailed certification program can be designed. Independently of these broad considerations, there is also a number of important procedural program elements which, while not presenting major issues, nevertheless require specific formulation in order to permit the construction of a certification plan which is sufficiently explicit for effective review by EPA. These elements are identified and discussed in the following Section of this report which deals with Phase IV of this study, namely, the development of a proposed certification plan.

Phase IV: Development of the Preferred Option

Methodology

The term "Preferred Option" as used above is intended to have a more inclusive meaning than the one employed in the preceding discussion in which it denoted a preferred alternative approach to the resolution of a specific defined issue. Here, "Preferred Option" relates to a more or less comprehensive certification program which was formulated for EPA's consideration. It is a "preferred option" in the sense that it is based on the recommended alternatives identified above.

In the design of the proposed certification plan, these alternatives supplied the broad, overall structure and defined generic policy positions. However, for more complete program formulation, a number

of other plan factors and elements also required consideration. In some instances, these are independent of specific plan structure. In others, they relate to decisions which would affect the manner in which recommended issue approaches would be implemented. In addition, various potential problem areas were identified and the manner in which a certification program could be applied in order to maximize its benefits to EPA was defined.

General Considerations

The following discussion addresses several diverse topical areas of the types referenced above.

. Program Authority

A major and pervasive consideration, which is independent of specific program structure, is that of the authority under which such a program would operate. It was pointed out earlier in this report that the authorizing legislation or statutes which current certification programs cite as their formal authorization vary considerably with respect to explicitness.

In the case of EPA, there does not appear to be any explicitly legislative authority for the certification of environmental monitoring laboratories by the Agency itself or for its requiring that States certify or license such laboratories within their boundaries. By "explicit authority" in this context is meant a defined mandate similar to that provided to HEW under the Clinical Laboratories Improvement Act of 1967 which specifically requires the licensing of clinical laboratories engaged in interstate commerce. However, it is quite possible to develop an argument for the existence of implied authority through the use of such reasoning as the following:

a) Under current legislation (for example, Sec. 20 of the Federal Environmental Pesticide Control Act of 1972) EPA has a clearcut responsibility for environmental monitoring (directly and via the States).

b) Monitoring data, however, are of limited value unless their reliability conforms to some minimal standard of acceptability (as determined by monitoring objectives).

c) Even with the support of QA program, there is no final assurance that minimum data quality standards will be attained unless some regulatory mechanism is implemented, i.e., certification or licensing of environmental monitoring laboratories.

d) Therefore, the authority for environmental laboratory certification is logically implicit in EPA's legislated monitoring responsibilities and additional authority is not required.

Furthermore, it can be argued that certification authority is already inherent in the regulatory powers of the Administrator, as broadly stated in existing legislative instruments.* However, it must be noted that these powers may be invoked only to the extent that they are "necessary" for the implementation of the Administrator's "functions" under the Act in question and that there is always the possibility that their exercise in a specific case might not withstand testing in the courts.

In general, there are at least three procedural options open to consideration by the Agency which relate to the issue of certification program authority, although not all of these would satisfy the key objective of such a program, namely that of establishing an enforceable position with respect to data acceptance or rejection.

Formulated Options

Option A

EPA attempts to obtain passage of specific legislation authorizing the establishment and operation of an environmental laboratory certification program. This legislation would, preferably:

- incorporate certification authority for all pertinent programs (i.e., air, water, pesticides, etc.) within a single statutory instrument
- authorize EPA to reject environmental data from uncertified sources
- forbid the introduction of data from uncertified sources as evidence in legal actions involving the Agency

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* For example, Sec. 501(a) of the Federal Water Pollution Control Act Amendments of 1972 states that "The Administrator is authorized to prescribe such regulations as are necessary to carry out his functions under this Act." Similar language appears in Sec. 301(a) of the Clean Air Act, as amended 1970, and in Sec. 25(a) of the Federal Environmental Pesticide Control Act of 1972.

- authorize EPA to certify or accredit State environmental agencies with respect to:

    a) State laboratory facility and performance

    b) State agency licensing of intrastate laboratories (including municipal, county and private laboratories)

- provide sufficient time for accomplishment of certification on a national basis (assuming that it may be implemented progressively)

- appropriate sufficent scheduled funds for EPA program support within the Agency and for the disbursement of grants to States as required both for the supplementation of existing programs and for the establishment and operation of new programs where there are none at present.

- enable EPA to license intra-state laboratories in event of default by or inability of State agencies

- not require EPA to impose changes in existing State programs or to prescribe details of proposed State programs, provided that the standards and criteria for laboratory licensing under these programs are no less stringent than those to be employed as the basis for State laboratory certification.

Option B

On the basis of implied authority under existing legislation, EPA promulgates a laboratory certification regulation without seeking additional statutory support. (Note that there is no inherent reason for the content of a regulation formulated under this option to be different in principle from one which would be drafted in response to legislation obtained under Option A.)

Option C

EPA enters into agreements with cooperating States for the implementation of a voluntary certification program.

Option Assessment

Option A

Pro

The passage of specific authorizing legislation would provide the most secure legal basis for a laboratory certification program and underlying regulatory issuances. Further, such legislation is very likely to include funding appropriations.

Con

The passage of explicit authorizing legislation could require a considerable period of time for its achievement. Meanwhile, if EPA were to rely exclusively on this approach, the Agency would be left without means of ensuring its minimum data quality requirements are uniformly met.

Option B

Pro

Implementation of this option would permit EPA to institute certfication program with minimum delay

Con

Election of this option would expose the Agency to the possible future risk of an adverse court decision should the legal basis of its certification authority be contested. It is quite possible that such a decision, if sustained, could seriously set back EPA's certification program for a considerable period. (It can be argued, conversely, that such an adverse decision could also provide the basis for seeking authorizing legislation.) The magnitude of this risk is virtually impossible to predict and opinions on this point expressed by members of EPA's legal staffs varied over a considerable range.

Option C

Pro

Assuming the willingness of State agencies to cooperate, this option would also permit the early establishment of a certification program. (On the basis of various State agency officials interviewed during this study, it is believed that the requisite cooperation would be forthcoming in many cases.)

Con

A voluntary certification program would obviously lack regulatory force and, to this extent, would not meet key objectives. (However, such a program could provide a useful preliminary training experience.)

Comments

Of the three options presented, Option B appears to be the most attractive because it would both facilitate the early establishment of a certification program and endow this program with legal force. On the other hand, it carries with it an identifiable element of risk. In any case, Option B would lend itself to progressive certification of State agencies as recommended (see Issue VI, Scheduling of State Agency Certification) as well as to simultaneously certification, should EPA so elect. Furthermore, there may also be advantages to proceeding with Option C (voluntary agreements between EPA and State agencies) as an interim measure in order to provide time for program development and refinement prior to its formal establishment, even though Option B may be adopted in the long run. Because of the magnitude and significance of the possible long-term implications of this issue for the future of EPA's contemplated certification program, it is considered that option selection would be most appropriately made by the Agency's legal staff.

. Relation of Certification by EPA to Existing State Programs

It was previously recommended that EPA, in initiating certification of State agencies, include some States currently conducting water laboratory approval of licensing programs. There will inevitably be differences between EPA's program for the evaluation of State agency capability and performance and the programs currently operated by States for the assessment of intra-state laboratories. Such differences may apply both to standards and criteria for capability and performance evaluation and to procedural details (such as the frequency of post-certification proficiency testing). The position taken in this study is that the certification program as a whole will be most effective if the minimum standards and criteria adopted as well as the qualifying procedures set by EPA are uniformly applied nationally to laboratories at all levels (State, municipal, private). On the other hand, it is obvious that the program will operate more smoothly to the degree that the States are least required to alter their own existing programs to conform to provisions set by EPA. Therefore, it is recommended that the "no less stringent than" principle be applied in evaluating on-going State programs in terms of EPA's evaluatory standards and procedures, once these have been established. For example, the number of standard deviations within which proficiency testing results must fall with respect to the target figure could be based on EPA's promulgated requirements with the proviso that corresponding State program standards would be acceptable if they were no less stringent than the Agency's. (This proviso is similar to that relating State water quality standards to those set by EPA.) On the other hand, if EPA's

requirements with respect to facility evaluation or to proficiency testing prove to be more demanding than the equivlent procedures designated by a State agency and would thus require the expenditure of additional resources to "upgrade" them, supplemental funding by the Agency may prove the only practicable solution. (In this connection it is noted that the findings of this study show many State certification programs to be underfunded and unable to meet their formal demands as they now exist.) It is believed that, on the whole, the assessment of existing State programs which are to be made part of the total certification operation should be based on essentially pragmatic considerations. That is, any modification of these programs which may be required by EPA should be restricted to those necessary to achieve compliance with the minimal data quality standards.

. Program Benefit

As stated earlier, the objective of certification is unlike that of the QA inter-laboratory program in that it addresses the establishment of acceptable "threshold" standards of data quality as opposed to the overall upgrading of laboratory performance without defined limits. Therefore, the purpose of certification is not to assure EPA that environmental data developed under the program will be of the highest quality technologically possible within reasonable economic constraints, but rather to assure the Agency that environmental data quality will be at least minimally adequate for the satisfaction of the most stringent monitoring objectives. It is evident, accordingly, that if a certification program is to successfully serve this function, it must be geared to a set of standards and criteria which reflect EPA's needs and not to one which seeks to be responsive to particular levels of laboratory capability which are believed to be prevalent in various analytic categories in order to assure that most evaluated laboratories will qualify under the program. Accepting the viewpoint, therefore, that certification is intended primarily for the benefit of EPA directly (unlike the QA inter-laboratory program which may benefit State laboratories directly and hence EPA indirectly), the question now at hand is, how is EPA to realize this benefit most expeditiously? The answer is that, as a means for assuring the development of environmental data of not less than minimally acceptable quality, certification is no more than a mechanism by which data from nonqualifying sources may legally be rejected by the Agency. (In addition, there are some subsidiary benefits to be expected from the program, such as imposition of uniform specifications of probable measurement error and the like.) From the viewpoint of this study, the only really compelling reason for undertaking a laboratory certification program is that this would provide EPA with

the enforceable authority to prevent the use of environmental data developed by non-certified laboratories for any purpose or operation falling within the regulatory and mandated domains of the Agency. In relation to this it is noted that EPA's Proposed Rules in regard to "Water Quality and Pollutant Source Monitoring", which were published in the Federal Register, August 28, 1974, state (under Paragraph P) that "Laboratories (or combinations of laboratories) supporting the State monitoring program shall provide physical, professional and analytical capabilities and quality assurance as follows:..." Many of the details which follow identify quality assurance practices and procedures which, presumably, would be required of any laboratory prior to certification. However, this Proposed Rule, which appears to concern intrastate laboratories performing effluent and ambient water analyses, does not address the consideration of the minimum data quality acceptable and provides no effective mechanism for regulatory control by the Agency of laboratories failing to comply with the stated QA requirements.

. Scope of Laboratory Approval

Certification of a laboratory as a total entity will, in many cases, be totally unrealistic inasmuch as it may prove, after evaluation, unevenly qualified in various analytic areas. This suggests the advisability of "fractional" certification rather than across-the-board certification. It is recommended, accordingly, that the certificate of approval, or equivalent document, state specific categories of analytical procedure for which the laboratory is qualified. (Although proficiency testing, if thoroughly conducted, may involve a large number of specific analytic procedures, these usually can be grouped by class so that the variety of certifiable categories can be kept within reasonable limits. For example, CDC recognizes six such categories.) It is pointed out that independently certifying a water laboratory for trace metal procedures under one set of criteria and for toxic organic compounds under an other is, in principle, basically no different from certifying two neighboring but separate laboratories, each of which is engaged in only one of these analytic categories.

. Formal Program Designation

The question of what the program is to be called is not considered trivial. Arguments against the use of the term

"certification" were presented earlier and, of the various possible alternatives, such as "approval," "accreditation," "qualification," and "licensure," "licensure" is preferred, particularly with respect to private laboratories because it most strongly suggests a process endowed with regulatory force. (Note: The term "licensure" is used by CDC under the authority of the Clinical Laboratories Improvement Act of 1967.) It is suggested that State and lower governmental laboratories be "qualified' and that private laboratories be "licensed." (The latter may not be readily feasible in cases in which existing State programs have historically used some other term, as in California where water laboratories are "approved".)

. Possible State Resistance to Participation

It is expected that some States will welcome the program, particularly those already conducting laboratory approval operations, because it will open the possibility of supplementary funding support for the improvement of their own programs. With respect to water laboratory licensure, however, a possible problem is foreseen with respect to those States which apparently do not plan to participate in the NPDES program. Conceivably, they may resist licensing intrastate water laboratories on the basis of the following logic:

- Effluent compliance monitoring is the major activity of environmental water laboratories.

- If the State does not participate in the NPDES program, then EPA is required to assume permitting responsibility within that State.

- Therefore, licensing water laboratories within the State should be EPA's responsibility (or, as a minimum position, what incentive does the State have to conduct a licensing program?)

It would appear that in order to assure ultimate complete national coverage under the licensing program (whose value would otherwise be severely impaired) participation cannot be voluntary, but must be required of the States in the same sense that participation in areawide waste management planning (under Sec. 208 of the FWPCAA) is required. (Considerations of this kind emphasize the need for explicit legislative program authority.)

Recommended Program

The essential features of the recommended program which were previously identified and discussed are the basis of the environmental monitoring laboratory certification plan proposed for EPA's consideration. The plan is presented in the following outline:

[Note: Some of the recommendations presented belwo do not apply directly to the formal certification process itself (as proposed for EPA), but rather to evaluatory and other procedures which, in the context of this study, are treated as pre-certification or certification maintenance actions. However, such actions are addressed where considered appropriate because of their obvious relationship to the prospective attainment of certification program goals.]

Environmental Monitoring Laboratory Certification Program

Purpose:

To assure that environmental data accepted and used by EPA is in conformity with defined minimum standards of quality and reliability.

Principal Structural Elements: (applicable to EPA program)

- The program should be managed by EPA directly (rather than through contracted services.
- Responsibility for formal laboratory certification, which is considered as an incremental step beyond the laboratory capability and performance evaluatory process, should be conducted by a new distinct and centralized EPA entity.
- Responsibility for evaluating laboratory capability and performance should be borne by the QA interlaboratory program.
- Certification as expanded should be administered on an integrated basis for all EPA programmatic areas.
- EPA should directly certify or qualify State agencies only, with the States assuming responsibility for the certification or licensing of intra-state laboratories. (Note: The intra-state laboratories engaged in intra-state commerce may required Federal licensing also.)*

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* As far as could be determined, EPA's responsibilities with respect to laboratories engaged in inter-state commerce are as follows: If the

Principal Procedural Elements: (applicable to EPA and/or State Programs)

- EPA must first determine whether a program is to be initiated on a mandatory or voluntary basis (see preceding discussion of program authority).

- The program should initially address itself to water analysis laboratories, then air laboratories and, later, to radiation laboratories and subsequently, possibly, to pesticide laboratories.

- The program should be initiated with a small number of States which have on-going water laboratory approval programs and should include at least one State without a current qualification program. The Connecticut and California State agencies, both of which conduct water laboratory approval programs, are suggested as appropriate for initial consideration.

- It is essential that the procedures and operations employed for the determination of laboratory eligibility by State agencies be no less exacting than those employed by EPA in evaluating State laboratories in order not to compromise the entire purpose of the program.

Structural and Procedural Program Details: (applicable to EPA and State programs)

- Establishment of Laboratory Evaluatory Standards and Criteria

  Monitoring data quality requirements should be determined by the program offices in terms of the most exacting applications. This information will enable the QA staff to furmulate criteria and standards of laboratory capability and performance which the facilities must meet, as a minimum, to satisfy the above data quality requirements. The terms "criteria and standards" are used here in a comprehensive sense to include laboratory equipment and organization and internal quality control operations as well as analytic procedures and personnel performance.

Agency determines that such laboratories are unfairly restricted under State statutes in the exercise of their rights, EPA then has a regulatory responsibility. If the Agency determines that no such restrictions exist, it may, at its option, permit these laboratories to continue operation under State statutes.

- Establishment of Laboratory Evaluation Methods and Proficiency Testing Procedures Designed and Addressed to the Above Criteria and Standards.

  It is expected that the establishment of these methods and procedures by the QA staff will be accomplished largely through appropriate modifications and adaptations of existing interlaboratory program elements to meet the specific needs of pre-licensing and licensing maintenance evaluatory processes.

- Categorization of Licensure

  The QA staff should classify analytical laboratory procedures on a categorical basis to permit the qualification of laboratories only for the specific areas in which they have demonstrated satisfactory levels of capability and performance.

- Information Feedback

  The certification and licensure programs should provide mechanisms through which facility evaluation and proficiency testing restuls can be expeditiously provided both to candidate and participating laboratories. (The experience of other programs shows that such information is quite helpful to laboratories in the correction of observed deficiencies.)

Certification Program Establishment and Operation

The following outlines a program plan specifically designed for the certification of State agencies by EPA which addresses:

a) Initial setting of standards and criteria for laboratory capability and performance evaluation

b) Operation of the program

The EPA elements to be involved in the implementation of this plan are identified below. Their specific responsibilities will obviously be different during the developmental stages of the program from those to be discharged during subsequent program operation. The plan design as set forth is essentially independent of whether certification is to be established on a regulatory basis or is to be initially implemented on a voluntary basis with cooperating State agencies. The resource and staffing levels required for its operation at various points in time will obviously depend on whether certification of State agencies is to be implemented progressively or simultaneously.

Involved EPA Elements (only major responsibilities are listed - others appear on flow charts)

a) Program (air, water, etc.) staff and other Agency personnel concerned with monitoring data analysis and applications.

Responsibilities:

. Standard Setting

These personnel will determine data quality and reliability requirements in terms of the most stringent normal data application and use (this does not include more exacting requirements which may be appropriate for research purposes).

. Program Operation

No responsibilities

b) Quality Assurance Division, Headquarters

Responsibilities

. Standard Setting

Reviews data quality requirements proposed by program and other staff. Determines their feasibility.

. Program Operation

No major responsibilities

c) Quality Assurance Staff, NERCS

Responsibilities

. Standard Setting

Establishes standards and criteria for laboratory capability and performance evaluation which will reflect the data quality requirements the laboratories are to satisfy.

Determines pollutant categories within which laboratories are to be certified.

. Program Operation

Prepares inventory of proficiency testing reference samples and provides these to laboratory being evaluated and to laboratory being qualified for certification maintenance.

Evaluates proficiency testing results and scores laboratory performance.

d) Regional Office QA Coordinator/Surveillance and Analysis (S&A) Personnel

Responsibilities

- Standard Setting

  No responsibilities

- Program Operation

  Performs on-site inspection and facility evaluation.

  Maintains liaison with laboratory and with Certifying Officer.

e) Certifying Officer

The Certifying Officer and his staff constitute a new EPA element which is to be independent of the QA organization and to be based at headquarters. The staff is to include field personnel who will provide support services to the RO's, but will be organizationally independent of them. It is estimated that a total staff of six (Certifying Officer, secretary, and four field personnel) should suffice for all fifty States because the functions of this group are to be administrative only.

Responsibilities

- Standard Setting

  No responsibilities

- Program Operation

  Reviews applications submitted by State agencies.

  Checks results of facility evaluation and proficiency testing against defined standards and criteria.

  Makes formal certification decision.

  Implements certification actions.

  Participates in RO site to laboratories which have failed to qualify.

The principal actions involved in the development of evaluation criteria and standards are presented in flow-chart form in Figure 1. A second flow-chart (Figure 2) delineates the overall certification process. The charts identify the involved EPA elements and their functions.

As discussed in this report, the pre-certification and certification evaluatory processes focus on potential laboratory capability (as assessed through on-site inspection) and on performance (as assessed through proficiency testing). It is to be noted that the assessment of personnel qualifications has not been included as a factor in determining laboratory eligibility for certification, although such assessment is found in other programs. There are several reasons for this omission. First, surveys performed during this study indicate that educational levels and degrees are not always reliable indicators of laboratory personnel capability and conscientiousness. (This refers to laboratory technicians performing routine analyses as opposed to those engaged in research investigations.) Second, it is considered that considerable discretion should be left to laboratory directors in matters relating to personnel evaluation. Third, the capability of laboratory personnel would be assessed during the proficiency testing process in any case.

The program operating plan as depicted in Figure 2 provides for initial certification, but not for the maintenance of certification. The latter process would involve the same kinds of evaluatory procedures as were employed for the initial establishment of laboratory certification eligibility. A recommended design for a certification maintenance program includes:

a) Annual on-site visits and facility evaluations

b) Quarterly proficiency testing in all pollutant categories for which laboratory has been previously qualified.

If the results of (a) and (b) are found satisfactory, no further action is necessary other than formal renewal or extension of the existing certification. If the results of (a) and/or (b) are found unsatisfactory, the Regional Office issues a deficiency notice to the Laboratory Director and, after a suitable period, a reevaluation is made of those facility or performance elements cited as deficient. If, following reevaluation, cited deficiencies persist, a site visit is then made by the Certifying Officer's field representative and appropriate Regional Office personnel. The purpose of this visit is to aid the laboratory in determining the cause of the problem (i.e., administrative, technical or personnel related) and to provide guidance and assistance in its correction. The laboratory is then allowed 60 days in which to prepare for a second reevaluation. If the results are satisfactory, certification renewal is automatic. Otherwise, a 30 day delisting notice is issued by the Certifying Officer. During this period, the laboratory may appeal to the Certifying Officer for review. Similar procedures should be followed by State agencies with respect to intra-state laboratories.

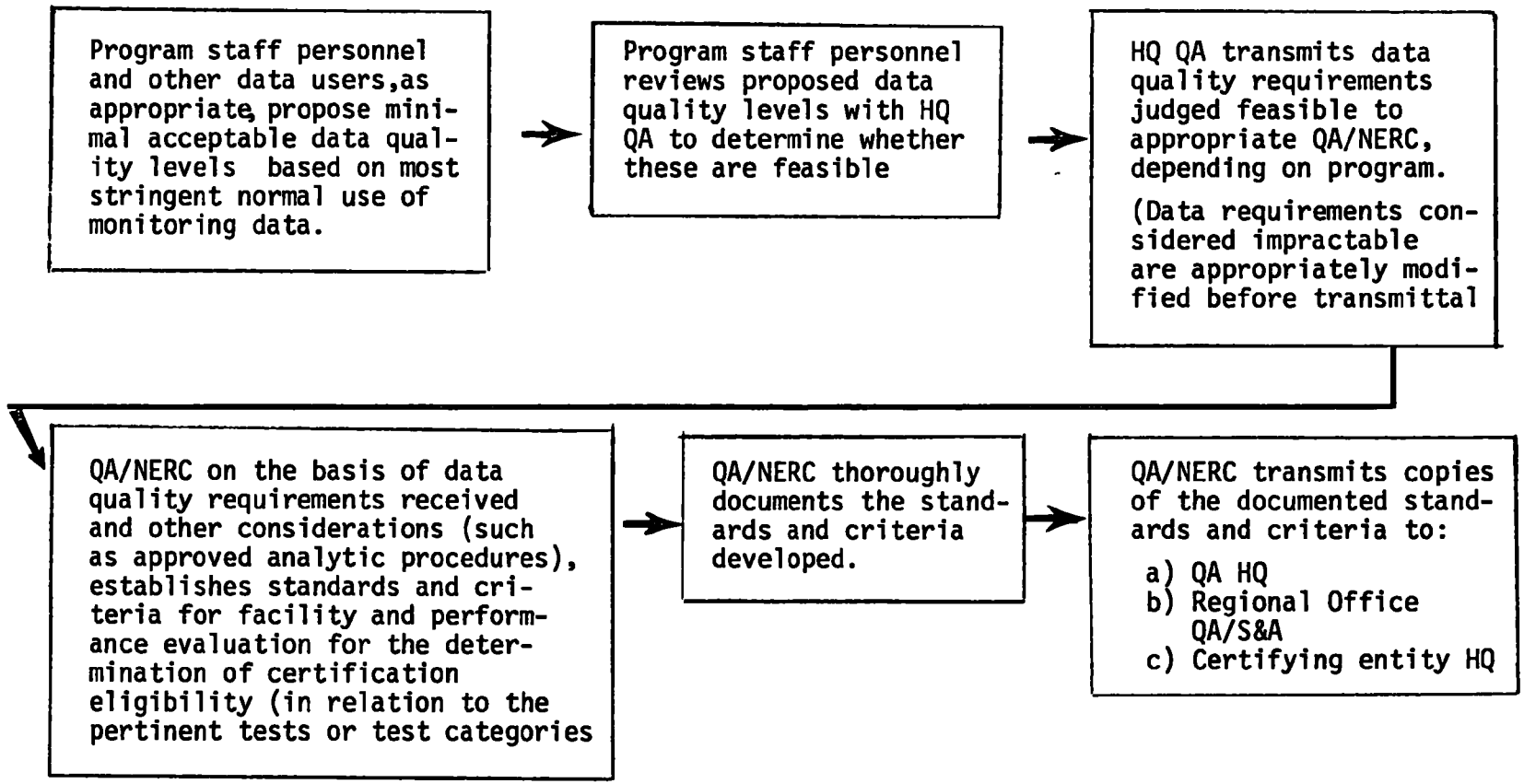


Figure 1. Flow Chart of Development and Distribution of Certification Criteria and Standards

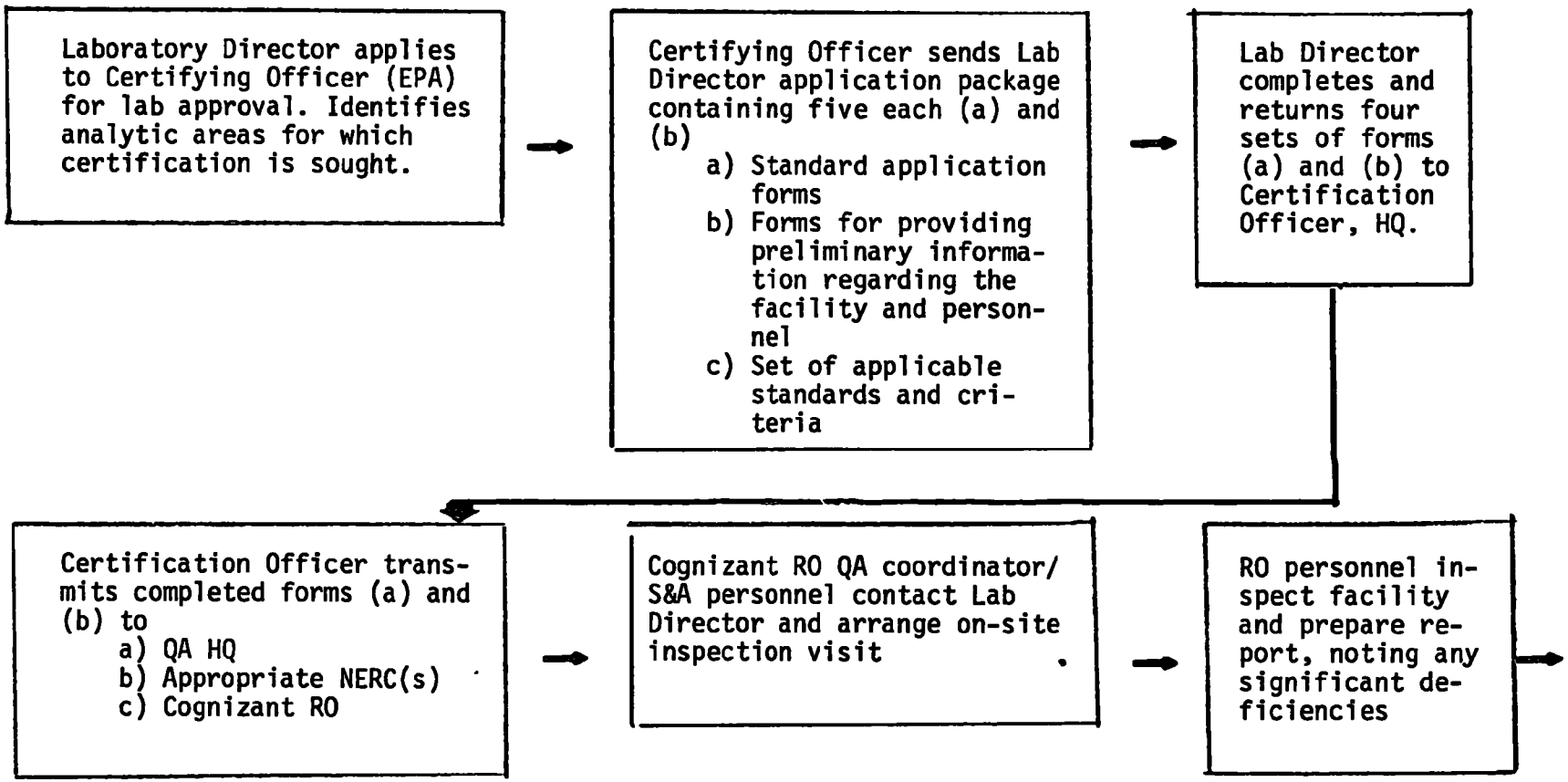
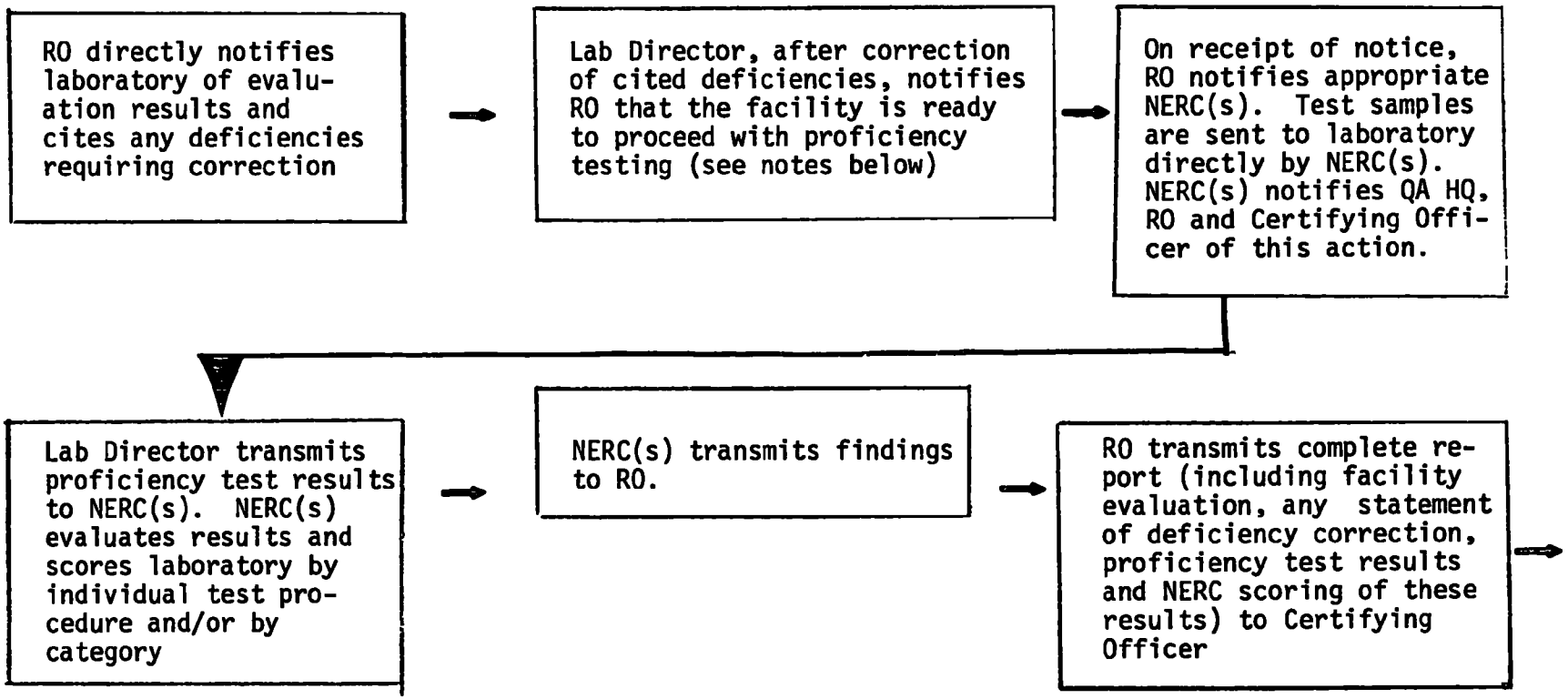


Figure 2. Flow Chart of Certification Process



Notes: 1. Proficiency testing should not be initiated until significant facility deficiencies have been corrected.
2. Except in extremely doubtful cases, EPA would accept the laboratory's notice of deficiency correction.

Figure 2. continued

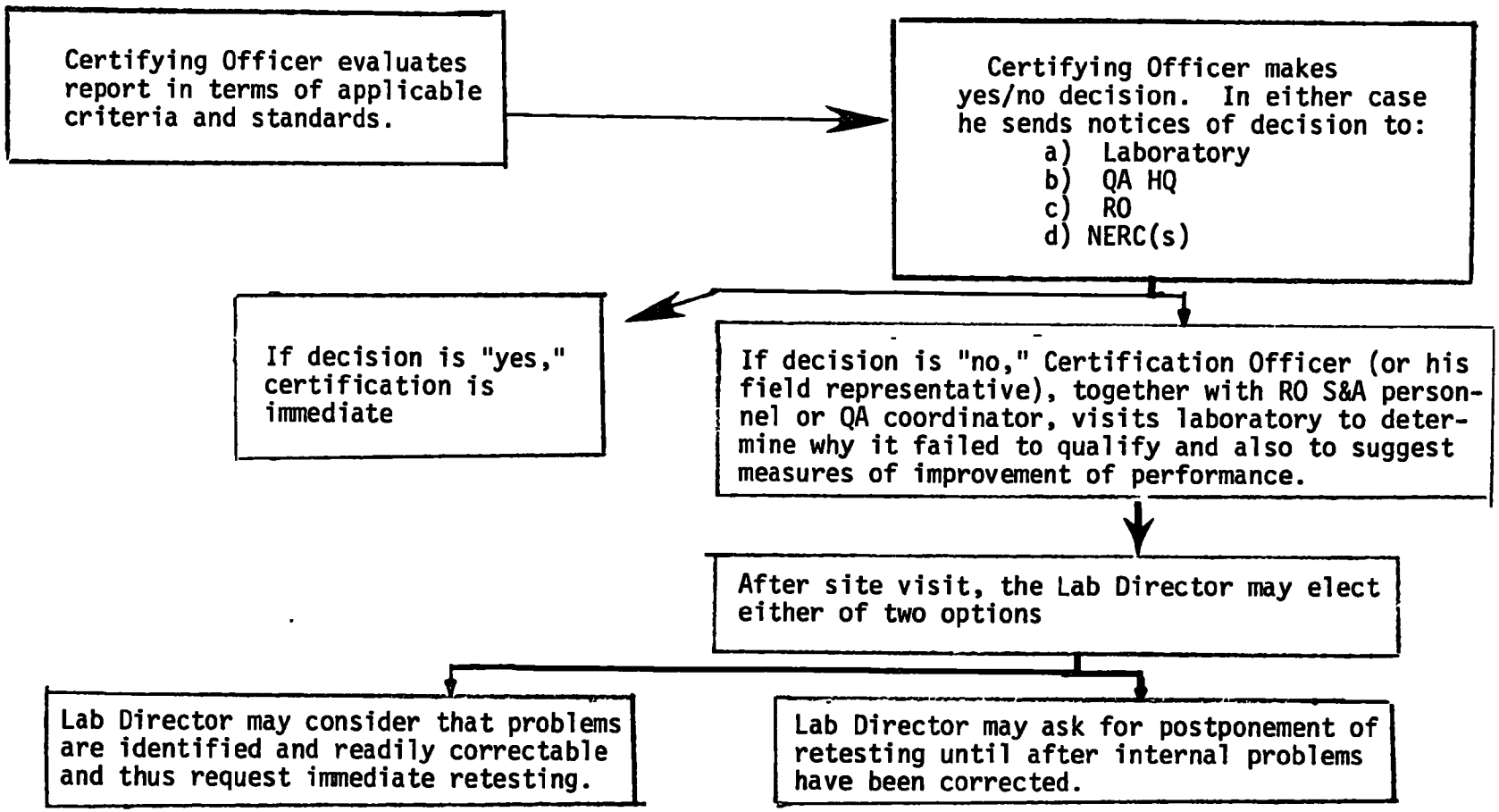


Figure 2. continued

Program Evaluation: (applicable to EPA and State programs)

. Need

The need for a certification program derives from the Agency's requirement for environmental data of adequate quality and reliability. Implementation of a legislatively authorized certification system would provide the Agency with a firm legal base for enforcement. Although the present QA Program encourages data quality improvement, it cannot in itself ensure the attainment of environmental data quality objectives

. Feasibility

The feasibility of the certification program in terms of its practical implementation rests largely on these factors:

a) Authority

Either new explicit legislative authority or a determination by the Agency that its existing statutues provide sufficient authority is necessary in order to provide the legal basis for a mandatory program.

b) Availability of Resources

Establishment and operation of the certification program will obviously require both funding resources and additional personnel for qualifying the State agencies only. Furthermore, intra-state programs will pose additional funding demands to meet the needs of State agencies and of EPA, should it be required to certify intra-state laboratories because of State default.

c) Program Scheduling

Although desirable on technical grounds, it may not prove feasible to certify all States simultaneously, partly because of EPA's relative inexperience in the laboratory qualification process and partly because of the level of costs which would be incurred. For the same reasons, it is recommended that certification in all programmatic areas should not be implemented at once. From the vantage point of this study, it is believed that program establishment and operation will prove more feasible if conducted on a progressive basis.

. Probability of Attaining Program Objectives

Over the long run, this is considered to be high provided that the key problems of authority and resource support (for both EPA and State operations) are satisfactorily resolved.

. Probable Impact of Program on Existing Laboratories

Considering water laboratories specifically (which the program is to cover initially) it is quite possible that many marginal commercial laboratories may fail to survive. The severity of this impact would depend, in large measure, on the licensing standards to be established. Large and well qualified facilities should encounter no significant problems. The capabilities and performance levels of many local governmental laboratories as well as of some State agencies which are now inadequately funded will necessarily improve.

. Ease of Program Implementation

From a purely technical standpoint, EPA should experience no major difficulty in establishing and operating a program for the certification of State laboratories. The existing QA Inter-laboratory Program and the NERCs provide the nucleus of the required mechanism for laboratory capability and performance evaluation. Given adequate funding support and the additional professional and technical staffing which will be needed, there is no inherent reason why these Agency elements cannot be developed and expanded to the point of adequately supplying all certification technical support functions. Furthermore, it is expected that the two Agency sponsored studies previously referenced, namely, the development of a system for conducting inter-laboratory tests for water quality and effluent measurements, and the development and preparation of a protocol for laboratory inspection, should contribute directly to the formulation of detailed procedures for both laboratory evaluation and the proficiency testing of water laboratories.

Problems associated with intra-state program operations will, in most instances, probably reflect inadequate funding levels. Furthermore, the salary schedules prevailing in some States may be insufficiently high to attract qualified professional personnel.

. Program Costs and Benefits

The prospective major benefit of the program to EPA has already been identified as the provision of a mechanism for enabling the Agency to legally reject data of uncertain quality. From another point of view, the program will provide EPA with environmental data whose quality and reliability will have a high probability of meeting or exceeding minimum acceptance standards. Reliable monitoring data are essential to the Agency for the proper discharge of many of its major responsibilities.

The cost to EPA of operating the formal or administrative portion of the program through which the State laboratories are to

be certified should be relatively low because the pertinent functions can be accomplished with a small staff (estimated at six). On the other hand, the costs of pre-certification and certification maintenance evaluation of State laboratories could be considerable. The following analysis is based on interviews with personnel associated with on-going certification programs. The analysis assumes one annual inspection per laboratory and a quarterly proficiency testing schedule.

Laboratory Inspection and Evaluation

Given ten EPA Regions and fifty States, the average annual number of inspections to be performed per Region would be five. The time required for each laboratory review is estimated to be six man-days. This is based on the allotment of two days to travel, two days for inspection and evaluation and two days for report preparation. Thus, the aggregate average time required per region (excluding clerical time) would be about thirty days annually. In some instances, Regional Offices may possibly be able to accommodate the laboratory inspection function within existing staffing resources. In any case, the addition of one individual to the staff of each Regional Office should be sufficient.

Proficiency Testing

Assuming quarterly testing of fifty water laboratories per year for five pollutant categories (organic, inorganic, trace metals, oxygen demand,microbiological), it is estimated that the required effort could be accomplished by a staff such as the following:

Function	Number
Proficiency Testing Program Director	1
Reference Sample Preparation Technicians	5
Statistician	1
General Laboratory Support	1
Clerical Support	2
Total	10

Additonal costs such as travel, materials, data processing, laboratory equipment maintenance and general overhead are difficult to estimate in advance of actual experience, but should not substantially exceed 1.5 times the direct costs (assuming 100% overhead). If it is assumed that each Region acquires one additional staff member to provide the laboratory inspection and evaluation function, the total staffing increment would be twenty personnel and the annual program budget could be as high as $750,000,if overhead is taken into account. This figure approximates a "worst case" and actual cost experience may indicate that it is high. In event of State agency default, EPA would then have to assume

responsibility for certification of intra-state laboratories for defaulting States. It has been estimated that there about 3,000 privately operated water laboratories, most of which are located in relatively prosperous industrial States, that is, those States least likely to default. Assuming the number of laboratories in defaulted States to aggregate 500, EPA's certification program would have to be augmented by a factor of 10/1. This, however, does not necessarily imply that staffing and related costs would increase correspondingly. A factor of 5 or 6 to 1 is probably more realistic.

The costs of State agency programs will necessarily vary considerably from State to State, depending on such factors as the number of laboratories per State, and whether certification programs have already been established. As indicated earlier, it is inevitable that most States will require resource support if they are to implement certification programs at a level of effectiveness acceptable to EPA. One obvious source of such support is the Federal grant mechanism which may, however, prove difficult for the Agency to employ without targeted appropriations. Another possibility is that State agencies may require that licensing and proficiency testing fees be paid by private laboratories. In the cases of small facilities, however, fees of significant size may impose an intolerable burden and effectively force these laboratories out of existence.

APPENDIX I

OUTLINES OF CERTIFICATION PROGRAMS REVIEWED

INTRODUCTION

This Appendix presents synopses of various laboratory certification programs examined during this study which were considered relevant to EPA's interests, including those which were the subjects of site visits performed under the Phase II portion of the project. The synopses are grouped by the level of the certifying organization, e.g. Federal, State and private.

FEDERALLY OPERATED CERTIFICATION PROGRAMS

HEW, PUBLIC HEALTH SERVICE, FDA, BUREAU OF FOODS

I Background

A. Nature of Program

Approval by the Bureau of Foods of State laboratories and their personnel performing analysis of milk and certification of State laboratory evaluation officers responsible for the approval of laboratories performing such analyses at substate levels.

B. Authority

Grade "A" Pasteurized Milk Ordinance (1965 recommendations of the United States Public Health Service).

C. Objective

To establish conformity of laboratory procedures with those prescribed in "Standard Methods for the Examination of Dairy Products" and "Official Methods of Analysis of the Association of Official Analytical Chemists".

II The Certification Process

A. Scope

The Bureau of Foods directly approves all State Central Milk Testing Laboratories and certifies their analysts for the performance of specific tests. In addition, the Bureau influences state certification of municipal, and commercial milk industry laboratories (which must be officially designated by the States) in the following ways:

- The Bureau sets the standards against which laboratory procedures and practices are to be assessed.
- The Bureau prescribes the methods by which laboratories are to be evaluated (in terms of facilities, personnel, etc.)
- The Bureau certifies State officials responsible for the approval of officially designated laboratories (municipal, commercial and industry labs).
- The Bureau periodically performs check evaluations of milk laboratories of participating states in order to ensure compliance with prescribed standards.

B. Laboratory Elements Evaluated

Laboratory facility and operating elements for which standards and evaluatory methods have been established may be grouped into the following categories:

Facility

- work areas
- apparatus and equipment
- materials (and their preparation)

Procedures

- sampling*
- general cultural procedures
- test methods (and preparation for tests)
- internal quality control**
- reports and records

Personnel

Note: While laboratory survey forms require only that the survey officer ascertain whether "personnel (are) adequately trained or supervised", all forms for both laboratory surveys (including a "narrative report" which accompanies all completed survey forms in which individual tests are observed) and split sample analyses require that the name of the analyst performing the specific test be noted. On this basis an analyst is certified for the performance of a specific test.

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* At the State level, examination of sampling practices may be delegated to appropriate State milk evaluation officers.

** Quality control procedures are specified for all tests for which the laboratory is approved. When the agar plate method, for example, is used test counts must be duplicable within 5 percent for a single analyst and within 10 percent when performed by another analyst.

C. Certification Procedures

FDA Activities

- FDA certifies State Central Laboratories (once every three years) by means of announced on-site visits.
- FDA certifies State laboratory certification officers principally through an examination of their proficiency in performing evaluations when accompanied by FDA examiners.
- FDA distributes split samples for testing by State central laboratories at least annually.
- FDA is required to survey for reapproval all State central laboratories at least every three years.
- FDA reevaluates State laboratory certification officers at least every five years.

State Activities

- States evaluate municipal, commercial and milk industry laboratories (and their personnel) by means of announced on-site visits.
- State milk laboratory certifying agencies are required to split samples at least twice per year with each official and/or officially designated milk laboratory.
- States are required to evaluate for reapproval all official and officially designated milk laboratories at least once every two years.
- States are required to send annually to FDA a list of approved laboratories (including the date of the last evaluation test(s) for which approved).

III Identified Problem Areas

The implementation of the "milk program" is not currently experiencing any difficulties. The success of the program is attested to by the recent request of many State laboratories that FDA implement a laboratory standardization program for food testing similar to that for milk.

IV Program Administration and Evaluation

The administration of the program is the responsibility of technical

personnel only. The branch relies on the quality of the results received from participating laboratories for their evaluation of the program as a whole.

V Cost and Level of Effort Estimates

Laboratory evaluations performed by the Bureau are financed on a case by case basis, each requiring approximately 20 manhours of effort (exclusive of travel time). Cost estimates for the program as a whole have not been made since 1964.

USDA - ANIMAL AND PLANT HEALTH INSPECTION SERVICE

I Background

A. Nature of Program

The Health Inspection Service (APHIS) certifies private and industrial laboratories to perform tests on meat samples for the meat industry.

B. Authority

General Meat Inspection Act of 1906.

C. Objective

The objective of this certification program is twofold:

- To relieve the government laboratories of the burden of testing all processor meat samples
- To ensure that tests performed by private and industry laboratories conform with procedures selected by APHIS from the "Official Methods of Analysis of the Association of Official Analytical Chemists"

II The Certification Process

A. Scope

APHIS directly certifies each of the 166 laboratories which participate in the Agency's program. It also performs periodic check evaluations of USDA meat inspectors who select and prepare split samples for analysis by both USDA itself and by laboratories being examined for certification or recertification; APHIS also prescribes the testing standards and methodologies for the performance of specific analyses.

B. Laboratory Elements Evaluated (during laboratory visit)

Facility

- the general appearance of the laboratory

Procedures

- precision in following test methods prescribed by APHIS is evaluated

Personnel

Note: Other than the requirement that the laboratory supervisor must hold a degree from an accredited college or university, no rigorous evaluation of personnel (independent of their proficiency in testing) is performed. Personnel qualifications and performance are more carefully scrutinized only where testing problems arise.

Records

An updated version of the "standards book" as well as complete test records are required.

C. Certification Procedure

APHIS certifies laboratories for an indefinite period by:

- Examination of laboratory qualifications (e.g., fulfillment of educational requirements by supervisory personnel
- Split sample testing (successful performance on 30 tests is required prior to certification). Subsequently a minimum of 4 split sample analyses per month (of which one is randomly selected for analysis by USDA) is required for maintenance of certification.
- On-site laboratory surveys on an as needed basis

APHIS periodically checks regional inspectors principally through:

- Verbal examination (these examinations are conducted in the field)
- Examination of inspector's records

III Identified Problem Areas

No problems associated with program effectiveness as a whole were identified.

IV Program Administration and Evaluation

All on-site laboratory visits are performed by a single evaluator from the Washington office of the service. Sample collection is the responsibility of USDA regional personnel.

V Economic Aspects of the Program

The laboratory certification program resulted in a savings of approximately $200,000 in Federal funds in 1973 because of the reduced number of sample analyses required to be performed by Federal laboratories. Local laboratory certification also represents a cost savings to the meat industry which has found that the use of local laboratories reduces mailing expenses and delays in waiting for test results. For these reasons, although Federal sample analysis is provided without charge to the meat packers, they prefer, in many cases, to pay private laboratories to perform these tests.

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
PUBLIC HEALTH SERVICE, CENTER FOR DISEASE CONTROL
LABORATORY LICENSURE SECTION

I Background

A. Nature of Program

Clinical laboratories receiving specimens in interstate commerce are licensed to perform tests in six broad categories. The types of laboratories licensed under this program are:

. Hospital

A laboratory located in a hospital, or, if outside the hospital, is operated by, or under the supervision of the hospital or its organized medical staff, and serves the hospital's patients.

. Independent

A laboratory which is independent of both the attending or consulting physician's office and of a hospital.

. Industrial

A laboratory owned and operated by a company or corporation primarily for its own employees' medical care.

. Public Health

A laboratory belonging to a governmental unit and primarily involved in obtaining public health information.

B. Authority

The Clinical Laboratories Improvement Act of 1967.

C. Objective

The licensure program is intended to foster the improvement and maintenance of quality of laboratory performance by contributing to the conformity of laboratory procedures with standards prescribed by the Public Health Service.

II The Certification Process

A. Scope

Any laboratory soliciting or accepting specimens in interstate

commerce is required to hold a license or letter of exemption issued by the Secretary, Department of Health, Education and Welfare. Approximately 800 laboratories have been approved to date. At the discretion of the Secretary, a laboratory which is accredited by an HEW approved accrediting body or which agrees to a special inspection and/or records submittal arrangement with CDC may qualify for a letter of exemption from the Secretary.

B. Laboratory Elements Evaluated

Facility

- work and storage space
- safety equipment
- condition of equipment
- temperature and humidity

Procedures

Test procedures in

- microbiology and serology
- clinical chemistry
- immuno-hematology
- hematology
- pathology
- radiobioassy

Quality control procedures (including preventive maintenance of equipment, labelling of reagents, QC records maintenance, etc.) fire safety and laboratory accident control procedures.

Personnel

Evaluation of personnel qualifications and duties is based on essentially the same criteria as those used in the Social Security Administration's Medicare (Health Insurance for the Aged) program. Qualifications for the laboratory director are described below as an example. The Director must be either:

- physician certified in anatomical and/or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology, or possess qualifications equivalent to those required, or

- physician certified by American Board of Pathology or the American Osteopathic Board of Pathology in at least one laboratory specialty, or is certified by the American Board of Microbioloby, the American Board of Clinical Chemistry, or other national accrediting board acceptable to the Secretary in one of the lab specialties, or subsequent to graduation has had four or more years of general laboratory training and experience of which two years were spend acquiring proficiency in one of the laboratory specialties at the doctoral level, or

- holder of an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as his major subject and is certified by the American Board of Microbiology, the American Board of Clinical Chemistry or other accrediting board acceptable to the Secretary in one of the laboratory specialties, or subsequent to graduation has had four or more years of general clinical laboratory training and experience, of which at least two years were spent acquiring proficiency in one of the laboratory specialties in a clinical laboratory with a director at the doctoral level.

It should be noted that special emphasis is placed on personnel qualifications in the application forms.

Records and Reports

- records of observations and specimens

- records retention

- adequacy of reports to DHEW

- methodology documents

C. Certification Procedure

Subsequent to application by a laboratory for licensure, CDC initiates a laboratory evaluation in which the following steps are included:

- laboratory personnel (principally the director, general supervisor and technical supervisor) are appraised.

- an announced on-site visit is performed.

The laboratory as a whole is then evaluated and, if all CDC conditions are met, is licensed for the performance of specific tests. After licensure, laboratories participate in a proficiency testing (PT) program (in which blind samples are distributed to reference laboratories as well as to participating laboratories). Continued licensure is dependent, or course, on satisfactory PT results.

Maintenance of licensure requires:

- continued satisfactory PT results
- satisfactory results of annual on-site visits

III Identified Problem Areas

Minor technical problems have arisen within CDC with reference to the internal changeover to a computer operated data system. It is expected, however, that these problems will soon be resolved. A more serious problem is a legal one and is associated with "adverse actions" on the part of CDC. According to the Clinical Laboratories Improvement Act of 1967, a laboratory which does not conform to the requirements of the CDC (e.g., does not return results on proficiency testing samples) will be subject to "adverse action" by the Center, resulting in a revocation of the laboratory's license. According to personnel in the Laboratory Licensure Section, however, "adverse actions" have not been initiated in a timely manner, with the consequent continued operation of laboratories which do not meet CDC performance standards. The cause of this problem has not yet been isolated but the delay is, at present, a major internal concern of the agency.

IV Program Administration and Evaluation

The Laboratory Licensure Section of the CDC, which is responsible for the performance of the tasks outlined above, currently employs eleven examiners. In addition to their responsibilities with respect to CDC licensure, these examiners check a minimum of 10% of State and private agency certified laboratories in cases where State or private accreditation programs (e.g., of the College of American Pathologists) have been rated as equivalent to CDC licensure.

CDC relies principally upon input from licensed laboratories and from PT results to determine the effectiveness of its licensure program.

V Cost and Level of Effort Estimates

Independent of travel expenditures associated with the on-site visit, the estimated cost of licensing a laboratory is approximately $125.00. Laboratories pay a fee of $25.00 for each section examined.

VI Comments

Relationships With Other Agencies

- CDC has approved the inspection and accreditation program of the College of American Pathologists as equivalent to CDC licensure as well as some State programs. Only New York is equivalent in all testing areas, although programs of the States of Utah and Wisconsin have been approved in part. CDC does some licensing at the State level for the Medicare program of the Social Security Administration.

DEPARTMENT OF LABOR, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION
DIVISION OF SAFETY STANDARDS

I Background

A. Nature of Program

OSHA is considering accreditation of independent laboratories which evaluate the safety of specified products, devices, systems, materials and installations.*

B. Authority

- Williams-Steiger Occupational Safety and Health Act of 1970
- Contract Work Hours and Safety Standards Act

C. Objective

To facilitate the enforcement of occupational safety and health standards.

II The Certification Process

A. Scope

Under the proposed program all laboratories engaged in product safety testing would be required to obtain accreditation from OSHA in order to continue performance of these tests. Accredited laboratories would, in effect, act as extensions on OSHA in their role as product testers and certifiers.

B. Laboratory Elements Evaluated

Facility

- the availability and condition of facilities and equipment relevant to the testing of the product for which accreditation is requested
- housekeeping practices

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* 29 CFR 1907, which sets forth "Criteria and Procedures for Accrediting Testing Laboratories", may be revoked because of significant errors in the text. Public comments concerning proposed changes are now being evaluated by the agency. Information presented here is derived principally from the original text of 29 CFR 1907.

Procedures

General duties and qualifications are evaluated for:

- laboratory director
- technical director (chief engineer)
- technical supervisor (department manager)
- testing monitor
- technical staff

C. Certification Procedure

Initial Accreditation

- Subsequent to the filing of an application by a testing laboratory, OSHA would perform an on-site survey to verify the information supplied by the laboratory. The period of accreditation is two years.

Maintenance of Accreditation

- In addition to maintaining those laboratory and testing conditions required for initial accreditation, a laboratory must demonstrate its ability to perform functions associated with the following general areas:
  - product acceptance
  - recordkeeping
  - reports

  In addition, the laboratory must:

  - grant OSHA the right to conduct unscheduled laboratory inspections
  - participate, at its own expense, in periodic reference sample test programs under the direction of OSHA.

III Identified Problem Areas

None

IV Program Administration and Evaluation

Neither administrative nor evaluatory procedures have been finalized to date.

V Cost and Level of Effort Estimates

None currently available.

HEW SOCIAL SECURITY ADMINISTRATION
BUREAU OF HEALTH INSURANCE

I Background

A. Nature of Program

The Bureau of Health Insurance (HEW) provides fiscal support for independent clinical laboratories performing services under the Medicare program. This support takes the form of reimbursement to laboratories complying with the conditions specified by the Administration under the supplementary medical insurance part of the Health Insurance Program for the Aged and Disabled.*

B. Authority

The Administration Procedures Act (5 USC 553).

II The Certification Process

A. Scope

The Bureau of Health Insurance (BHI) of the Social Security Administration certifies approximately 3,000 laboratories, using State certifying personnel. In addition the BHI:

- sets the standards against which laboratory procedures and practices are to be assessed
- prescribes the methods to be used by State examiners during laboratory inspections
- approves all officials designated by the State to perform on-site evaluations of laboratories

B. Laboratory Elements Evaluated

Facility

- adequacy of space
- ventilation

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* Proposed new implementing regulations, which will slightly alter the requirements for eligibility, were made public on July 2, 1974 and are expected to be finalized with only minor modifications.

- fire and safety precautions

Equipment

- adequacy of equipment
- calibration

Procedures

- quality control procedures*
- test methods

Personnel

Qualifications and duties are prescribed for:

- laboratory director
- laboratory supervisor
- technical personnel

Records and Reports

- notebooks describing current laboratory methods
- specimen records
- laboratory reports

Note: BHI notes that a laboratory's compliance with personnel qualifications requirements is the most significant factor determining its initial accreditation. Subsequent maintenance of accreditation however, relies more heavily on other laboratory elements, such as quality control procedures and the ability to demonstrate accurate and correct test methods.

C. Certification Procedure

Laboratory Approval

- The applicant laboratory completes forms supplied to it by the State.

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* Proposed quality control requirements are identical to those required by the Center for Disease Control (CDC).

- State inspection officials (or licensure inspectors where State laboratory licensure programs exist) who are approved by BHI, perform an on-site visit to the applicant laboratory.

- Regional personnel of the Social Security Administration review the laboratory's application as well as the recommendation of the State inspector and make the final accreditation decision.

- Maintenance of accreditation requires that the laboratory participate in one of several approved proficiency testing programs (e.g., a State licensure testing program, CDC, College of American Pathologists).

- The program calls for annual reexamination of each participant laboratory.

Inspector Approval

- State laboratory inspectors are selected principally on the basis of their academic qualifications.

- The performance of State laboratory inspectors is usually evaluated every two years. This is accomplished in the following manner:

  - spot checks are performed on laboratories approved by an examiner

  - HEW regional personnel accompany the State examiner on selected laboratory inspections

III Identified Problem Areas

Because the details of the proposed regulations are not available, it is as yet uncertain to what degree the program modifications will affect the level of future State participation. There is concern within the administration that a reduction of State responsibility may be implicit in these program modifications and, in such case, certain BHI personnel believe that BHI-State relations may deteriorate with as yet unforseeable results to the program.

IV Program Administration and Evaluation

The majority of BHI's laboratory approval functions are performed by the Agency's regional offices. Only in cases of "problem laboratories" are decisions referred to the Central Office. In addition, the Central Office makes all decisions regarding approval policy.

BHI relies principally on the efforts of the Program Validation and Integrity Branch of the Agency, which uses such evaluatory techniques as site studies and surveys to evaluate the operation of its approval program. In addition to the activities of this branch, inspections of State survey operations every two years provide data on which program evaluations are based.

V Cost and Level of Effort Estimates

None was available from the Bureau.

VI Comments

The structure of the BHI laboratory approval program contains two features which may be of interest to EPA. These are:

- Reliance of the central office on regional offices for program operation
- Extensive use of State laboratory examiners

EPA WATER QUALITY OFFICE, WATER SUPPLY DIVISION

I Background

A. Nature of Program

Certification, by EPA, of State laboratories analyzing potable water on interstate carriers and of State laboratory certification officers who examine laboratories at substate levels.

B. Authority

- Presidential Reorganization Plan No. 3 which establishes EPA and transfers to it responsibility for this program.
- Interstate Quarantine Regulations of the Public Health Service

C. Objective

Conformity of laboratory procedures for microbiological testing with those prescribed in "Standard Methods for the Examination of Water and Wastewater" to ensure data quality.

II The Certification Process

A. Scope

EPA's Water Supply Division (WSD) directly certifies all State Central Water Laboratories with respect to potable water quality testing. In addition, EPA influences state certification of local agency and private laboratories within each state in the following ways:

- WSD sets the standards against which laboratory procedures and practices are to be assessed
- WSD prescribes the methods by which laboratories are to be evaluated (in terms of facilities, personnel, etc.)
- WSD approves state officials responsible for the certification of municipal and commercial water laboratories. (All data gathered by these state laboratory certification officers must be made available to WSD.)

Typically, WSD certifies one central laboratory and approves two evaluation officers in each state.

B. Laboratory Elements Evaluated

Note: The procedures for sample testing methods for use by state laboratories, laboratory evaluation methods and criteria as well as the potable water quality standards themselves are currently being reviewed and revised. Guidance documents reflecting these revisions are not available. For this reason the information presented below, while current, is subject to change.

Identical elements are examined for initial certification of laboratories at both the state and local levels as well as for their periodic recertification. Laboratory facility and operating elements for which standards and evaluatory methods have been established may be grouped into the following categories:

Procedures

- sampling
- sterilization
- test methods
- laboratory safety practices

It is noted that there are few explicit requirements for the establishment and maintenance of internal laboratory quality control procedures.

Facility

- special purpose space (e.g., incubator room, work space)
- apparatus and equipment

C. Certification Procedure

- WSD certifies state laboratories and state laboratory certification officers
- States certify local and commercial laboratories
- At both Federal and State levels certification is accomplished through announced on-site visits
- WSD procedures call for triennial reviews of state central laboratories by on-site visits as well as for biennial reviews of State laboratory certification officers by on-site visits

- WSD may directly review local laboratory performance if considered necessary

III Identified Problem Areas

Relationships with the State Laboratories

Corrective approaches employed:

- WSD has used its certification program to provide technical assistance to laboratories. The regulatory purposes of certification have been deemphasized.

- Research undertaken by WSD has resulted in technical innovations which, when used by State laboratories, have resulted not only in improved water quality testing procedures, but also in cost and time savings for the laboratories.

IV Cost and Level of Effort Estimates

An average laboratory evaluation requires 56 manhours (two days for on-site evaluations and five days for report preparation) of grade levels thirteen through fifteen personnel. In addition, approximately eight manhours are required for the typing of each report. Detailed cost data, beyond these manhour estimates are currently unavailable.

STATE OPERATED CERTIFICATION PROGRAMS

NEW YORK DEPARTMENT OF HEALTH
DIVISION OF LABORATORIES AND RESEARCH

I Background

A. Nature of Program

The State Health Department approves laboratories to test samples from public water supplies in cases where the data generated is to be used to show compliance with the State sanitary code.

B. Authority

New York State Health Rules and Regulations, Title 10 parts 5 and 72

C. Objective

To ensure that all data generated by approved laboratories will meet minimum standards and to ensure reliability of laboratory results.

II The Certification Process

A. Scope

The Health Department approves approximately 100 laboratories for the performance of chemical and biological tests on water.

B. Laboratory Elements Evaluated

Facility

- adequacy of space
- availibility and condition of specified equipment

Procedures

- test procedures*
- safety procedures
- internal quality control

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* The Department uses EPA forms [EPA 103 (Cin) (Rev 3-71)] to evaluate bacteriological test procedures.

Personnel

- Qualifications stress educational background in the case of technical managerial personnel. Technicians are rated in terms of their skills and experience.

Records and reports

- test records are reviewed for completeness of information

C. Certification Procedure

- A laboratory makes application to the State Health Department for initial approval
- Laboratory staff personnel of the Health Department perform an on-site evaluation of the laboratory in which the elements noted above are examined
- Acceptable laboratories are approved for submittal of data as evidence of public water supply complience with sanitation code
- Laboratories are scheduled for examination (for renewal of approval) every two years

III Identified Problem Areas

The principal problem with which the operation of this program contends is financial. The Department receives no special allocation for its approval program and must, therefore, use funds needed for Department laboratory operations to perform its approval related functions. The following program deviciencies have been identified by the Division as attributable to the lack of adequate financial support:

- inability to consistently perform on-site visits for renewal of approval as scheduled (every two years)
- lack of a reference sample program (the Division considers such a program to be essential to effective approval program)

IV Program Administration and Evaluation

The program has no full time staff for the operation of its approval program. Health Department laboratory staff members are used to perform on-site evaluations and department supervisory personnel make all final approval decisions.

There is no existing satisfactory feedback mechanism through which the Department can assess the effectiveness of its program.

OKLAHOMA DEPARTMENT OF HEALTH, SYPHILIS SEROLOGY PROFICIENCY TESTING PROGRAM

I Background

A. Nature of Program

The Health Department certifies the following categories of laboratories to perform premarital and prenatal blood sample testing:

- a laboratory in a hospital currently licensed by the Oklahoma Department of Health
- a laboratory owned and/or directed by a physician licensed to practice in Oklahoma
- a public health laboratory operated by a County or Municipality and staffed by personnel classified under the State Merit System or equivalent personnel administrative system
- a private laboratory certified in the specialty of microbiology, subspecialty serology, under provisions of "Conditions of Coverage of Services", Social Security Administration, U.S. Department of Health, Education, and Welfare

B. Authority

- 43 O.S. 1971 Sec 31-37
- 63 O.S. 1971 Sec 1-515

C. Objective

The maintenance of a satisfactory level of performance in the serological testing of blood samples.

II The Certification Process

A. Scope

The Department has so far certified about 200 laboratories which comply with the standards and procedures prescribed by the Health Department.

B. Laboratory Elements Evaluated

Facility

- space, ventilation, temperature control, lighting
- equipment*

Procedures

- compliance with minimal technical standards for test procedures authorized by the Commissioner of Health

Personnel

- Both academic and experimental qualifications are specified for all laboratory personnel performing serologic tests for syphilis.

Records and reports

- adequacy of report forms which accompany test samples
- quality control records
- adequacy of reference materials

C. Certification Procedure

For initial certification a laboratory must:

- demonstrate proficiency in testing methods as well as the adequacy of facility, personnel and records
- analyze four series of ten samples with a grade of 90% or better

For maintenance of certification a laboratory must:

- analyze six series of ten samples each year with a grade of 90% or better

The proficiency testing program uses the services of three referee laboratories to evaluate each applicant ("test") laboratory. Samples are split among the referee and test laboratories and successful performance is measured in terms

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* Equipment prescribed in the "Manual of Tests for Syphilis" HEW, PHS Publication No. 411 is required to be available.

of the applicant laboratory's ability to:

- produce results which are in agreement (by no less than 90%) with those of the reference laboratory
- reproduce, when required, results of past analyses

In the event of inadequate proficiency test performance, a laboratory is placed on "probation" (during which it is debarred from performing tests for the public) for six months. During this period laboratory personnel receive training from State officials in correct laboratory procedures.

III Identified Problem Areas Currently Identifiable

No problems.

IV Program Administration and Evaluation

The Health Department relies principally upon the results of its participation in a CDC sample testing program for the evaluation of its technical capability to assess test results from laboratories which it accredits. However, as is true of most certification programs, no formal internal quality assurance mechanisms exist with respect to the administrative and/or on-site evaluation aspects of its program.

V Cost and Level of Effort Estimates

The program supervisor estimates that one to two manhours are required to evaluate laboratory performance in a specific test area. No dollar cost estimates were available.

OKLAHOMA STATE CERTIFICATION PROGRAM
OKLAHOMA WATER RESOURCES BOARD

I Background

A. Nature of Program

Water laboratories receiving water analysis specimens within the state of Oklahoma are licensed to perform tests in three broad categories.

- "A" laboratories are mineral and metal water analysis laboratories having a limited scope of activities.
- "AA" laboratories are mineral and metal water analysis laboratories able to perform under all or nearly all of the test range surveyed by the OWRB.
- "AAA" laboratories are laboratories which qualify under the "AA" classification and also have a biological capability.

B. Authority

The program is operated under the rather broad authority of long standing legislation.*

C. Objective

The licensure program is intended to improve reliability of laboratory analytical results and to promote the maintenance of high quality standards.

II The Certification Process

A. Scope

Any laboratory doing water analysis work within the state of Oklahoma is eligible to be licensed by the OWRB. The list of licensed laboratories published by the Board is a powerful driving force which compels most Oklahoma Water Analysis laboratories to enter the program. There are thirty-seven laboratories active in the program at present.

B. Laboratory Elements Involved

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* Identification of the specific legislation was not provided.

Facility

- equipment
- physical plant

Personnel

- number and types
- qualifications

Procedures

- metal analysis
- mineral analysis
- biological analysis
- quality control

Proficiency testing

- number of categories
- accuracy

III Identified Problem Areas

Insufficient funds (the present funding level is approximately $5,000) permit only annual proficiency testing. Reference samples, as obtained from the United States Geological Survey, sometimes do not reflect "real life" conditions. Annual on-site evaluations of all laboratories are not possible within present resource allocations.

CONNECTICUT, STATE DEPARTMENT OF PUBLIC HEALTH

I Background

A. Nature of Program

The Health Department approves and registers private and municipal laboratories as public health laboratories for the examination of water and sewage and trade wastes.*

B. Authority

The Connecticut Public Health Code Section 19-13-A35

C. Objective

To safeguard the public health, safety and welfare

II The Certification Process

A. Scope

The Health Department approves and registers approximately sixty private and municipal water laboratories within the State. Private laboratories are approved to test discharge samples for industries on a fee basis. Municipal laboratories are registered to perform tests on municipal water supplies and sewage.

B. Laboratory Elements Evaluated

Facility

- special purpose space
- apparatus and equipment

Procedures

- sampling
- sterilization
- laboratory safety practices

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* Laboratories may also be approved for the performance of tests on dairy products and some foods under this program.

- test methods*

  Note: The laboratory must be able to demonstrate its ability to perform bacteriological, physical and chemical tests using either methods identical to those found in the American Public Health Association's Standard Methods for the Examination of Water and Wastewater or other methods which are acceptable to the Department.

Personnel

- Qualifications of the laboratory director and key personnel are evaluated prior to consideration of a laboratory for registration by the Health Department. The requirements for the laboratory director are described in "C" below.

C. Certification Procedure

Before a laboratory may be registered by the Department of Health, the laboratory director must receive State approval. In order to qualify he must:

- hold at least a B.A. in a field related to the work area for which his laboratory is requesting certification
- have at least one year's experience in water and sewage analysis
- pass a qualifying examination given by the Health Department

When the availability of a director meeting the specifications outlined above is established, the laboratory may make formal application for approval. The following steps are typical of the laboratory approval process:

- An announced on-site inspection of the laboratory facility is performed.
- A technical review of the site visit results and information contained in the application of the laboratory is

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* Forms describing the required test methods for bacteriological analyses are identical to those used by EPA's Water Supply Division.

made. Any significant deficiencies are noted and the laboratory is advised to correct these deficiencies.

- When the facilities and personnel of the laboratory meet the specifications of the Laboratory Division, the laboratory is approved and registered.

Each laboratory is re-registered and approved annually. The following are the principal criteria used in annual evaluations.

- The adherence of the laboratory to all regulations and statutes of the State.

- The laboratory's performance in the State proficiency evaluation program. (Water samples for this program are currently supplied on a yearly basis by NERC-Cincinnati. By 1975, however, the State Health Department expects to prepare its own samples and to distribute them biannually.)

- The laboratory's performance during an on-site inspection.

III Identified Problem Areas

As is the case with similar State programs, the operation of the Connecticut registration and approval program is hampered by a lack of funds and work space and by an inadequate number of trained examiners. Currently, one examiner is responsible not only for the registration and approval of private and municipal water laboratories but also for the evaluation of laboratories testing milk, foods and food utensils.

IV Program Administration and Evaluation

The laboratory approval programs are the responsibility of a single person within the Health Department. He relies principally on the results of proficiency tests to determine the effects of the approval and registration program on data quality.

V Cost and Level of Efforts Estimates

No information is currently available in this area.

CALIFORNIA, STATE DEPARTMENT OF PUBLIC HEALTH
WATER LABORATORY APPROVAL

I Background

A. Nature of Program

The Public Health Department approves both commercial and non-commercial laboratories for the performance of bacteriological and chemical tests on water. Any laboratory engaged in these tests is required to obtain such approval from the State.

B. Authority

The California Administrative Code. Chapter 2, subchapter 1, Group 6, Sections 1174-1184 inclusive.

C. Objective

To assure a level of reliability of data on water quality which will safeguard the State's water supply and enable the Department of Public Health to carry out its responsibilities.

II The Certification Process

A. Scope

State Public Health Department employees are responsible for the approval of approximately 450 laboratories. Nearly one-third of these were visited in 1974 for reapproval and about 25 laboratories were evaluated for initial approval.

The program is currently financed by a grant from EPA in the amount of $116,000. These funds, which are disbursed by the California Water Resources Board, are being used to expand the staff of the Laboratory Services Division of the Public Health Department in order to augment both the scope and expertise of the Division.

B. Laboratory Elements Evaluated

Facility

- housing

- equipment and apparatus
- supplies

Procedures

- sample analysis
- recordkeeping
- reporting

Personnel

- qualifications of supervisory personnel are examined

C. Certification Procedures

After an application for approval is submitted by a laboratory within the State, the laboratory must perform successfully on:

- an on-site visit
- analyses of reference samples

in order to be approved.

Maintenance of approval requires the following:

- annual bacteriological reference sample tests

Renewal of approval of laboratories, including on-site visits, will be required every three years under the new EPA funded program.

III Identified Problem Areas

Problems associated with the implementation and effectiveness of the approval program as revised and expanded with the use of EPA funds are not yet identifiable because the program has so recently been restructured. (Note: The program which will be implemented with EPA support is the one synopsized here.) Problems of the previous program, which this new structure is designed to alleviate, can be grouped into two categories:

- Problems associated with the use of inadequately trained staff. This is especially an issue where chemical analyses must be evaluated by this staff because knowledge in the field of chemical analysis techniques is incomplete.

. Problems associated with a numerically inadequate staff.

IV Program Administration and Evaluation

The laboratory approval program is administered by a professional staff of five chemists. These chemists have a variety of responsibilities, the most significant of which is their role as laboratory evaluation officers.

The Health Department relies principally upon the results of its participation in the EPA reference sample program administered from NERC-Cincinnati for an evaluation of its technical capability to assess test results from laboratories which it accredits. In addition, the overall approval program was recently evaluated both by EPA and by the Department itself when EPA funds were made available and designations for their use were necessary.

V Cost and Level of Effort Estimates

The laboratory approval program is funded principally through the EPA grant referenced above. This grant of $116,000 provides support for four chemists and microbiologists, one laboratory assistant and a clerk. In addition, the State provides approximately $20,000 per annum for an additional chemist.

The program director estimates that, under the approval program as it is being revised, about one man day will be required for an on-site evaluation of a single laboratory. Manhour estimates for other aspects of the approval program were not available.

CALIFORNIA, STATE DEPARTMENT OF PUBLIC HEALTH
CLINICAL LABORATORY LICENSURE

I Background

A. Nature of Program

The Public Health Department licenses all commercial clinical laboratories in the State, except those directly owned and operated by a licensed physician or surgeon for work performed on his own patients.

B. Authority

- California Administrative Code, Title 17, Chapter 2, Subchapter 1, Group 2.
- California Business and Professions Code, Division 2, Chapter 3, Sections 1200-1322.

(Additional authority for laboratories participating in the Medicare program is provided by Social Security Administration regulations.)

C. Objective

To assure the capability and satisfactory level of performance of facilities and personnel engaged in the provision of clinical laboratory services.

II The Certification Process

A. Scope

At present about 2,000 laboratories and 22,000 laboratory personnel are licensed under the program. There are also about 8,000 physicians' office laboratories which are currently required to participate in an approved proficiency testing program, although they are exempt from licensing as such.

B. Laboratory Elements Evaluated

Facility

- work bench space
- work area arrangement
- ventilation

- storage of volatile chemicals
- safety precautions

Procedures

- record keeping
- internal quality control (written program is required)

Note: Analytical methods are not specified.

Personnel

- education, training and experience are all evaluated on the basis of detailed criteria established for a variety of work categories.

C. Certification Procedures

An application for a license is submitted by the applicant together with a fee of $100.00. Licensing requirements include:

- favorable evaluation of facility by licensed State survey personnel
- licensed status of laboratory personnel
- enrollment in a State approved proficiency testing program

Licensing of both the facility and personnel is subject to annual review.

III Identified Problem Areas

Most of the problem areas identified, such as the inability to conduct on-site visits with desired frequency, were traceable to funding limitations.

IV Program Administration and Evaluation

In addition to its direct licensing function, the State agency also issues guidelines to laboratories operating under its jurisdiction. These guidelines are generally addressed to the goal of laboratory improvement and deal with various specific topics such as management practices, personnel, laboratory performance control and evaluation and other germane areas.

Because the agency lacks an adequate capability for review of proficiency testing data (available statistical and computer services are quite limited), its competence to review the effectiveness of its licensing program is severely restricted.

V Cost and Level of Effort Estimates

Exact cost figures were not available. However, for Fiscal Year 1974-1975, a total of $465,199 was budgeted for an average of 37.8 positions. A budget prepared in 1970 showed the following:

Estimated Expenses

Salaries (31 persons)		$ 194,568
Travel		6,963
Statistical services		30,081
Data processing		18,237
Directory		7,500
	Total	$ 257,349

Estimated Income

Clinical laboratory fees		$ 147,700
Personnel licenses		
trainees		9,168
technologists		133,593
bioanalysts		14,052
	Total	$ 304,513

PRIVATELY OPERATED CERTIFICATION PROGRAMS

AMERICAN INDUSTRIAL HYGIENE ASSOCIATION

I Background

A. Nature of Program

AIHA accredits laboratories which perform analyses both of air samples from the workplace and of biological specimens related to exposures in the work place. Program planning was initiated in October 1970 and the current operation is supported by a contract by NIOSH. A full accreditation program was in force as of January 1974.

B. Objective

To foster improvement in the performance of industrial hygiene laboratories.

II The Certification Process

A. Scope

The AIHA performs either directly or through contracted services, the following program operations:

- The establishment of standards against which laboratory procedures and practices are to be assessed.
- The identification of the elements of laboratory facilities and operation to be assessed and the methods for their assessment.
- The evaluation of applicant laboratories and their personnel.

AIHA retains full responsibility for the approval of laboratories evaluated. (Thus, although proficiency testing was performed by NIOSH and privately contracted, AIHA uses the results of these tests to make decisions regarding laboratory accreditation.)

Participation in the AIHA accreditation program is voluntary. Currently, approximately 160 applications have been requested and about 60 returned, of these 32 have been approved. The remainder of the applicants will be evaluated following completion of site visits to the laboratories.

B. Laboratory Elements Evaluated

Facility

- space design

- ventilation
- services
- Safety equipment
- other equipment and apparatus

Procedures*

- quality control procedures
- safety procedures

Personnel

- qualifications are specified for:

  laboratory director
  laboratory supervisor

- qualifications and duties are specified for:

  industrial hygiene technologists**
  industrial hygiene technicians**

Records

- record system for each sample
- records of checking system for calibration and standardization of equipment and of internal control samples

C. Certification Procedure

- Laboratory submits application for accreditation to AIHA

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* It is the view of the Association that the specification of detailed test procedures tends to inhibit innovation. For this reason internal quality control methods, rather than procedures are examined by the AIHA. Also, the validity of analytic procedures is assessed through proficiency testing in any case.

** The difference between a technologist and a technician is that a technologist must have a baccalaureate degree.

- AIHA examines the qualifications of the applicant laboratory by:
    - reviewing the application submitted
    - enrolling the laboratory in the PAT (Proficiency Analytical Testing) Program of NIOSH and reviewing the results of tests made
    - performing on-site visit to the laboratory
- AIHA accredits those laboratories which meet its requirements for a period of three years. Reaccreditation is based on a new application or a certification that original application is still valid (that is, if no changes in the laboratory organization and personnel have occurred).
- Satisfactory PAT tests and results of annual on-site visits are required to maintain accreditation. PAT performed every two months. (NIOSH contracts out testing now - will be every three months.)

III Identified Problem Areas

Only problems associated with the initiation of the accreditation program are currently identifiable.

IV Program Administration and Evaluation

The laboratory accreditation committee is composed solely of laboratory directors and supervisors who have in-depth knowledge in the field of industrial hygiene. It is the view of the AIHA coordinator, who is also a technologist, that it is equally important for the Committee evaluators (who review PAT test results and on-site evaluations) to be technically knowledgeable as it is for those who actually perform the sample analyses and on-site evaluations on which the Committee decisions are based.

AIHA is aware of the need for continuing evaluation of the adequacy of its program. However, because a program of this nature, unlike that of a laboratory, for example, is not amenable to internal evaluation by means of quality control or similar measures, AIHA perceives the need for a separate and independent evaluating body for the performance of this function.

V Cost and Level of Effort Estimates

The AIHA accreditation program is designed to be self-supporting on a non-profit basis. Laboratory fees for accreditation services (ranging from $50.00 to $300.00 exclusive of application fees) are

intended to cover the costs of providing all services except for site visits. The level of effort which will be required when the program is fully operational is not yet known. At present, the annual cost of the coordinator's operation, including personnel and overhead, is about $50,000 annually. The estimated average site visit cost $350.00 (including compensation).

VI Comments

AIHA has entered in an agreement with the Health Physics Society under which the Society will participate in the laboratory accreditation program. It is anticipated that 3 members of the Society will become members of the Laboratory Accreditation Committee and that other members of the society will serve as regional representatives, laboratory appraisers or site visitors to health physics laboratories.

In addition to its contract arrangement with NIOSH referenced above, AIHA relies heavily on information generated from laboratory participation in the NIOSH PAT program and, in conjunction with NIOSH, conducts courses relating to the establishment and accreditation of industrial hygiene laboratories.

AIHA is currently trying to establish a reciprocal certification agreement with the Center for Disease Control. To date, however, only some preliminary discussions have been held.

AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS
AND COLLEGE OF AMERICAN PATHOLOGISTS

I Background

A. Nature of Program

The American Society of Clinical Pathologists (ASCAP), through its National Committee for Careers in the Medical Laboratory, certifies laboratory personnel. The College of American Pathologists inspects and accredits both independent and hospital laboratories.

B. Objective

Programs of both organizations are designed to develop and implement the highest possible standards in the practice of laboratory medicine.

II The Certification Process

A. Scope

The ASCP certification program includes an assessment of both academic and experiential qualifications of clinical laboratory personnel. In addition, the program uses proficiency examinations to further evaluate personnel capabilities.

The College of American Pathologists (CAP) certifies approximately 8,000 laboratories. Its inspection and accreditation program relies principally on proficiency testing and on-site evaluations for laboratory accreditation. As an independent organization, its program is, of course, voluntary.

B. Laboratory Elements Evaluated

Facility

- offices
- patient services area
- library, conference rooms, etc.
- inventory and supplies storage

Procedures

- Detailed procedures are examined in the following testing areas:

- hematology
- chemistry
- urinalysis
- microbiology
- blood bank
- diagnostic immunology and syphilis serology
- nuclear medicine
- anatomic pathology and cytology

. Specimen collection procedures

. Safety procedures

. Water sterilization and purification

. General recordkeeping

. Quality control programs*

. Personnel

Personnel policies of the laboratory are examined (e.g., administrative organization and personnel responsibilities).

C. Certification Procedure

ASCP Certification

. ASCP certifies medical personnel in the following categories:

- laboratory assistant
- medical laboratory technician
- medical technologist

. In addition it grants special certifications in the following test areas:

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* This program includes an examination of the maintenance and reliability of procedure manuals.

- blood banking
- chemistry
- microbiology
- hematology
- nuclear medical technology
- cytotechnology
- histology

- for certification in each of these areas include various combinations of the following:
  - academic degree(s)
  - experience
  - successful performance in the applicable proficiency exam(s)

CAP Inspection and Accreditation

- Laboratory submits necessary application forms and enrolls in proficiency testing program. In addition it must notify CAP that its supervisor is certified by the ASCP.
- CAP regional commissioners are notified of an application within their region and appoint appropriate volunteer inspectors
- An announced on-site visit is performed during which the laboratory elements identified in part II B are inspected and evaluated.
- On the basis of the on-site visit (including applicant's responses to questions asked*) and the applicant's participation in the proficiency testing program, the CAP

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* The questions used in the on-site evaluations fall into three phase categories. Phase "0" questions relate to detailed points of information. While the considerations involved may be used by a laboratory for self evaluation, they are not essential to the certification process. Phase I questions address issues which are somewhat more

makes its decision.

- Maintenance of certification requires that the laboratory continue to demonstrate proficiency (quarterly) in a quality evaluation program.

- CAP certification is valid for a two year period at the end of which an on-site visit is scheduled.

- In years when no on-site inspection is scheduled, laboratories are provided with a CDC computer processed check list for self evaluation.

III Identified Problem Areas

None was identified by CAP personnel.

IV Program Administration and Evaluation (CAP)

The Inspection and Accreditation activities of the CAP central office require a staff of approximately four persons. This staff provides support and background information to a central Board of Commissioners which makes all decisions regarding the accreditation of individual laboratories. The Commission also includes ten regional commissioners who, in addition to their own activities, recruit volunteers to perform on-site visits. The College relies principally on the quality of the data generated by laboratories it accredits to evaluate the effectiveness of its program. Laboratory data resulting from split sample tests has shown up no major problems in the program to date. Minor deficiencies noted by laboratory personnel, inspectors, etc. are brought to the attention of the Commission for remedial action.

V Cost and Level of Effort Estimates (CAP)

Accredited laboratories are billed for CAP services according to the number of separate disciplines or categories for which they are accredited (e.g., chemistry, hematology, etc.). The fee schedule is as follows:

- 1-4 disciplines $125 per year

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significant but which are not certification criteria. Phase II questions address criteria which directly relate to accreditation eligibility.

- 5-8 disciplines $200 per year

- 9 or more disciplines $200 per year plus $50 per year for each additional four disciplines or portions thereof

VI Comments

Relationships With Other Organizations (CAP)

- The CAP program has been approved by the Center for Disease Control (CDC) as equivalent to Federal licensure under the Clinical Laboratories Improvement Act of 1967 with the proviso that CAP perform annual on-site inspections of those laboratories who use CAP for CDC equivalency accreditation. This approval is maintained through a procedure in which CDC performs annual random checks on 10% of those laboratories accredited by the College. The College's inspection and accreditation program not only meets the standards of the CDC but also of the Food and Drug Administration and of the Joint Commission on the Accreditation of Hospitals.

APPENDIX II

EXAMPLES OF FORMS USED IN PROGRAMS REVIEWED

INTRODUCTION

This Appendix contains reproductions of forms used by some of the certifying organizations surveyed in this study for various purposes, such as applications for certifications and laboratory evaluations.

HEW, FDA, BUREAU OF FOODS*

* These forms apply to the milk analysis laboratory certification program.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

Survey Form for Milk Laboratories

PHS-1500-1
(Rev. 5-65)

Indicating conformity with the Pasteurized Milk Ordinance — 1965 Recommendations of the United States Public Health Service

SURVEY BY

X=DEVIATION U=UNDETERMINED O=NOT USED

LABORATORY

LOCATION

DATE

SAMPLING

APPARATUS

1. Thermometer ——
Mercury filled (or having a distinctively colored fluid with freezing point less than +30°F), or dial type ——
Graduation interval not to exceed 2° ——
Suitable range, 0-220°F, or shorter-scale if satisfactory ——
Accuracy checked with thermometer certified by National Bureau of Standards, or one of equivalent accuracy ——
Periodically recheck thermometers for accuracy ——

2. Agitator ——
Metal disc (6" diameter on end of metal rod long enough to reach bottom of container) ——
Or bowl-type (3" diameter, 1" deep, welded to 30" solid metal handle), with pouring spout at 90° angle from handle ——

3. Sample transfer instrument ——
Seamless metal tube (aluminum preferred, 24" by 1/4" I.D.) ——
Or metal dipper with long handle, capacity 10 ml ——
Or single-service paper sampling tube ——
Or other means for removing sample aseptically ——

4. Sampling instrument case ——
Box to protect instruments during and after sterilization, metal preferred, tight cover ——

5. Sample containers, sterile ——
Clean and dry, 0.5-1.0 oz. (optionally 2-8 oz.) ——
Suitable place for identification of sample ——
Screw-cap vial or bottle top ground or molded smoothly ——
Leakproof closure (do not use cotton plugs) ——
Corrosion-resistant metal or satisfactory plastic cap ——
Proper skirt length to be leakproof ——
With rubber liner in non-toxic plastic or metal cap ——
Or sterile evacuated equipment for collecting 10-ml portions ——
Or presterilized suitable non-toxic plastic bags, adequate size ——

6. Cooling bath ——
Provided where samples not cooled promptly in sample case ——
Adequate to cool samples promptly and keep at 32-40°F ——
Provided where necessary with racks, compartments, and/or baffles to hold sample bottles vertically ——
To keep neck of bottles above surface of cooling medium ——
To maintain cooling medium above height of sample, and ——
To allow sufficient ice and water, or other refrigerant ——
Optionally, use to transport samples to laboratory ——

7. Sample case ——
Rigid metal, plastic (or metal-lined wood) ——
With or without insulation, ample space for samples, and ——
For sufficient cracked ice or other refrigerant to cool samples promptly to and keep them at 32-40°F ——
Neck of bottles above surface of cooling medium ——
Unless containers are sealed or under continuous supervision until proper handling during transportation, attach handles and label "This Side Up" to top of case ——

8. Inner shipping case (for small sample vials) ——

PREPARATION

9. Cleaning sampling equipment ——
Rinse sampling instruments immediately after use in tap water ——
Clean instruments in hot water containing soapless detergent, alkaline phosphate, or other suitable material (avoid excessive exposure to strong alkali) ——
Use suitable brush to clean inside of tubes or containers ——
Immediately after treatment, rinse instruments thoroughly ——
Plastic caps, before first use, autoclaved twice while submerged in water, or mechanically washed with suitable detergent above 180°F, or equivalent procedure ——

10. Laboratory sterilization of sampling equipment ——
Sterilize whenever possible with dry heat ——
At not less than 170°C, for not less than 1 hour ——
Load properly distributed, sterilizer not overloaded ——
Or autoclave aluminum tubes and materials that are likely to be charred at 121°C for not less than 15 minutes ——

11. Practical sterilization of sampling equipment ——
For practical sterilization of stirrer, sampling tube, or dipper between samples, rinse first in one can of clean water (50-80°F) connected with a continuous flowing source ——
Then submerge in a second can of water kept continuously at not less than 180°F for at least 1 minute, or ——
Submerge in a hypochlorite solution maintained at not less than 100 ppm for at least 30 seconds (or use other halogens bactericidally equivalent) ——

SAMPLING PROCEDURE

12. Directions applying to both raw and pasteurized samples ——
Take samples at sufficiently frequent intervals to determine if supply continuously conforms to prescribed standard ——
Promptly identify each sample legibly and indelibly with official number, label, or tag ——
Cool immediately and maintain at 32-40°F (avoid freezing) ——
Where necessary transfer to shipping case (at 32-40°F) ——
Use adequate insulation during cold weather to prevent samples from freezing ——
Provide extra sample of milk or milk product for temperature control from first sampling point and ——
Record temperature of milk at all sampling locations ——
Record time and date of sampling ——
Protect samples at all times from potential contaminants ——
When sampling is complete, promptly deliver to laboratory ——
Where results may be used in court, apply official seal to container and deliver to analyst, or seal or lock sample case and ship intact ——

SAMPLING PROCEDURE (Continued)

13. Additional directions for sampling raw milk for pasteurization
(Also see item 15 for farm bulk tanks, item 16 for weigh vats, item 17 for milk cans, and item 18 for storage tanks) _____
Sample milk not partially frozen, lumpy, curdled, or churned _____
Use practical sterilization, as needed, for sampling equipment _____
Preferably, determine strength of sanitizing solution with applicable test kit _____
Sanitize thermometer before insertion into milk _____
Tank or vat thermometer in good repair, and _____
Checked for accuracy against a certified thermometer or one of equivalent accuracy (see item 1) _____
Take representative samples of producer's and/or dealer's milk _____
Thoroughly mix milk immediately before sampling _____
Use stirrer long enough to reach bottom of milk can or weigh-vat or tank _____
Where necessary to sample previously opened containers, such as milk cans or weigh-vats, agitate by sterile stirrer or any already in container _____
Hands should be clean and dry during sampling operation _____
Use sterile sampling tubes or dippers, or _____
Remove dipper or sampling tube from sanitizing solution and rinse twice in milk before transferring sample _____
When a sampling tube is used, insert it, not too rapidly, to bottom of container with top of tube left open _____
Place finger over open end, withdraw tube, and aseptically transfer contents to sterile sample container _____
Use separate sterile tube or dipper for each sample _____
Transfer from 5-10 ml to sterile, preferably precooled, sample container _____
Or, if necessary, aseptically catch sample in sterile receptacle as well-mixed liquid is poured from container _____
Handle sterilized sample bottles and closures aseptically _____
Fill sample containers not more than ⅔ to ¾ full _____

14. Precautions in sampling raw milk for pasteurization _____
Do not use metal disc or bowl-type agitator to mix milk in stationary storage tanks or tanks on trucks _____
Protect sterile sampling instruments from unnecessary exposure before use _____
Do not drop or lay sample bottle caps down _____
Do not touch or otherwise contaminate inner surface of caps _____

15. Raw milk for pasteurization samples — bulk tanks only _____
If milk height stick is removed from tank before sampling, sanitize prior to reinsertion into milk _____
Operate agitator for at least 5 minutes prior to taking sample _____
For each installation, when installed and periodically thereafter, and at older installations, determine agitation needed by testing 2 or more suitable sub-samples for butterfat (mean should not vary more than 0.1%) _____
Optionally, test sub-samples from first and last gallon of milk and periodically between (20, 40, 60, and 80%) or equivalent _____
Agitation procedure results available at each installation _____
During transfer of milk sample, do not hold container over milk in tank _____

16. Raw milk for pasteurization samples — weigh-vats only _____
For routine control, remove representative samples immediately after milk is dumped and mixed _____
Collect sub-samples to determine proper agitation time (see 15) _____
If weigh-vat is not large enough to contain milk from producer, collect proportionate amount of milk from each filling _____
Drain weigh-vat between successive deliveries so that residual milk does not exceed approximately 1 lb _____
Avoid use of strainers or other equipment in such manner that they unduly contaminate or interfere with mixing _____
Routinely rotate use of 2 or more tubes or dippers subjected to practical sterilization, as described in item 11 _____
Optionally, reuse same instrument, provided at least 1 minute is allowed for practical sterilization between samples _____

17. Raw milk for pasteurization samples — milk cans only _____
Rotate use of 2 or more sampling tubes or dippers, or optionally reuse same instrument, as described in items 11 and 16 _____
When sampling from one producer, optionally use same instrument and omit rinsing and sterilizing steps between cans _____
Collect proportionate or random samples from producer milk cans _____

18. Raw milk for pasteurization samples — storage tanks only _____
Use odor-free, pressurized filtered air, or electrically driven stirring equipment, or recirculation (all equipment sanitized before use in each successive tank where applicable) _____
Collect sub-samples to determine proper agitation time (see 15) _____
Collect sample from sampling cock on storage tank access door _____

19. Pasteurized milk and milk product samples _____
Take representative sample of each milk or milk product as delivered to consumer _____
Preferably collect samples from delivery trucks or retail stores while still in possession of processor _____
Periodically sample each size and style of container _____
Or, if necessary, after thoroughly mixing contents in container, aseptically transfer representative portion to sterile container _____
Or from milk dispensers, collect sample direct from spigot without sanitizing or flushing spigot opening _____
Otherwise, collect samples, as described in item 12 _____
When shipping, protect caps and lips by tightly fitted, waterproof-cover (protect paper containers from crushing) _____

20. Laboratory procedures _____
Record temperatures of samples on receipt at laboratory _____
Determine temperature of samples by inserting thermometer into separate pilot container treated exactly as sample _____
Do not insert thermometer into any sample intended for bacteriological examination before removal of test portion _____
At laboratory, store samples at 32-40°F until tested _____
Record time and date of analyses _____
If chemical tests are also to be made, aseptically remove portions for bacterial analysis first _____
When examining gassed or pressurized samples at laboratory, freeze contents solid by exposure in deep-freeze cabinet, then vent and allow gas to escape before _____
Transferring contents, aseptically, to sterile container _____
Periodically, determine sterility of sampling instruments by rinsing aseptically with sterile buffered water without neutralizer and plating portions _____

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

Survey Form for Milk Laboratories

PHS-1500-2
(Rev. 5-65)

Indicating conformity with the Pasteurized Milk Ordinance — 1965 Recommendations of the United States Public Health Service

SURVEY BY | X=DEVIATION U=UNDETERMINED O=NOT USED

LABORATORY | LOCATION | DATE

CULTURAL PROCEDURES — GENERAL REQUIREMENTS

APPARATUS

1. Work area ____
- Level table or bench, ample plating surface ____
- In clean, well-lighted, well-ventilated room, reasonably free from dust and drafts ____
- Microbic density of air less than 15 colonies/plate in 15 minutes ____

2. Storage space ____
- Cabinets, drawers, or shelves adequate for protection of glassware, apparatus, and other materials (especially when sterilized equipment is not used immediately) ____

3. Thermometer ____
- Appropriate range 0-220° F or shorter scale range ____
- Graduation interval not to exceed 2° ____
- Accuracy checked with thermometer certified by National Bureau of Standards, or one of equivalent accuracy, or ____
- Optionally use automatic temperature-recording instruments ____
- Periodically recheck thermometers for accuracy ____

4. Refrigeration ____
- Sufficient to keep samples at 32-40° F until tested ____

5. Pipettes ____
- Walls straight, tips ground to deliver APHA specifications ____
- Delivery 1.0 ml, 1.1 ml for successive 0.1-ml and 1.0-ml deliveries without recharging, or 11 ml if needed ____
- Graduation distinctly marked with contrasting pigment ____
- Use unbroken pipettes; discard those with broken tips ____
- Pipettes recalibrated if required for regulatory work (such recalibration desirable under all conditions) ____

6. Pipette containers ____
- Use for sterilization, storage, and handling ____
- Box, metal preferred, 2-3" x 16" (optionally use paper wrappings) ____

7. Dilution bottles ____
- Bottles, resistant (preferably borosilicate) glass ____
- Tops ground or molded smoothly ____
- About 6 oz, marked indelibly at 99 ± 1 ml graduation level (or otherwise for special purposes) ____
- Closed with rubber stoppers (not cotton plugs) or corrosion-resistant metal or suitable plastic screw caps ____
- Caps proper length for leakproof contact, suitable liner ____
- Plastic caps, before first use autoclaved twice while submerged in water, or mechanically washed with suitable detergent at not less than 180° F, or equivalent procedure ____
- Caps in use free from toxic substances ____
- Use new liners as required to make closure leakproof ____

8. Petri dishes (glass or plastic) ____
- Outside diameter 100 mm, depth 15 mm, with flat bottoms ____
- Free from bubbles, scratches, or other defects ____

9. Petri dish containers ____
- Used to protect and handle before and after sterilization ____
- Metal boxes with covers, coarsely woven wire baskets, or char-resistant paper sacks or wrappings ____

10. Hot-air sterilizing oven ____
- Size sufficient to prevent crowding of interior ____
- Constructed to give uniform and adequate sterilizing temperatures (check temperature variations within oven) ____
- Equipped with thermometer, suggested range 0° to 220° C ____
- Vents located to assure prompt and uniform heat penetration ____

11. Autoclave ____
- Size sufficient to prevent crowding of interior ____
- Constructed to provide uniform and adequate temperatures ____
- Equipped with accurate thermometer with bulb properly located to register minimal temperature within chamber ____
- Pressure gauges and properly adjusted safety valve ____
- Connected with suitable saturated steam line, or to gas or electrically heated steam generator ____
- Small pressure cookers may be substituted only in emergencies and only where satisfactory results are obtained ____

12. Incubator ____
- Either water-jacket (filled) or anhydric type, with low-temperature, thermostatically controlled electric heating units properly located and insulated in or adjacent to walls or floors ____
- Provided with shelves so spaced as to assure uniformity at 32° C, or other temperature as needed ____
- Determine temperature variations within incubator when filled with poured plates to maximal capacity ____
- Avoid use of anhydric incubators with inside dimensions less than 20" x 20" x 24" high (or equivalent space) ____
- Keep where temperatures do not vary excessively (50-80°F) ____
- Away from outside walls, windows, and drafts ____

13. Incubator room ____
- Optionally use walk-in rooms, well insulated, equipped with properly distributed heating units and forced-air circulation ____
- Provided areas conform to desired temperature limits ____
- Record daily range in temperature in areas used for plates ____

14. Colony counter ____
- Quebec colony counter, dark-field model preferred ____
- Or one providing equivalent magnification and visibility ____

15. Hand tally ____
- A mechanical counting device, of convenient type ____

16. pH meter, or colorimeter with standards ____
- Dependable potentiometer, or accurate color standards ____

17. Media-making utensils ____
- Pyrex, stainless steel, or other noncorrosive equipment ____
- Clean and free from foreign residues (as dried agar) and from toxic or foreign materials which may contaminate media (such as chlorine, copper, zinc, aluminum, antimony, or chromium) ____

18. Balance ____
- Sensibility reciprocal 53 mg, with weights as required ____

19. Water bath, or incubator ____
- Thermostatically controlled at 44-46° C ____
- Of appropriate size for holding melted medium ____

MATERIALS

20. Distilled water _____

Distilled water used for all media, reagents, blanks, etc. _____

Tested periodically for freedom from toxic contaminants _____

21. Dilution water _____

Use phosphate buffered distilled water for dilutions _____

Stock buffer correct formula, properly diluted _____

Optionally autoclave stock buffer and store in refrigerator _____

Test periodically for toxic substances by replating a series of milk dilutions at intervals of 10, 20, 30, and 45 minutes _____

Do not use if abnormally high mineral content or if toxic _____

Neutralize distilled water if free chlorine is present _____

22. Reagent chemicals and fermentable carbohydrates _____

Highest purity unless otherwise specified _____

23. Pancreatic digest of casein (USP) _____

24. Yeast extract _____

25. Agar _____

Bacteriological grade, granulated or chopped, of best quality _____

Practically free from thermophilic bacteria _____

Check microbial contamination (not over 50 colonies/2g) _____

26. Standard Methods agar _____

Brand _____, catalog No. _____, lot No. _____

PREPARATION

27 Cleaning pipettes _____

Preferably rinse immediately after use in water at 15-30° C _____

After rinsing, thoroughly wash with soapless detergent, an alkaline phosphate, or other suitable material _____

Rinse until all detergent residues are removed _____

Optionally at weekly or biweekly intervals, soak pipettes for 24 hours in strong cleaning solution _____

Wash acid-treated glassware thoroughly in alkaline waters and then repeatedly rinse in clean water _____

Before use, test several pieces in each batch for residual acid or alkali, with appropriate indicator (bromthymol blue) _____

28. Cleaning other glassware _____

Thoroughly wash with suitable detergent _____

Rinse thoroughly in clean water _____

Residual acid or alkali not present _____

Test glassware for freedom from bacteriostatic detergent residues _____

29. Sterilization of equipment _____

Sterilize whenever possible with dry heat _____

So center of load is not less than 170° C, for not less than 1 hour _____

Do not crowd oven (cover only 50-75% of shelf area in gravity ovens, 90% in mechanical convection) _____

When loaded to capacity preferably use longer periods or slightly higher temperatures _____

Where sterilization may be questionable, or where record may be required for testimony, record time oven reaches sterilization temperature, minimal temperature used, and time of discontinuing heat for each lot of materials _____

30. Sterilization of dilutions, media, plastics, etc. _____

Autoclave dilutions, media, and materials likely to char _____

At 121° C for 15 minutes (20 minutes for water blanks) _____

Apply minimal heat to insure sterilization _____

Slightly loosen stoppers to permit passage of steam and air _____

Force all air from sterilizer before allowing pressure rise _____

Should reach 121° C within 10 minutes after exhaust _____

Rely only upon a temperature registering gauge, preferably a mercury-filled thermometer of predetermined accuracy _____

Occasionally or routinely use time-temperature indicator _____

Avoid overloading autoclave _____

For nonliquid materials, or where packing arrangement or volume of materials retards penetration, allow longer time to reach 121° C, or sterilize longer _____

After sterilization reduce pressure with reasonable promptness _____

Remove media from autoclave _____

Where sterilization may be questionable or record may be required, record time autoclave reaches sterilization temperature, minimal temperature used, and time of discontinuing heat _____

31. Dilution blanks _____

Filled so after sterilization will contain 99 (or 9) ml _____

After sterilization but before use observe amount in each blank and discard those exceeding ± 2 percent _____

Predetermine approximate amount required before autoclaving _____

Optionally use correctly calibrated automatic measuring device _____

When using bulk sterilized diluent, measure directly into sterile containers, and use prepared blanks promptly _____

32. Agar preparation _____

Preferably use dehydrated medium of correct composition _____

Or prepared from specified ingredients (USP casein digest, yeast extract, glucose, best quality agar) in correct amounts _____

If prepared from ingredients, analysts must assume responsibility (periodical records demonstrating equivalence) _____

Keep containers tightly closed _____

Discontinue use if materials show contamination or decomposition _____

Check 10% solution of protein digests for microbic contamination by Gram stain of 0.01 ml (bacterial limit 10 per 10 fields) _____

Medium prepared with distilled water _____

Allow to soak 3-5 minutes _____

Boil mixture in suitable container until dissolved, stirring to prevent burning on bottom of container _____

Or expose in suitable container to actively flowing steam _____

Unless dehydrated or within range, adjust to pH 7.0 ± 0.1 _____

Use suitable color standards or electrometric equipment _____

Titrate if necessary, with diluted alkali or acid _____

Calculate and add NaOH solution to produce desired pH _____

Mix thoroughly, and again test reaction _____

If incorrect, further adjust; if error excessive, discard batch _____

If necessary clarify by centrifugation, sedimentation, or filtration so as not to remove or add nutritive ingredients _____

If necessary restore lost weight _____

Distribute in suitable containers _____

Limit amount so no part will be more than 2.5 cm from surface _____

Use suitable closures and autoclave _____

Prevent contamination and evaporation during storage _____

Determine pH of each sterilization batch of agar before use _____

Record reaction of medium (acceptable range pH 7.0 ± 0.1) _____

33. a. Adjustment of reaction — potentiometric _____

Allow electrodes to equilibrate at temperature of test _____

Adjust pH buffer solution to same temperature _____

Use 45° C if agar undiluted, or provided results are equivalent, lower temperature if diluted 1:1 with freshly (or 1:2 with freshly boiled) distilled water _____

Maintain required temperature until reading is complete _____

b. Adjustment of reaction — colorimetric _____

Use 2 clean tubes (identical with color standard tubes) _____

Add suitable amount of distilled water and liquefied agar _____

Add standard indicator solution to one tube _____

Using comparator block, superimpose tubes and standards _____

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

Survey Form for Milk Laboratories

PHS-1500-3
(Rev 5-65)

Indicating conformity with the Pasteurized Milk Ordinance — 1965 Recommendations of the United States Public Health Service

SURVEY BY

X=DEVIATION U=UNDETERMINED O=NOT USED

LABORATORY | LOCATION | DATE

AGAR PLATE METHOD

DILUTING SAMPLES

1. Selecting dilutions ____
- Normally plate two decimal dilutions per sample ____
- Select dilutions to yield one plate with 30-300 colonies ____
- If single plate of single dilution used routinely, identify analyses based upon plates outside limits, and ____
- Recheck such supplies promptly, using two dilutions ____

2. Identifying plates ____
- Before making dilutions, arrange plates in order ____
- Identify each with sample number and with dilution to be used ____
- Record date and plating time (AM or PM) for each set of samples ____
- If interval between sampling and analyses exceeds 4 hours, record both times on reports ____

3. Sample agitation ____
- Immediately before removal of any portion, thoroughly and vigorously mix contents of each container ____
- Invert filled retail containers repeatedly until contents are homogeneous ____
- Before opening container, remove potential contaminants from closure ____
- Optionally wipe top with sterile, alcohol-saturated cloth ____
- Where practicable, mix wholesale and process samples in containers which are not more than ⅔ to ¾ full ____
- Immediately before transferring each test portion (except from filled containers) shake each container 25 times ____
- Each shake a complete up-and-down movement of about 1 foot ____
- Within 7 seconds ____

4. Sample measurements ____
- Use sterile pipette for initial transfers from each container ____
- Tips not dragged over exposed exteriors of pipettes in case ____
- Pipettes not wiped or dragged across lip or neck of container ____
- Not inserted more than 0.5-1" below surface ____
- When removing measured portions, touch off liquid at tip (allow lower side of pipette to contact inside of container) ____
- Drainage apparently complete, excessive liquid not adhering ____
- Add test portions to dilution waters preferably at 15-25° C ____
- Complete each transfer within 2-3 seconds ____
- Let column drain from graduation to apparent rest point in tip (promptly and gently blow out last drop) ____
- Make transfers carefully and do not rinse pipettes in dilution waters ____

5. Dilution agitation ____
- Immediately before transferring each test portion of dilutions, shake each container 25 times ____
- Each shake a complete up-and-down movement of about 1 foot ____
- Within 7 seconds ____
- Optionally use approved mechanical shaker for proper time ____

6. Dilution measurements ____
- Use a sterile pipette for initial transfers from each successive dilution container ____
- Tips not dragged over exposed exteriors of pipettes in case ____
- Do not wipe or drag pipette across lip or neck of container ____
- Pipette not inserted more than 0.5-1" below surface ____
- When removing measured portions, touch off liquid at tip (allow lower side of pipette to contact inside of container) ____
- Drainage apparently complete, excessive liquid not adhering ____
- Measure accurately, make transfers carefully ____
- Gently lift cover of petri dish only high enough to insert pipette ____
- Hold pipette at angle of 45° with tip touching inside dish (or inside neck of dilution bottle, or rod or rubber stopper) ____
- Allow 2-3 seconds for diluted milk or cream to drain from graduation mark to apparent rest point in tip of pipette ____
- Then touch pipette tip once against a dry spot on glass ____
- In measuring 0.1 ml, do not similarly touch dry area ____
- Do not prepare, dispense dilutions, or plate in direct sunlight ____

7. Cream samples ____
- Using an accurate balance, preferably weigh 1 gm (or 11 gm) aseptically into dilution bottles or sterile butterboats ____
- Preferably use dilution blanks heated to 35-40° C ____
- If necessary to measure portions with 11-ml pipettes, predetermine ability to deliver exactly 11 ml of cream ____
- When making dilution, let column drain to apparent rest point in tip and promptly blow out last drop ____

PLATING

8. Plating ____
- Melt agar quickly in boiling water, or expose to flowing steam ____
- Avoid prolonged exposure to high temperatures during and after melting (do not melt more than will be used within 3 hours) ____
- Promptly cool melted agar to about 45° C, and store until used at 44-46° C ____
- For temperature control of medium, insert thermometer in separate pilot bottle (containing water) of type used for agar ____
- Expose blank to same melting and cooling condition used for agar ____
- Select number of samples in any series so that all will be plated within 20 minutes after diluting first sample ____
- After depositing test portions, promptly introduce 10-12 ml of liquefied (not lumpy) medium at 44-46° C into each plate ____
- Gently lift cover of petri dish only high enough to pour medium ____
- Flame lips of media containers immediately before (except screw-cap bottles) and periodically during pouring (and when completed, if portions remaining are to be used later) ____
- Agar and test portions thoroughly mixed, by rotating and tilting without splashing, and mixture spread evenly ____
- Allow to solidify within 5-10 minutes on level surface ____
- Invert (unless clay tops are used) and promptly incubate ____

CONTROLS

9. Sterility controls ____

Check sterility by pouring control plates for each sterilization lot of dilution blanks and medium used ____

Pour control plates for each series of samples ____

Where control tests have shown contamination, wipe plating area with damp towel immediately before plating ____

INCUBATION

10. Incubation ____

Remove plates from containers (unless these permit plates to reach incubation temperature within 2 hours) ____

Arrange so each plate or pile is separated by at least 1" from adjacent piles, and from top and walls of chamber ____

Place piles directly over each other on successive shelves ____

Incubate for 48 ± 3 hours, at 32° C ____

Incubate plates in suitable places only ____

Determine temperatures by not less than two thermometers (1 on top and 1 on bottom shelf, and in between as needed) ____

Thermometer bulbs submerged in water or other liquids, within small, tightly closed vials or flasks ____

Optionally use automatic devices of predetermined accuracy for controlling and recording temperatures (periodically supplement with readings from standard thermometers) ____

Unless recording thermometers are in continuous operation, preferably install maximal and minimal registering thermometers to indicate gross temperature deviations (do not depend upon such readings for daily records) ____

Preferably keep daily records of temperatures (early AM and late PM) in areas used, especially where temperatures are apt to vary or where records may be required for court testimony ____

To reduce spreader formation, avoid excessive humidity ____

To prevent excessive drying, control ventilation and air circulation (agar should not lose more than 15% weight in 48 hr) ____

COUNTING COLONIES

11. Counting aids ____

Count colonies with aid of magnification under uniform and properly controlled artificial illumination (equivalent to dark-field Quebec colony counter) ____

Routinely use guide plates ruled in square centimeters ____

Mechanically record total colonies with a hand tally ____

Avoid mistaking particles of undissolved medium or precipitated matter in plates for pin-point colonies ____

To distinguish colonies from foreign matter, examine doubtful objects carefully, using higher magnification where required ____

12. Selecting and counting plates ____

After incubating plates for 48 ± 3 hours, promptly count all colonies on selected plates ____

Where impossible to count at once, store plates at about 5° C for not more than 24 hours, but avoid this routinely ____

Normally select spreader-free plates with 30-300 colonies and count all colonies including those of pin-point size ____

If consecutive dilutions yield 30-300 colonies, report arithmetic average (unless higher computed count is more than twice the lower, in which case report the lower computed count) ____

If spreaders occur on plates selected, count colonies on representative portion only when colonies are well distributed, and when area covered or repressed does not exceed ½ of plate ____

If no 30-300 plates, use plate over 300 having nearest 300 colonies ____

If plates from all dilutions yield less than 30 colonies each, record actual number on lowest dilution, but report count as "less than" 30 times corresponding dilution ____

If all plates from any sample show no colonies, have excessive spreader growth, are known to be contaminated, or otherwise unsatisfactory, report as "No colonies" (NC), "Spreaders" (Spr), "Laboratory accident" (LA), or "Growth inhibitors" (GI) ____

If only one of duplicate plates yields 30-300 colonies, count both (unless otherwise excluded), and average ____

Where one or more duplicates from consecutive dilutions are counted, compute average count per dilution before determining if higher computed count is more than twice the lower one ____

13. Estimating counts ____

Where colonies per plate appreciably exceed 300, count colonies in portions representative of distribution and estimate total ____

Where less than 10 colonies per sq cm, count 12-14 areas, selecting, if representative, 6 or 7 consecutive squares diagonally across plate and 6 or 7 consecutive squares at right angles ____

Where over 10 per sq cm, count 4 representative areas ____

Multiply average number per sq cm by appropriate factor ____

Avoid reporting counts as TNTC ____

14. Counting spreaders ____

When spreaders must be counted, count each as single colony ____

Count chains from separate sources as separate colonies ____

If 5 percent of plates are more than ¼ covered by spreaders, take immediate steps to eliminate this trouble ____

15. Personal errors ____

Avoid inaccurate counting due to carelessness or impaired vision ____

Periodic eye examination if eye distress or if counts differ ____

Discover cause and correct if unable to duplicate own counts on same plate within 5 percent ____

And counts of other analysts within 10 percent ____

REPORTS

16. Recording counts ____

Record dilutions used ____

And number of colonies on each plate counted ____

Record results of sterility control tests on materials ____

Correctly multiply number of colonies (or average or estimated number) per plate by the reciprocal of the dilution used ____

Record only first two left-hand digits, raising second digit to next higher number when third digit is 5 or more ____

Record as "Standard Plate Count" SPC/ml, or SPC/g ____

Record incubation temperature used ____

Report estimated counts made according to directions as SPC ____

When estimates are not obtained according to standard procedures, use appropriate terminology in lieu of "Standard" ____

MISCELLANEOUS

17. Recommended laboratory practices ____

Personnel adequately trained or supervised ____

Copy of Standard Methods (11th ed) available in laboratory ____

Floors clean, walls and ceilings smooth ____

Doors and windows screened, or insects and rodents absent ____

Space adequate, free from confusion ____

Used for laboratory purposes only ____

Table space, storage, and utilities adequate ____

Cabinets, shelves, and equipment neat, clean, and orderly ____

Clean outer garments worn ____

Clothing stored outside laboratory or in closet ____

HEW, PHS, CENTER FOR DISEASE CONTROL

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
Bureau of Laboratories
Atlanta, Georgia 30333

APPLICATION FOR LICENSURE UNDER CLINICAL LABORATORIES IMPROVEMENT ACT OF 1967

PART 1 – GENERAL INFORMATION

1. NAME OF LABORATORY.

2. TELEPHONE NUMBER: (include area code)

ADDRESS: Street No. City State Zip Code

NAME OF DIRECTOR:

5. KIND OF LABORATORY (check one):

☐ Hospital ☐ Independent ☐ Industrial ☐ Public Health

6. If you wish a license in a CATEGORY or Subcategory, place an "L" in the box provided. If you contemplate accepting at least one specimen but not more than 100 specimens in a CATEGORY during a calendar year and wish a letter of exemption rather than a license, enter "E" and complete the enclosed application for exemption from licensure in those CATEGORIES (Form No. HSM 5 639 (CDC)) If you are accepting no specimens in interstate commerce in a CATEGORY or Subcategory and you wish neither licensure nor exemption, enter a zero Each box must have an entry.

A. ☐ MICROBIOLOGY AND SEROLOGY
- ☐ Bacteriology
- ☐ Mycology
- ☐ Parasitology
- ☐ Virology
- ☐ Serology (Syphilis)
- ☐ Serology (non-Syphilis)

B. ☐ CLINICAL CHEMISTRY
- ☐ Blood and Cerebrospinal Fluid Chemistry
- ☐ Endocrinology
- ☐ Toxicology
- ☐ Urinalysis

C. ☐ IMMUNOHEMATOLOGY

D. ☐ HEMATOLOGY (including Hemoglobin)

E. ☐ PATHOLOGY
- ☐ Exfoliative Cytology
- ☐ Histopathology
- ☐ Oral Pathology

F. ☐ RADIOBIOASSAY

For specimens solicited or accepted in interstate commerce, attach a current list of all tests performed in your laboratory or services provided.

8. PERSONNEL SUMMARY.

Indicate the number of all personnel employed in this laboratory who are involved in the procedures or categories for which you are applying for a license.

	Full Time	Part Time		Full Time	Part Time		Full Time	Part Time
Directors			Technologists			Trainees		
Supervisors			Technicians			Other		

ACCREDITATION OF LABORATORY.

Is your laboratory licensed or accredited by any professional or governmental agency (except business license)? ☐ Yes ☐ No

If "Yes", which ones?

		License or Accreditation Expires
A. ☐	Certified by Medicare	_____, 19 ____
B. ☐	Licensed by State	_____, 19 ____
C. ☐	Accredited by JCAH	_____, 19 ____
D. ☐	Accredited by AOA	_____, 19 ____
E. ☐	Accredited by AABB	_____, 19 ____
F. ☐	Accredited by AAB	_____, 19 ____
G. ☐	Accredited by CAP	_____, 19 ____
H. ☐	Other professional or governmental accreditation	_____, 19 ____

(specify) _____

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION
CENTER FOR DISEASE CONTROL
Laboratory Division
Atlanta, Georgia 30333

APPLICATION FOR LICENSURE UNDER CLINICAL LABORATORIES IMPROVEMENT ACT OF 1967

(To be completed by and reflect qualifications of person whose name appears in Block 1)

PART II-A – PERSONNEL – DIRECTOR

Date:	1. Name: Last	First	Middle Initial	2. Social Security No.:

3. Check the subparagraph under which you consider yourself qualified to direct a laboratory by the standards prescribed in the Code of Federal Regulations, Title 20, Chapter III, Section 405.1312, paragraph (b), subparagraph.

☐ (1) ☐ (2) (i) ☐ (2) (ii) ☐ (2) (iii) ☐ (3) (i) ☐ (3) (ii) ☐ (4) (i) a ☐ (4) (i) b ☐ (4) (i) c

. Have you qualified to direct a laboratory or serve as technical supervisor through the Public Health Service-sponsored examination for laboratory directors?

☐ Yes ☐ No

If "Yes", indicate in which of the following a satisfactory grade has been achieved ☐ General Section

Specialty Sections: ☐ Microbiology ☐ Serology ☐ Clinical Chemistry ☐ Hematology
☐ Blood Grouping and Rh Typing

Check those CATEGORIES and Subcategories for which you consider yourself qualified as a TECHNICAL SUPERVISOR. Refer to Section 405.1314.

☐ MICROBIOLOGY AND SEROLOGY
- ☐ Bacteriology
- ☐ Mycology
- ☐ Parasitology
- ☐ Virology
- ☐ Serology (Syphilis)
- ☐ Serology (non-Syphilis)

☐ CLINICAL CHEMISTRY
- ☐ Blood and Cerebrospinal Fluid Chemistry
- ☐ Endocrinology
- ☐ Toxicology
- ☐ Urinalysis

☐ IMMUNOHEMATOLOGY
- ☐ ABO Group and Rh Type only

☐ HEMATOLOGY (including Hemoglobin)

☐ PATHOLOGY
- ☐ Exfoliative Cytology
- ☐ Histopathology
- ☐ Oral Pathology

☐ RADIOBIOASSAY

6 How many hours per week do you spend on site in the technical and scientific direction of this laboratory? _____

Is there an associate, qualified as a director, who serves this laboratory as assistant director? ☐ Yes ☐ No

8. Do you serve as director to other laboratories? ☐ Yes ☐ No If yes, how many? _____ List below.

Name of Laboratory	Is there an associate, qualified as director, who serves as assistant director?	Address of Laboratory
	☐ Yes ☐ No	
	☐ Yes ☐ No	
	☐ Yes ☐ No	

9. Are you readily available for personal or telephone consultation? ☐ Yes ☐ No

0 EDUCATION

Name and Location of College or University	Major	Attended		Degree
		From	To	

For administrative use only. Do not complete this space.

Reviewer _____ Date _____ Remarks _____

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
Bureau of Laboratories
Atlanta, Georgia 30333

APPLICATION FOR LICENSURE UNDER CLINICAL LABORATORIES IMPROVEMENT ACT OF 1967

(To be completed by and reflect qualifications of person whose name appears in Block 1)

PART II-B – PERSONNEL – SUPERVISOR

Date:	1. Name: Last	First	Middle Initial	2. Social Security No.:

3. Do you consider yourself qualified to serve as general supervisor in the laboratory? ☐ Yes ☐ No

If "Yes" The qualifications to supervise a laboratory are met by the standards prescribed in the Code of Federal Regulations, Title 20, Chapter III, Section 405 1313, paragraph (b), subparagraph *(check one)*:

☐ (1) ☐ (2) ☐ (3) ☐ (4) ☐ (4) (1) ☐ (4) (2) ☐ (4) (3) ☐ (4) (4)

Check those CATEGORIES and Subcategories for which you consider yourself qualified as a technical supervisor Refer to Section 405.1314

☐ MICROBIOLOGY AND SEROLOGY
- ☐ Bacteriology
- ☐ Mycology
- ☐ Parasitology
- ☐ Virology
- ☐ Serology (syphilis)
- ☐ Serology (non-syphilis)

☐ CLINICAL CHEMISTRY
- ☐ Blood Cerebrospinal Fluid Chemistry
- ☐ Endocrinology
- ☐ Toxicology
- ☐ Urinalysis

☐ IMMUNOHEMATOLOGY
- ☐ ABO Group and Rh Type only

☐ HEMATOLOGY (including Hemoglobin)

☐ PATHOLOGY
- ☐ Exfoliative Cytology
- ☐ Histopathology
- ☐ Oral Pathology

☐ RADIOBIOASSAY

Are you on the laboratory premises during all hous in which tests are routinely performed? ☐ Yes ☐ No

If "No", attach a schedule of supervisory assignments to show that this requirement is met (See 20 CFR 405 1313(a) (1))

EDUCATION:

Name and Address of College or University	Major	Attended From (mo., yr.)	Attended To (mo., yr.)	Degree

If you have college credits but no degree, or a bachelor's degree from a foreign or non-accredited United States college or university, please enclose a transcript of your college credits.

LABORATORY TRAINING *(attach extra sheets if necessary)*

Check one. ☐ Internship ☐ Residency ☐ Medical Technology ☐ Other *(specify)* _____

Name and Address of Institution	Laboratory Specialty in which trained	From (mo., yr.)	To (mo., yr.)	Name and Degree of Immediate Supervisor during Training

For administrative use only. Do not complete this space.

Reviewer _____ Date _____ Remarks _____

LABORATORY TRAINING· *(continued)*

Check one ☐ Internship ☐ Residency ☐ Medical Technology ☐ Other *(specify)* _____

Name and Address of Institution	Laboratory Specialty in which trained		Name and Degree of Immediate Supervisor during Training
	From (mo., yr.)	To (mo., yr.)	

Check one: ☐ Internship ☐ Residency ☐ Medical Technology ☐ Other *(specify)* _____

Name and Address of Institution	Laboratory Specialty in which trained		Name and Degree of Immediate Supervisor during Training
	From (mo., yr)	To (mo., yr)	

8. Are you currently licensed to practice: ☐ Medicine ☐ Osteopathy ☐ Dentistry

List State(s)· _____

and Registration Number(s)· _____

9. BOARD CERTIFICATION: Are you board certified or board eligible? ☐ Yes ☐ No If yes, list below·

Certifying Authority	Board Eligible	Date Certified	Specialization

10. Were you previously employed in ☐ A Licensed CLIA Laboratory? ☐ A Medicare Laboratory? If yes, list below:

Name of Laboratory / Address	From (mo , yr)	To (mo., yr.)	Job Title
CLIA and/or Medicare Code Nos. _____			
Name of Laboratory / Address	From (mo., yr)	To (mo., yr.)	Job Title
CLIA and/or Medicare Code Nos. _____			

PART II-B PERSONNEL – SUPERVISOR *(continued)*

11. EXPERIENCE FOLLOWING GRADUATION – bachelor's degree· *(list most recent first - attach extra sheets if necessary)*

Name and Address of Institution	Name and Degree of Laboratory Director	Employed From (mo , yr)	Employed To (mo , yr.)	Job Title	Served as Title From (mo , yr)	Served as Title To (mo., yr.)

Experience was in the following *(if more than one, give length of time in each)*

☐ General Clinical Laboratory (not specialized)_____ ☐ Clinical Microbiology_____ ☐ Serology_____ ☐ Clinical Chemistry_____
☐ Immunohematology_____ ☐ Hematology_____ ☐ Pathology_____ ☐ Radiobioassay_____

escription of duties: _____

Name and Address of Institution	Name and Degree of Laboratory Director	Employed From (mo , yr)	Employed To (mo., yr)	Job Title	Served as Title From (mo., yr.)	Served as Title To (mo., yr.)

cperience was in the following. *(if more than one, give length of time in each)*

☐ General Clinical Laboratory (not specialized)_____ ☐ Clinical Microbiology_____ ☐ Serology_____ ☐ Clinical Chemistry_____
☐ Immunohematology_____ ☐ Hematology_____ ☐ Pathology_____ ☐ Radiobioassay_____

escription of duties: _____

Name and Address of Institution	Name and Degree of Laboratory Director	Employed From (mo , yr)	Employed To (mo., yr.)	Job Title	Served as Title From (mo., yr.)	Served as Title To (mo., yr)

xperience was in the following: *(if more than one, give length of time in each)*

☐ General Clinical Laboratory (not specialized)_____ ☐ Clinical Microbiology_____ ☐ Serology_____ ☐ Clinical Chemistry_____
☐ Immunohematology_____ ☐ Hematology_____ ☐ Pathology_____ ☐ Radiobioassay_____

Description of duties: _____

Name and Address of Institution	Name and Degree of Laboratory Director	Employed From (mo., yr)	Employed To (mo., yr.)	Job Title	Served as Title From (mo., yr.)	Served as Title To (mo., yr)

Experience was in the following· *(if more than one, give length of time in each)*

☐ General Clincial Laboratory (not specialized)_____ ☐ Clinical Microbiology_____ ☐ Serology_____ ☐ Clinical Chemistry_____
☐ Immunohematology_____ ☐ Hematology_____ ☐ Pathology_____ ☐ Radiobioassay_____

Description of duties. _____

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING THIS APPLICATION

Statements or Entries Generally: Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than $10,000 or imprisoned not more than five years, or both. (U.S. Code, Title 18, Sec. 1001)

CERTIFICATION: I CERTIFY that all of the statements made in this application are true, complete, and correct to the best of my knowledge and belief and are made in good faith.

12. Signature of applicant *(sign in ink)* _____ Date _____
(name in Block 1)

CERTIFICATION: I have viewed the entries made herein and to the best of my knowledge they are true, complete and correct.

13 Signature of Current Laboratory Director *(sign in ink)* _____ Date _____

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
Bureau of Laboratories
Atlanta, Georgia 30333

APPLICATION FOR LICENSURE UNDER CLINICAL LABORATORIES IMPROVEMENT ACT OF 1967

(To be completed by and reflect qualifications of person whose name appears in Block 1)

PART II-C – PERSONNEL – TECHNOLOGIST ☐ CYTOTECHNOLOGIST ☐ TECHNICIAN ☐

1. Date:	Name: Last	First	Middle Initial	2. Social Security No.:

3. Do you consider yourself qualified to serve as a Technologist or Technician by the standards prescribed in the Code of Federal Regulations, Title 20, Chapter III, Section 405.1315? ☐ Yes ☐ No If yes, by which subparagraph? *(check one)*

Technologist: ☐ (b) (1) ☐ (b) (2) ☐ (b) (3) ☐ (b) (4) (i) ☐ (b) (5) Technician: ☐ (d) (1) ☐ (d) (2) ☐ (d) (3) ☐ (d) (4)

3a. Do you consider yourself qualified to serve as a Cytotechnologist under CLIA – 1967 Regulations, Section 74.31 (J)? ☐ Yes ☐ No

If yes, by which paragraph? *(check one)* ☐ (1) ☐ (2) ☐ (3)

Check those CATEGORIES and Subcategories in which the individual performs tests and give the name of immediate supervisor if the test is performed under direct supervision:

☐ MICROBIOLOGY AND SEROLOGY Name of Supervisor _____
- ☐ Bacteriology _____
- ☐ Mycology _____
- ☐ Parasitology _____
- ☐ Virology _____
- ☐ Serology (syphilis) _____
- ☐ Serology (non-syphilis) _____

☐ CLINICAL CHEMISTRY Name of Supervisor _____
- ☐ Blood and Cerebrospinal Fluid Chemistry _____
- ☐ Endocrinology _____
- ☐ Toxicology _____
- ☐ Urinalysis _____

☐ HEMATOLOGY (including Hemoglobin) Name of Supervisor _____

☐ PATHOLOGY Name of Supervisor _____
- ☐ Exfoliative Cytology _____
- ☐ Histopathology _____
- ☐ Oral Pathology _____

☐ IMMUNOHEMATOLOGY _____ ☐ RADIOBIOASSAY _____

Do you have a current license as a clinical laboratory technologist ☐ cytotechnologist ☐ technician ☐ issued by the State?

☐ Yes ☐ No License No. _____ List National Registry _____ Registry No. _____

EDUCATION

Name and Address of High School: Graduated 19 _____

Name and Address of College or University	Major	Attended From	Attended To	Degree

If you have college credits but no degree, or a bachelor's degree from a foreign or non-accredited United States college or university, please enclose a transcript of your college credits.

LABORATORY TRAINING *(attach extra sheets if necessary)*

Check one: ☐ Medical Technology ☐ Cytotechnology ☐ Other *(specify)* _____

Name and Address of Institution	Laboratory Specialty in which trained	From (mo., yr.)	To (mo., yr.)	Name and Degree of Immediate Supervisor during training

Check one: ☐ Medical Technology ☐ Cytotechnology ☐ Other *(specify)* _____

Name and Address of Institution	Laboratory Specialty in which trained	From (mo., yr.)	To (mo., yr.)	Name and Degree of Immediate Supervisor during training

For administrative use only. Do not complete this space.

Reviewer _____ Date _____ Remarks _____

PART II-C – PERSONNEL – TECHNOLOGIST, CYTOTECHNOLOGIST, OR TECHNICIAN *(continued)*

. LABORATORY EXPERIENCE FOLLOWING GRADUATION *(list most recent first – attach extra sheets if necessary)*

Name and Address of Institution	Name and Degree of Immediate Supervisor	Employed From (mo., yr.)	Employed To (mo., yr.)
		(mo., yr.)	(mo., yr.)

You performed the duties of a clinical laboratory technologist ☐ cytotechnologist ☐ technician ☐ from _____ to _____

Experience was in the following: *(if more than one, give length of time in each)*

- ☐ Bacteriology _____
- ☐ Mycology _____
- ☐ Parasitology _____
- ☐ Virology _____
- ☐ Serology (syphilis) _____
- ☐ Serology (non-syphilis) _____
- ☐ Immunohematology _____
- ☐ Hematology (including Hemoglobin) _____
- ☐ Blood and Cerebrospinal Fluid Chemistry _____
- ☐ Endocrinology _____
- ☐ Toxicology _____
- ☐ Urinalysis _____
- ☐ Exfoliative Cytology _____
- ☐ Histopathology _____
- ☐ Oral Pathology _____
- ☐ Radiobioassay _____

Name and Address of Institution	Name and Degree of Immediate Supervisor	Employed From (mo., Yr.)	Employed To (mo., yr.)
		(mo., yr.)	(mo., yr.)

You performed the duties of a clinical laboratory technologist ☐ cytotechnologist ☐ technician ☐ from _____ to _____

Experience was in the following: *(if more than one, give length of time in each)*

- ☐ Bacteriology _____
- ☐ Mycology _____
- ☐ Parasitology _____
- ☐ Virology _____
- ☐ Serology (syphilis) _____
- ☐ Serology (non-syphilis) _____
- ☐ Immunohematology _____
- ☐ Hematology (including Hemoglobin) _____
- ☐ Blood and Cerebrospinal Fluid Chemistry _____
- ☐ Endocrinology _____
- ☐ Toxicology _____
- ☐ Urinalysis _____
- ☐ Exfoliative Cytology _____
- ☐ Histopathology _____
- ☐ Oral Pathology _____
- ☐ Radiobioassay _____

Name and Address of Institution	Name and Degree of Immediate Supervisor	Employed From (mo., yr.)	Employed To (mo., yr.)
		(mo., yr.)	(mo., yr.)

You performed the duties of a clinical laboratory technologist ☐ cytotechnologist ☐ technician ☐ from _____ to _____

Experience was in the following: *(if more than one, give length of time in each)*

- ☐ Bacteriology _____
- ☐ Mycology _____
- ☐ Parasitology _____
- ☐ Virology _____
- ☐ Serology (syphilis) _____
- ☐ Serology (non-syphilis) _____
- ☐ Immunohematology _____
- ☐ Hematology (including Hemoglobin) _____
- ☐ Blood and Cerebrospinal Fluid Chemistry _____
- ☐ Endocrinology _____
- ☐ Toxicology _____
- ☐ Urinalysis _____
- ☐ Exfoliative Cytology _____
- ☐ Histopathology _____
- ☐ Oral Pathology _____
- ☐ Radiobioassay _____

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING THIS APPLICATION

Statements or Entries Generally: Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statements or entry, shall be fined not more than $10,000 or imprisoned not more than five years, or both. (U.S. Code, Title 18, Sec. 1001).

CERTIFICATION: I CERTIFY that all of the statements made in this application are true, complete, and correct to the best of my knowledge and belief and are made in good faith.

Signature of applicant *(sign in ink)* _____ Date _____
(Name in Block 1)

CERTIFICATION: I have reviewed the entries made herein and to the best of my knowledge they are true, complete and correct.

10. Signature of Current Laboratory Director *(sign in ink)* _____ Date _____

EXAMINATION SUMMARY

Code:_____

)oratory:_____ Examiner(s)_____ _____

_____ Date:_____

_____ Arrival_____

Departure_____

rector(s)_____ Hours of Operation Fr_____To_____

_____ Day_____Night_____

pe of Examination: ☒ Original ☐ Annual ☐ Re-examination ☐ Expansion ☐ Other

Requested:	A_1	2	3	4	5	6	B_1	2	3	4	C	D	E_1	2	3	F
Expansion																
Withdrawal																

Multiple Sites: Yes ☐ No ☐

Examined: Yes ☐ No ☐

Recommendations: License ☐ Continue Licensure ☐ Request CAS ☐ Field Conference ☐

Re-examine: Before Licensure ☐ Revoke ☐ Before Renewal ☐ Deny ☐

No Deficiencies N.A.

Refer to Compliance ☐ Date Referred_____

GENERAL:

BACTERIOLOGY: ☐ ☐

...COLOGY: ☐ ☐

PARASITOLOGY: ☐ ☐

[ROLOGY: ☐ ☐

SEROLOGY (Syphilis): ☐ ☐

Code: _____

	No Deficiencies	N.A
SEROLOGY (Non-Syphilis):	—	—
	—	—
CHEMISTRY:		
BLOOD & CSF:	☐	☐
ENDOCRINOLOGY:	☐	☐
TOXICOLOGY:	☐	☐
URINALYSIS:	☐	☐
IMMUNOHEMATOLOGY:	☐	☐
HEMATOLOGY:	☐	☐
CYTOLOGY:	☐	☐
HISTOPATHOLOGY:	☐	☐
ORAL PATHOLOGY:	☐	☐

Code:_____

	No Deficiencies	N.A.
ADIOBIOASSAY:	☐	☐

COMMENTS & OBSERVATIONS:

STATE OF NEW YORK*

* These forms are used in the water laboratory certification program.

Form No. FS-1

Division of Laboratories and Research
New York State Department of Health

Approved Laboratory Inspection for Chemical Examination of Water

Name of laboratory: _____

Location: _____ County: _____ Inspection Date: _____

Director: _____

LABORATORY PERSONNEL: Qualifications, Degrees

GENERAL APPEARANCE:

Space:
Square Feet, approx.:
Lighting:

Cleanliness:

EQUIPMENT:

1. (a) Distilled water still:
   (b) Double distilled water:
   (c) NH_3-free water:
2. Demineralizer:
3. Drying oven:
4. Analytical Balance:
5. Pan balance:
6. Desiccator:
7. Muffle furnace:
8. pH meter:
9. B.O.D. incubator:
10. Refrigerator:
11. Turbidimeter:
12. Spectrophotometer:
13. Filter photometer:
14. Pipets:

15. NH_3 still:

16. Kjeldahl digester:

17. C.O.D. reflux unit:

18. Hot plate:

19. D.O. meter:

20. Glassware supply:

21. Conductivity meter:

22. Hot water bath:

23. Atomic absorption:

24. Specific ion meter:

25. APHA "Standard Methods":

26. Sample bottles:

27. Steam bath:

28. Fume hood:

29. Arsine generator:

30. Cyanide still:

31. Other:

REAGENTS AND SOLUTIONS:

1. Dry chemicals:
   Quality or grade:

2. Reagents-purchased or prepared:

3. Standard solutions-purchased or prepared:

TESTS AND METHODS:

1. pH:

2. Alkalinity:

3. Hardness:

4. Cl:

5. Oxygen consumed:

6. C.O.D.:

7. Odor:

8. Conductivity:

9. Na

10. K:

11. As:

12. Free NH_3

13. Alb. NH_3

14. Organic nitrogen:

15. Nitrites NO_2:

16. Nitrites NO_3:

17. Color:

18. Turbidity:

19. Fe:

20. Mn:

21. F:

22. Cl_2 residual

23. CO_2

24. Phenol:

25. CN:

26. SO_4:

27. PO_4:

28. Surfactants:

29. Ba:

30. Total dissolved solids:

31. Ca:

32. Mg:

33. Al:

34. CCE:

35. Si:

36. Hg:

37. Cd:

38. Cu:

39. D.O.:

40. Total Cr:

41. Cr^{+6}:

42. Ni:

43. Pb:

44. Se:

45. Ag:

46. Zn:

47. Other:

MISCELLANEOUS:

1. Result sheet (obtain 1 copy)

2. Results reported how:

3. Sample identification:

4. Laboratory methods notebook:

5. Standard curves:

6. General attitude:

7. Sample preservation - (a) CN^-
   (b) Phenol:
   (c) Metals:

8. ARS participant:

9. Number samples analyzed annually:

REMARKS:

Date_____ Inspecting Chemist:_____

Title:_____

STATE OF CONNECTICUT*

* These forms are used in the water laboratory certification program.

CONNECTICUT STATE DEPARTMENT OF HEALTH
LABORATORY DIVISION
HARTFORD, CONNECTICUT

APPLICATION FOR APPROVAL AS A LABORATORY DIRECTOR

(WATER, DAIRY, FOOD, FOOD UTENSILS)

Part I

1. Last Name | First Name | Middle Initial

2. Home Address

street | town | state | zip | phone number

3. Work Address

street | town | state | zip | phone number

4. Sex

5. Date of Birth

month-day-year

6. Citizenship

☐ USA ☐ Other-specify

7. Education

Name of University	Address	Major	Dates Attended	Degrees

NOTE: OFFICIAL COPIES OF PERTINENT ACADEMIC TRANSCRIPTS MUST ACCOMPANY THIS APPLICATION OR SENT TO THIS OFFICE BY THE ACADEMIC INSTITUTION. THE APPLICATION WILL NOT BE PROCESSED UNTIL SUCH TRANSCRIPTS ARE RECEIVED

8. Are you currently licensed by the Connecticut State Department of Agriculture to perform microbiological examinations of dairy products?

☐ NO ☐ YES

if yes, give type of license and number

type _____ number _____

PART II

1. Experience: list only those positions which indicate your ability to perform and supervise laboratory work. List most recent first; attach extra sheets if necessary.

Name and Address of Institution	Name & Address of Director or supervisor	Your Title	Dates from	Dates to

Description of duties (be specific)

Name and Address of Institution	Name & Address of Director or Supervisor	Your Title	Dates from	Dates to

Description of Duties

Name and Address of Institution	Name & Address of Director or Supervisor	Your Title	Dates from	Dates to

Description of Duties

Name and Address of Institution	Name & Address of Director or Supervisor	Your Title	Dates from	Dates To

Description of Duties

PART III

Type of laboratory you wish to direct (check one or more)

- ☐ Milk and dairy products
- ☐ Food (microbiological)
- ☐ Food (chemical)
- ☐ Food Utensils
- ☐ Water (see attached memo from Commissioner of Health)

Tests you wish to perform in your laboratory:

- ☐ Water
  - ☐ Basic tests of sanitary significance
  - ☐ Heavy metals analysis
  - ☐ Specialized tests on wastewaters and trade wastes
- ☐ Microbiological examination of milk and dairy products
- ☐ Microbiological examination of food utensils
- ☐ Chemical examination of food utensils
- ☐ Microbiological examination of foods
- ☐ Chemical examination of foods
- ☐ Other- specify in detail

_____

_____

I, the undersigned, do hereby certify that the information provided in this application is to the best of my knowledge correct and accurate.

_____
Applicant's Signature

_____
Date Signed

Please type or print below the mailing address to which you wish all correspondence concerning this application be directed:

_____
street and number

_____
town, state, and zip code

LABORATORY DIVISION
CONNECTICUT STATE DEPARTMENT OF HEALTH

For State Use Only	
recd _____	reg to Comm _____
Dir appd _____	reg issued _____
Insptd _____	Reg No. _____
Tech Rev _____	

APPLICATION FOR INITIAL REGISTRATION AND APPROVAL OF A PUBLIC HEALTH LABORATORY

Part I

1. Name of Proposed Laboratory

2. Date of Application
mo day year

3. Address of Proposed Laboratory
street town state zip

4. Type of Laboratory

☐ Water ☐ Food ☐ Other (specify) _____

☐ Dairy ☐ Food utensil

5. Type of Ownership

☐ Private Individual ☐ Corporation (nonprofit)

☐ Partnership ☐ Corporation (profit)

☐ Government ☐ Other (specify) _____

Owners (enter name of corporation on first line when applicable)

6.
last name first name MI address

7.
last name first name MI address

8.
last name first name MI address

9. Registrant (if laboratory is owned by more than one person or by a corporation, enter the name of the individual designated by the owners or corporation to be the responsible registrant. If the laboratory is owned by a single individual, enter his or her name)

last name first name MI title address

Part II

Directors of Proposed Laboratory (directors must be approved as qualified by the department of health prior to the filing of this application)

10. Director

last name	first name	MI	degrees	address

11. Co-Director

last name	first name	MI	degrees	address

12. Supervisor of Laboratory

last name	first name	MI	degrees	address

Describe the experience and training of the laboratory supervisor:

Specialists (personnel who will assist the director(s) and supervisor in the performance of specialized examinations)

	name	degrees	address	area(s) of specialty
13.				
14.				
15.				
16.				

Affiliations with other laboratories or institutions - if a director or supervisor is affiliated in any way with another laboratory of any kind, information concerning this affiliation must be supplied. The following information is required: nature of affiliation with other laboratory, nature of duties, time spent at other laboratory. Attach this information to this application.

Part III

Equipment to be used (list all equipment that will be present in the laboratory at the time of inspection. Be specific. Use additional pages if necessary)

17. Refrigeration Equipment

18. Water baths

19. Incubators

20. Centrifuges

21. Microscopes

22. Safety hoods

23. Sterilization Equipment

24. Ovens

25. pH meters

26. Colorimeters, spectrophotometers, and fluorometers

27. Automated Equipment for Chemistry

28. Other equipment (specify)

Part IV

29. ☐ Basic Sanitary Examinations of Water

As a minimum, the laboratory must be able to perform the following:

A. Bacteriological examinations by MPN method (MF method can be used also but lab must have MPN method capability at all times)

B. Physical tests (odor, color, turbidity, pH)

C. Chemical tests (nitrates, nitrites, ammonia nitrogen by direct nesslerization, methylene blue active substances (detergents), chlorides, iron, and manganese)

Check one or both:

☐ Methods used for above will be identical to those found in the most recent edition of Standard Methods for the Examination of Water and Wastewater (APHA)

☐ Other methods used - detailed methodology must be attached to this application

30. ☐ Specialized Examinations of Water and Wastewater

☐ Heavy Metals analyses

☐ "Standard Methods" used

☐ Other methods used - attach to application

☐ Specialized examinations of wastewater and tradewastes (BOD, COD, etc.)

☐ "Standard Methods" used

☐ Other method used - attach to application

Part IV, Continued

31. ☐ Dairy Microbiology

A. ☐ Direct microscopic bacterial count
B. ☐ Agar Plate bacterial count
C. Screening Tests for abnormal milk
   ☐ Direct microscopic leucocyte count
   ☐ Direct microscopic somatic cell count
   ☐ Modified Whiteside test
   ☐ Wisconsin mastitis test
D. ☐ Laboratory pasteurization test
E. ☐ Coliform determination
F. ☐ Phosphatase determination (state procedure to be used)_____
G. ☐ Other (specify)

32. ☐ Food Bacteriology

A. ☐ Aerobic plate count
B. ☐ Detection and enumeration of Staphylococcus aureus
C. ☐ Coliforms
D. ☐ Detection and identification of Salmonella and Shigella
E. ☐ Other (specify)

33. ☐ Examination of Food Utensils

A. ☐ Bacteriological
B. ☐ Chemical
C. ☐ Other (specify)

Part V

34. Date that laboratory facilities will be avialable for inspection by a representative of the State Department of Health:

_____ ☐ definite ☐ Approximate
month . day year

35. Furnish the name of the person (either registrant or director) who can be reached by the Department to discuss this application and to make arrangements for inspections and reviews:

Name Title Address Phone Number

We, the undersigned, individually and jointly certify that the information that has been provided in this application is to the best of our knowledge and belief accurate and correct.

If registration and approval of this laboratory is granted by the Commissioner of Health, we agree to comply fully with all regulations of the State of Connecticut and directives pursuant thereto that may be issued by the Commissioner of Health or his representatives.

We fully understand that the Commissioner of Health may at any time revoke or suspend the registration and approval of this laboratory if, in his opinion, the laboratory has violated any regulation of the State of Connecticut or directive pursuant thereto, or if the continued operation of the laboratory is not in the best interest of the health and safety of the citizens of the State of Connecticut.

In witness whereof, we have hereunto set our hands and seal this _____ day of _____, 19____.

_____ _____
Signature of Director Signature of Registrant

_____
Signature of Co-Director

State of _____
County of _____ ss.

Then personally appeared before me _____
(name of notary)

duly qualified to administer oaths, _____
(names of registrant, director, and

_____ and subscribed and made
co-director)

oath to the truth of the foregoing affidavit.

_____
Notary Public

STATE OF CALIFORNIA*

* Forms starting on page 180 apply to the clinical laboratory licensure program.

Forms starting on page 190 apply to the water laboratory approval program.

State of California
Department of Health

APPLICATION FOR CLINICAL LABORATORY LICENSE

(Chapter 3, Division 2, Business and Professions Code)

INSTRUCTIONS:

Please use typewriter or print in ink. Complete this application and personnel report and return with $100 fee (no fee is required of District, City, County or State).

SEND TO State of California, Department of Health
Laboratory Field Services
P.O. Box 1525
Sacramento, CA 95807

1. Name of Laboratory (Exactly as desired on license)

Street Address

City | Zip Code | Telephone number including area code

2. New Laboratory Opening Date on _____ Date
Name of Laboratory Changed on _____ Date
Address of Laboratory Changed on _____ Date
Director of Laboratory Changed on _____ Date
Owner of Laboratory Changed on _____ Date

3. Type of Ownership

☐ Individual
Give Name:

☐ Partnership
Give Name of One Partner:
(List others in Item 5)

☐ Corporation
Give Name of President or Hospital Administrator:
(List Board of Directors in Item 5)

☐ District, City, County or State
Give Name of Administrator.

☐ Other (Association, Company, etc.)
Give Name of Administrator:

4. Exact Name of Corporation, District, or Association Owning Laboratory Is.

5 The Names of All Other Members of Partnership or Corporation Board of Directors Are.

6. Laboratory Director(s): Give First, Middle, and Last Name	California License Number	Hours/Week To Be Spent In Lab	Code Number Med. Spec. (See Over)

I declare under penalty of perjury that the foregoing statements are true and correct, that I have read and understand Chapter 3, Division 2 of the California Business and Professions Code; and Group 2, Subchapter 1, Chapter 2 of Title 17, of the California Administrative Code; and that if a license is granted upon this application, the laboratory regulated by it will be conducted in accordance with the provisions of the aforementioned laws and regulations. I also certify that my connection with the above laboratory is bona fide, as shown; and that no subterfuge or mental reservation exists in connection with this application.

7. CERTIFICATION OF OWNER WHOSE NAME IS GIVEN UNDER (3) ABOVE:

▶ _____ Signature _____ Date

8. CERTIFICATION OF A DIRECTOR WHOSE NAME IS GIVEN UNDER (6) ABOVE:

▶ _____ Signature _____ Date

(Rev. 9-1-73) Form 242-202

For use by physician laboratory directors in completing Item 6 on reverse.

CODING OF AMERICAN MEDICAL SPECIALTY BOARD CERTIFICATION

CODE	MEDICAL SPECIALTIES
11	Clinical Pathology and Pathologic Anatomy
12	Clinical Pathology
13	Pathologic Anatomy
14	Other Pathology Specialties
20	Internal Medicine
30	Pediatrics
40	Obstetrics and Gynecology
50	All Other Medical Specialties

State of California
Department of Public Health

APPLICATION FOR APPROVAL TO PERFORM PREMARITAL AND PRENATAL SEROLOGIC TESTS FOR SYPHILIS

INSTRUCTIONS: Complete in duplicate. RETURN ORIGINAL *to Laboratory Field Services, 2151 Berkeley Way, Berkeley 94704, and keep duplicate copy for your own file. Use* INK *or* TYPEWRITER.

1. Name of Laboratory

2. Address - Street

City Zip

3. Phone No. - Area Code ( )

FOR DEPARTMENT USE ONLY

Released by _____ Date _____

Copy to L.A. _____

4. Check test(s) for which approval is requested

☐ VDRL Slide ☐ FTA-ABS ☐ RPR (Circle) Card

☐ Automated Reagin (ART) ☐ Automated FTA (AFTA)

Check items which are in the laboratory and will be used in the performance of the test(s):

5. Reference manual of serologic tests for syphilis

☐ California ☐ USPHS Edition: _____ Year

6. Water bath thermostatically controlled ☐ 56°C

7. Centrifuge

☐ Horizontal head

☐ Other head (specify) _____

8. Refrigerator ☐

9. Serum controls

☐ Reactive, quantitative ☐ Weak reactive

☐ Reactive, qualitative ☐ Nonreactive

☐ Other (specify) _____

Source: _____

10. Pipettes (unetched and unbroken) ☐

11. Microscope

☐ Eyepiece 10X (VDRL)

☐ Filters (FTA)(specify) _____

☐ Others (specify) _____

12. Rotator, mechanical

☐ 100 RPM (RPR) ☐ Fixed speed

☐ 180 RPM (VDRL) ☐ Variable speed

13. Slides

☐ Flat-bottomed, with ceramic rings (VDRL)

☐ Plastic Coated cards with 18 mm circle spots (RPR)

☐ Glass approx. 1 mm thick with etched circles 1 cm inside diameter (FTA)

☐ Other (specify) _____

14. Bottle, round 30 ml., flat bottomed (VDRL)

Stopper: ☐ Glass ☐ Other (specify) _____

15. Needles, without bevels, calibrated for test

☐ VDRL ☐ RPR

16. Automated system

☐ AFTA ☐ ART

Source and model (specify) _____

17. Air supply (AFTA)

☐ 30-40 psig

18. Magnetic Stirrer (ART)

Micro Stirring Bar

☐ Length 1/2" x 1/8" diameter

☐ Length 1/4" x 1/8" diameter

19. Filter paper #402 (ART) ☐

20. Vacuum pump (ART)

☐ 15-20 in. Hg. suitable for continuous operation

21. Sample cups (ART)

☐ 0.5 ml. size - qualitative

☐ 2.0 ml. size - quantitative

I have read the regulations relating to premarital and prenatal serologic tests for syphilis as contained in Title 17, Chapter 2 of the California Administrative Code and agree to abide by these regulations. I will participate in a State operated or State approved proficiency testing program as prescribed by the State Department of Public Health.

▶ _____ _____

Signature of Laboratory Director Date

(Rev. 9-1-71) Form 242-200

State of California
Department of Health

LABORATORY SURVEY REPORT

Laboratory Field Service
Form 242-306 (Rev. 4-1-7

1. Name of Laboratory		3. Provider No.	4. State ID No.
2. Address	Telephone: Code ( )	5. Date of Survey	6. By (Initial)
7. Person(s) Interviewed a. Director b. Owner c. Technologist d. Bioanalyst e. Admin./Manager f. _____ Date of Prior Survey _____ Cert. Class _____		8. Location ☐M.D. Office ☐Office Bldg. ☐Hospital Other _____	9. Approvals and License ☐STS ☐F.A. ☐PKU ☐Water ☐Train. ☐J.C.A.H ☐C.L.I.A. ☐

		Yes	No	N/A
10.	**I. STATE AND LOCAL LAWS (405.1310)**			
11.	☐In Sub. Compliance ☐Not in Sub. Compliance ☐Change Since Last Survey ☐No Change			
12.				
13.				
14.				
15.	(a) Licensure ☐Met ☐Not Met			
16.	(b) Licensed Staff ☐Met ☐Not Met			
17.	(c) Fire and Safety ☐Met ☐Not Met			
18.				
19.	**II. LABORATORY DIRECTOR (405.1312)**			
20.				
21.	☐In Sub. Compliance ☐Not in Sub. Compliance ☐Change Since Last Survey ☐No Change			
22.				
23.				
24.	(a) Administration ☐Met ☐Not Met			
25.	Director is owner	—	—	—
26.	# Other labs directing _____			
27.	Hrs. of oper. _____ to _____ days/wk _____			
28.	Reg. hrs. (Dir.)_____ to _____(Co-dir.) _____ to _____			
29.	(1) Director serves	—	—	—
30.	(2) Qualified in all specialties performed	—	—	—
31.	(3) Direction 1050(b)			
32.	Determine technics	—	—	—
33.	Determine control program	—	—	—
34.	Assess activities & controls	—	—	—
35.	Hrs. spent/wk _____			
36.	Reports reviewed % _____			
37.	Estab. qual. for lab personnel	—	—	—
38.	Determine forms format	—	—	—
39.	Confer with lab staff	—	—	—
40.	Freq. _____			
41.	Confer with users	—	—	—
42.	(4) Employment	—	—	—
43.	(5) If absent	—	—	—
44.	Name of Sub. _____			
45.	Qual. of Sub. _____			
46.	(b) Qualifications ☐Met ☐Not Met			
47.	(1) MD A or C Pathologist	—	—	—
48.	(2) MD Other Board + 4	—	—	—
49.	(3) Other doctorate	—	—	—
50.	Cert. Board _____			
51.	(4) Directed 1 yr. between 1961 and 1968	—	—	—
52.	(i) M.D. + 4	—	—	—
53.	(ii) Masters + 4	—	—	—
54.	(iii) Bachelor + 6	—	—	—
55.	(iv) PHS exam.	—	—	—
56.				
57.	**III. SUPERVISION (405.1313)**			
58.				
59.	☐In Sub. Compliance ☐Not in Sub. Compliance ☐Change Since Last Survey ☐ ☐No Change			
60.				
61.				
62.	(a) Supervision ☐Met ☐Not Met			
63.	Director Serves	—	—	—
64.	#Gen. _____ #Technical _____			
65.	#and spec. of tech. sup. NOT full time			
66.				
67.	Gen. Sup.: on premises during testing	—	—	—
68.	Technical Supervisor: adequate time	—	—	—
69.	readily available	—	—	—
70.	Emergency work reviewed	—	—	—

		Yes	No	N/A
71.				
72.	(b) Qualifications ☐Met ☐Not Met			
73.	(1) Doctorate + 2 # _____	—	—	—
74.	(2) Masters + 4 # _____	—	—	—
75.	(3) Clin. Tech + 6 # _____	—	—	—
76.	(4) Acad. + Exp. = 15 # _____	—	—	—
77.				
78.	**IV. TESTS PERFORMED (405.1314)**			
79.				
80.	☐In Sub. Compliance ☐Not in Sub. Compliance ☐Change Since Last Survey ☐No Change			
81.				
82.				
83.	Proficiency Test 1052 ☐Met ☐Not Met			
84.				

85.	Specialty	Annual Volume	Medicare Only
86.	Bacteriology		
87.	Mycology		
88.	Parasitology		
89.	Syph. Serol.		
90.	Non-Syph. Serol.		
91.	Hematology		
92.	Bld Group		
93.	Bld Type		
94.	Clin. Chem.		
95.	Urinalysis		
96	Electrophoresis		
97.	Radiobioassay		
98.	Tissue Pathology		
99.	Cytology		
100.	EKG		
101.			
102.			

		Yes	No	N/A
103.				
104.	**V. TECHNICAL PERSONNEL (405.1315)**			
105.				
106.	☐In Sub. Compliance ☐Not in Sub. Compliance ☐Change Since Last Survey ☐No Change			
107.				
108.				
109.	(a) Tech. Duties ☐Met ☐Not Met			
110.	(1) Performs only in specialties qualified	—	—	—
111.	(2) Performs tests in specialties not qualified	—	—	—
112.	(3) Sufficient number to supervise	—	—	—
113.	# Technicians _____ # Train. _____			
114.	(b) Tech Qual. ☐Met ☐Not Met			
115.	(1) Med. Tech. Degree # _____	—	—	—
116.	(2) 90 Units + AMA Training # _____	—	—	—
117.	(3) Bachelors + 12 mo. # _____	—	—	—
118.	(4) 90 Units + adequate exp. # _____	—	—	—
119.	(5) Prior to '68 + 10 yrs. exp. # _____	—	—	—
120.	(c) Technician Duties ☐Met ☐Not Met			
121.	1245 (1) Pul. Function # _____	—	—	—
122.	Trained by M.D.	—	—	—
123.	Supervised by M.D.	—	—	—
124.	Report to M.D.	—	—	—
125.	1034.2 (2) Cytotechs # _____ Certificates	—	—	—
126.	(3) EKG techs # _____	—	—	—

		Yes	No	N/A
127.				
128.	1034.1 Aides # ____			
129.	1246 Phlebotomists # ____			
130.	1034 LVN # ____ Cert. # ____			
131.	(d) Technician Qual. ☐Met ☐Not Met			
132.	(1) HS + 1 yr. Approved School	—	—	—
133.	(2) HS + 2 yrs. Approved Lab.	—	—	—
134.	(3) HS + 50 wks. military course	—	—	—
135.	(4) Performed 5 yrs. prior to '68	—	—	—
136.	(e) Personnel Policies ☐Met ☐Not Met			
137.	☐Work hrs ☐Emp. procedures			
138.	☐Promotions ☐Accid. comp.			
139.	☐Dir. interview & select employees			
140.	(1) Employee records	—	—	—
141.	☐Training ☐Experience			
142.	☐Duties ☐Dates of employment			
143.	(2) Health Records	—	—	—
144.	☐P.E. ☐X.R. ☐Imm. ☐Illness			
145.	(3) Work Assignment agree with qual.	—	—	—
146.	(4) Employee orientation	—	—	—
147.				
148.	**VI. CLINICAL LABORATORY MANAGEMENT 1220**			
149.	(a) Laboratory Management ☐Met ☐Not Met			
150.	(1) Adequate workbench space	—	—	—
151.	Total Space ____ sq. ft.			
152.	(2) Work areas properly arranged	—	—	—
153.	: Blood collection area satisfactory	—	—	—
154.	(3) Properly ventilated	—	—	—
155.	(4) Volatile chemicals properly stored	—	—	—
156.	(5) Proper temp. and humid controls	—	—	—
157.	(6) Safety 1050(c)			
158.	Adequate fire extinguishers	—	—	—
159.	Fire plan posted	—	—	—
160.	Fume hood where needed.	—	—	—
161.	Bact. cabinet where needed	—	—	—
162.	☐Manometer ☐Satisfactory			
163.	Gas tanks chained	—	—	—
164.	Other ____	—	—	—
165.	____	—	—	—
166.	(b) Collection of Specs. ☐Met ☐Not Met			
167.	(c) Sterilization ☐Met ☐Not Met			
168.	Proper sterilized and wrapped syringes	—	—	—
169.	Disposable sterile syringes only	—	—	—
170.	Proper disposal 4143	—	—	—
171.	Contaminated material adeq. disinfected	—	—	—
172.	(1) Indicator used each cycle	—	—	—
173.	(d) Examinations & Reports ☐Met ☐Not Met			
174.	(1) Written request (patient)	—	—	—
175.	(2) Written request (specimen)	—	—	—
176.	(3) Receive from lab. report only to lab.	—	—	—

		Yes	No	N/A
177.				
178.	(e) Specimens - Records ☐Met ☐Not Met			
179.	Daily Accession Record			
180.	Records Kept	—	—	—
181.	(1) Specimens identified	—	—	—
182.	(2) Patient identified	—	—	—
183.	(3) Submittor identified	—	—	—
184.	(4) Date collected	—	—	—
185.	(5) Date received	—	—	—
186	(6) Condition of specimens	—	—	—
187.	(7) Test(s) performed	—	—	—
188.	(8) Date performed	—	—	—
189.	(9) Results and date reported	—	—	—
190.	(f) Laboratory Rep. & Record ☐Met ☐Not Met			
191.	Promptly sent to physician			
192.	(1) Lab. director responsible	—	—	—
193.	(2) Duplicate retained 2 yrs. or more	—	—	—
194.	(3) Acceptable terminology for tissue	—	—	—
195.	(4) Report to patient authorized	—	—	—
196.	(5) Compare with normal ranges	—	—	—
197.	(6) List of methods available	—	—	—
198.	(7) Referral lab. medicare certified	—	—	—
199.				
200.	**MISCELLANEOUS**			
201.	Clinical Laboratory License Posted	—	—	—
202.	Personnel Licenses Posted	—	—	—
203.	Licenses Not Photocopied	—	—	—
204.	Laboratory Serves			
205.	Directors private practice only	—	—	—
206.	Medicare/Medi-Cal	—	—	—
207.	Directors name on report 1055	—	—	—
208.	Name & address on report 1288	—	—	—
209.	Referred work properly reported 1288	—	—	—
210.	Adequate training 1035	—	—	—
211.	Lab. charges disclosed 655.5	—	—	—
212.	PM - PN reporting satisfactory	—	—	—
213.	Serology 1127	—	—	—
214.	D^u on Rh neg. 1056	—	—	—
215.	Reports properly stamped 1057	—	—	—
216.	Rubella satisfactory	—	—	—
217.	Pathology services retained part time	—	—	—
218.	Name ____			
219.	Path. & Cytol not priced 650	—	—	—
220	Discounts not offered 650	—	—	—
221.	24 hr. lab. coverage	—	—	—
222.	Blood supplier ____			
223.	Guidelines available	—	—	—
224.	Supplement available	—	—	—
225.	Specimens referred to ____			
226.	____			
227.	____			

QUALITY CONTROL SURVEY REPORT

State of California
Department of Health

Laboratory Servi
Form 242 306B (Rev. 4-1-

1. Name of Laboratory	3. Provider No.	4 State I.D. No.
2 Address	Telephone: Code ( )	5 Date of Survey / 6. By (Initial)

7. CLINICAL LABORATORY MANAGEMENT [1050(e)(3)]
8. (a) Procedure Manuals ☐Met ☐Not Met

9.	Name	Ref.	Rev.	Inst.	Cont	Std.	Coll.
10. Chemistry							
11 Hematology							
12 Microbiol.							
13 Immuno.							
14 N S. Serol.							
15.							
16.							
17.							

18.
19. QUALITY CONTROL
20 (a) Equipment - Reagents [1050(d)-(e)(2) ☐Met ☐Not Met
21.

22.	Prev. Maint.		Rep. & Repl.	Validate		Calibrate	
23.	Freq.	Rec.	Rec.	Freq.	Rec.	Freq.	Rec.
24. Photometer							
25. Radio Counter							
26. Blood Gas							X
27. pH Meter							X
28. Refrigerator							
29. Incubator							
30 Heat Block							
31. Water Bath							
32 Pro. Time							
33. Autoclave			---		X		
34. Centrifuge							
35. Hemat. Cent							
36. Auto. Chem							
37. Auto. Hemat.							
38.							
39							
40.							

41.	Yes	No	N/A
42. (5) Reagents and Solutions			
43. Properly Labelled - Date Rec./Opened			
44. Properly Stored			
45. Parallel Testing ☐Rec.			
46. (b) Specimen Stability ☐Met ☐Not Met			
47. Specimens Accepted Through Mail			
48. (1) Collection Procedure In Writing			
49. Patient Preparation			
50. Specimen Identification			
51. Storage and Preservation of Specimens			
52. (2) Only Stable Specimens Accepted			
53. (c) Methodologies 1050(e)(4)-(f) ☐Met ☐Not Met			
54. (1) Chemistry			
55. Each Method Checked Each Day of Use			
56. Control Results Stat. Analyzed			
57. ☐Charted ☐Graphed			
58. Out of Control Results Noted			
59. Available in Chemistry Area			
60. Action Limits Clearly Shown			
61. Written Plan For Out of Control			
62. Standard Included Each Day Each Procedure			
63. Calibration Curve Used			
64. Checked Freq _____ # Stds. _____ Dated ☐			

65.	Yes	No	N/
66. (2) Hematology - Controls			
67. Brand			
68. RBC - Freq ____ ☐Rec. ☐Limits			
69. WBC - Freq ____ ☐Rec. ☐Limits			
70. HCT - Freq ____ ☐Rec. ☐Limits			
71. HGB - Freq. ____ ☐Rec. ☐Limits			
72. Prothrombin Times in Duplicate			
73. Normal Control Each Day			
74. Abnormal Cont. Freq. _____			
75. (3) Immuno-hematology (NON HOSP)			
76 Antisera NIH Approved			
77. AB Cont Cells. Freq. _____ ☐Rec.			
78. Rh Cont. Cells. Freq. _____ ☐Rec.			
79 D^{u} On All Rh Negs. ☐Rec.			
80 Coombs Control ☐Rec.			
81 Pts Cell Control - Autoagglutinins ☐Rec.			
82. (4) Urinalysis			
83. Cont. Brand _____			
84 Chem. Freq. _____ ☐Rec.			
85. Physical Freq. _____ ☐Rec.			
86 (5) Microbiology			
87. Stains Checked Daily ☐Rec.			
88 Reagents Checked Each Batch ☐Rec.			
89. Antisera Checked Each Batch ☐Rec.			
90. Prepared Media			
91. Brand _____			
92. Each Batch Preparation Date			
93 Dated When Received			
94. Sterility Each Batch ☐Rec.			
95. Growth Characteristics ☐Rec.			
96. Suscep. Test Method _____			
97. Controls Freq _____ ☐Rec.			
98. Discs With Desiccant			
99. Parasite References Satisfactory			
100. ☐Micro Slides ☐Atlas			
101. (6) Serology (1127)			
102. Syphilis - Control Each Day ☐Rec.			
103. ☐R ☐W ☐N ☐TR			
104. USPHS Manual - Year _____			
105. Slides (Cards) Satisfactory			
106. Antigen Bottle Satisfactory			
107. Needles Satisfactory			
108. ☐Qual. ☐Quant ☐RPR			
109. Calibrated: Freq. _____ ☐Rec.			
110. Rotator Speed Chkd Freq. _____ ☐Rec.			
111. Non STS Control Each Day ☐Rec.			
112. (7) Radiobioassay			
113. Standards Each Time ☐Rec.			
114. Background Each Time ☐Rec.			
115. Control Each Time ☐Rec.			
116. ☐Limits ☐Chart ☐Graph			
117. (8) Cytology			
118. 10% Negatives Reviewed			
119. All Positive or Suspicious Smears Reviewed			
120. All Non GYN Smears Reviewed			
121. Smears Kept 2 Years			

		Yes	No	N/A
122.				
123.	(9) Histology			
124.	Stains Checked With Pos. Slides	—	—	—
125	Slides Kept 2 Yrs	—	—	—
126.	Blocks Kept 1 Yr	—	—	—
127.	Tissue In Fix Until Diagnosed	—	—	—
128.				
129.	TRANSFUSION SERVICE [1002(g)-(j)]			
130.	(g)(2) Recording Thermometer	—	—	—
131.	Recordings Kept One Year	—	—	—
132.	Second Thermometer	—	—	—
133.	Immersed In Liquid	—	—	—
134.	Temp. Recorded Twice Daily	—	—	—
135.	(g)(3) Alarm System			
136.	☐Audio ☐Visual	—	—	—
137.	Temperature Limits _____			
138.	Monitored 24 Hrs	—	—	—
139.	By Whom _____			
140.	Brings Immediate Action	—	—	—
141.	Last Tested _____			
142.	Only Blood Products Stored	—	—	—
143.	Auxilliary Power Source	—	—	—
144.	(g)(4) Air Circulating Fan	—	—	—

		Yes	No	N
145.				
146.	(g)(5) AABB Standards Followed	—	—	—
147.	Donor Blood Retyped	—	—	—
148.	Donor Blood Retained 7 Days	—	—	—
149.	Blood Inspected Before Transfusion	—	—	—
150.	Blood Request Forms Satisfactory	—	—	—
151.	Recipient Sample - Labelled At Bedside	—	—	—
152.	☐ABO Type ☐Reverse Type	—	—	—
153.	Antisera NIH # _____			
154	Cells NIH # _____			
155.	Expiration Dates Satisfactory	—	—	—
156.	Rh (D) Typing Only (D^u Not Done)	—	—	—
157.	Test For Autoagglutinins ☐Rec.	—	—	—
158.	Test For Unexpected Antibodies ☐Rec.	—	—	—
159.	Recipient Blood Retained 7 Days	—	—	—
160.	Lab Records Show Actual Results	—	—	—
161.	View Box Temp. Checked Daily ☐Rec.	—	—	—
162.	Optimum Centrifuging Time Determined	—	—	—
163.	Major Cross Match Performed	—	—	—
164.	☐Saline ☐Protein ☐Coombs	—	—	—
165.	Coombs Serum NIH # _____			
166.	Expiration Date Satisfactory	—	—	—
167.	Minor Cross Match	—	—	—
168.	Blood Not Removed Longer Than 30 Min.	—	—	—
169.	Records of Receipt & Disposition Adequate	—	—	—

170. COMMENTS

AMERICAN INDUSTRIAL HYGIENE ASSOCIATION

II. SUMMARY REPORT

These questions are intended principally to serve as as outline to guide the site visitor (laboratory appraisor) in preparing his summary report of the site visit.

		Y (1)	N (2)	N/A (3)
A.	General Information			
1.	On the basis of the laboratory appraisal the questions appearing under the subject heading of General Information, pages 2 & 3 of the questionnaire, were answered correctly by the laboratory management with the following exceptions:	___	___	___
	If any exceptions are noted please explain briefly.			
2.	The laboratory management appears to be competent.	___	___	___
	If no is checked, please explain.			
B.	Laboratory Procedures			
3.	The quality control program is well suited to the need of the laboratory	___	___	___
4.	Sample handling procedures are adequate to prevent loss or deterioration of samples, confusion with other samples or undue delays in processing.	___	___	___
5.	The written laboratory procedures are being satisfactorily handled.	___	___	___
6.	The laboratory record system is adequate and records are well kept. If not, please specify.	___	___	___
7.	The instrument logs are in good shape. If not, please specify in what way they are inadequate.	___	___	___
C.	Laboratory Facilities			
8.	Laboratory facilities are good. If not, specify in what way they are deficient.	___	___	___
9.	Laboratory safety practices are satisfactory. If not, specify in what respect they are deficient.	___	___	___

		Y (1)	N (2)	N/A (3)
D.	Air Sampling Program			
10.	Sampling methods and procedures are satisfactory. If not, specify in what respect they are deficient.	___	___	___
E.	Detector Tubes			
11.	Procedures for use, calibration, maintenance and storage are satisfactory. If not, please specify.	___	___	___
F.	Inorganic Substances			
12.	Analytical procedures are satisfactory. If not, specify in what respect they are inadequate.	___	___	___
G.	Organic Substances			
13.	Analytical procedures are satisfactory. If not, specify in what respect they are inadequate.	___	___	___
H.	Physical Measurements			
14.	Methods are acceptable. If not, specify in what way they are deficient.	___	___	___
I.	Radiometric			
15.	Methods are satisfactory. If not, specify in what respect they are deficient.	___	___	___

COMMENTS:

APPLICATION FOR APPROVAL OF A WATER LABORATORY

(Title 17, Chapter 2, Subchapter 1, Group 6, Sections 1174-1184, California Administrative Code)

Complete and Return to the California State Department of Public Health, Sanitation & Radiation Laboratory
2151 Berkeley Way, Room 238 Berkeley, California 94704

1. LABORATORY NAME

2. ADDRESS — City — Zip Code — County

3. LOCATION

4. OWNER(S)

5. LABORATORY TELEPHONE — Area Code — Number — Ext.

6. LABORATORY DIRECTOR

7. SUPERVISOR or person in immediate charge - Name _____

Education: Degree(s), Year(s), School(s) _____

Certificates or Licenses held: _____

Experience (relative to water analyses): _____

8. TYPE OF LABORATORY

☐ COMMERCIAL - Laboratory performing work on a fee or contract basis for water purveyors or for private individuals.

☐ NON-COMMERCIAL - Laboratory performing no work on a fee basis.

9. LABORATORY WORK FOR WHICH APPROVAL IS REQUESTED (A commercial laboratory may be approved for complete analyses, bacteriological, chemical or both. A non-commercial laboratory may be approved for specified tests or for complete analyses. Procedures are described in the latest edition of Standard Methods for the Examination of Water and Wastewater.)

☐ Complete BACTERIOLOGICAL

☐ Complete CHEMICAL

☐ Other, specify test(s):

NOTE: Before approval is granted a site visit will be made to assess the adequacy of the facilities and qualifications of the personnel. Satisfactory analysis of reference samples is also required for approval and is a condition of continued approval.

► _____ _____
Signature of Owner or Representative — Date

State of California
Department of Public Health

3540

Form 245-301
(Rev. 7-1-70)

State of California - Department of Health
Sanitation & Radiation Laboratory - Water Laboratory Approvals

Name of Laboratory	Date of Visit By
Address (Mail)	County
Address (Samples) : UPS ☐	Supervisor
	Person Interviewed
Location Directions	Telephone

	Equipment & Apparatus *(Use Symbols Listed below to indicate)	DESCRIPTION (Model #, Trade Name, etc.)		Housing and Safety
	Amperometric Titrator or Cl comp			Adequate floor space
	Analytical balance			Adequate bench space
	Atomic absorption			Exhaust hood
	BOD Cambility			Lighting
	Chemical Oxygen demand apparatus			Utilities arrangement
	Colorimeter; Spectrophotometer			Eye wash
	Conductivity meter			Fire extinguisher
	Dissolved oxygen meter			Fire blanket
	Distillation; Deionization			Safety shower
	Drying Oven			Chem storage
	Flame photometer			Glassware storage
	Fluoride Distillation apparatus			
	Gas chromatograph			
	Kjeldahl apparatus			
	Muffle furnace			
	pH meter			Imhoff cones
	Polarograph			Nessler tubes
	Soxhlet apparatus			Refrigerator
	Specific ion electrodes			Titration Set up
				Water bath
	Turbidimeter			

Laboratory Data: Reported _____ ☐ Attach samples of work sheets

Recorded _____

Laboratory records retained and available for reference _____ yrs.

Standard Methods ☐ No ☐ Yes _____ edition

Other references _____

* ✓ Item is in use or service is satisfactory
X Item missing or deviation in service or equipment : Use these symbols to indicate
O Not applicable

Ca_____

Cl_____

Cu_____

F_____

Fe_____

K_____

mg_____

Mn_____

Na_____

As_____

Cd_____

CN_____

Cr_____

Hg_____

Ni_____

Pb_____

Se_____

Zn_____

Alkalinity_____

Hardness_____

pH_____

SO_4_____

TDS_____

Conductivity_____

Color_____

Odor_____

Silica_____

Temperature_____

Turbidity_____

Chlorophyll_____

Organics_____

Pesticides_____

_____

_____

BOD_____

Chlorcs_____

COD_____

DO_____

Grease_____

MBAS_____

Nitrogen:

Ammonia_____

Nitrite_____

Nitrate_____

Organic_____

Phenol_____

Phosphate_____

Solids:

Settleable_____

Suspended_____

Total_____

Volatile_____

Sulfide_____

Volatile Acids_____

_____

_____

_____

State of California - Department of Public Health
Sanitation and Radiation Laboratory

REPORT OF VISIT TO WATER LABORATORY FOR BACTERIOLOGICAL APPROVAL

Name of Laboratory | Date of Visit | By

Address | Type of Approval: ☐ Complete Duct. ☐ Partial _____

Supervisor | Person Interviewed

TYPE OF TEST	TYPES OF SAMPLES TESTED	DILUTIONS USED	NUMBER PER MONTH
☐ Standard Plate Count	☐ Drinking Water		
☐ Coliform Presumptive Test	☐ Raw Water		
☐ Coliform Confirmed	☐ Sewage Effluents		
☐ Membrane Filter	☐ Industrial Wastes		
☐ Special Differentiation Tests	☐ Bathing Waters		

Check each if available; indicate number and type and note pertinent remarks. (If more space needed, use reverse.)

EQUIPMENT

- ☐ Incubator _____
  - Size _____
  - Thermometer ☐ No ☐ Yes _____
  - Temperature record ☐ No ☐ Yes _____
- ☐ Hot Air Sterilizing Oven _____
  - Thermometer ☐ No ☐ Yes _____
- ☐ Autoclave _____
  - Thermometer ☐ No ☐ Yes _____
  - Temperature record ☐ No ☐ Yes _____
- ☐ Colony Counter or equivalent _____
- ☐ Hydrogen Ion Equipment _____
- ☐ Balance _____
- ☐ Other: specify _____

GLASSWARE

- ☐ Media Preparation Utensils _____
- ☐ Pipettes _____
- ☐ Culture Tubes _____
  - Type of closure _____
- ☐ Dilution Bottles or Tubes _____
  - Graduation level indelibly marked _____
  - Type of closure _____
- ☐ Petri Dishes _____
  - Clear, flat bottoms ☐ No ☐ Yes
  - Glass or porous tops ☐ No ☐ Yes
  - Plastic ☐ No ☐ Yes
- ☐ Sample Bottles _____
  - Solvent resistant _____
  - Closure _____
  - Cover used on tops and neck of glass closure ☐ No
  - Dechlorinating agent in sterile bottles ☐

PREPARATION OF EQUIPMENT AND MATERIALS

Glassware
- Cleaning _____
- Sterilization: How _____
  - Time _____ Temperature _____

Culture Media
- Distilled water source _____
- Adjustment of Reaction ☐ No ☐ Yes
- Media Sterilization
  - ☐ Autoclave at 121°C. for 15 minutes _____
  - ☐ Arnold
  - ☐ Media removed as soon as pressure is zero

SAMPLE COLLECTION, STORAGE AND TRANSPORTATION
- Storage temperature between 0°C. - 10°C. ☐ No ☐ Yes
- Time between collection & analysis reported ☐ No ☐ Yes

STORAGE OF CULTURE MEDIA
- ☐ At approximately 25°C.
- ☐ Refrigerator temperature
  - ☐ Overnite at 35°C. before use

STANDARD PLATE COUNT

Media
- ☐ Tryptone glucose extract agar
- ☐ Tryptone glucose yeast agar
- ☐ Milk protein hydrolysate agar
- ☐ Buffered dilution water

Incubation
- ☐ At 35°C. (± 0.5°C.) for 24 ±2 hrs.
- ☐ At 20°C. (± 0.5°C.) for 48 ±3 hrs.

Method of Reporting Plate Count _____

PRESUMPTIVE TEST FOR COLIFORM

Media
- ☐ Lactose Broth
- ☐ Lauryl Tryptose Broth
- ☐ Buffered Dilution Water

Incubation at _____°C. for _____ hrs.

Read at end of 24 & 48 hrs. _____

CONFIRMED TEST FOR COLIFORM

Media
- ☐ Brilliant green lactose bile broth
- ☐ Eosin methylene blue agar
- ☐ Endo medium

Incubation at _____°C. for _____ hrs.

Read at end of ☐ 24 hrs. ☐ 48 hrs. ☐ 24 & 48 hrs.

COUNTING OF COLIFORM TESTS

	NO	YES
Most Probable Number per 100 ml.	☐	☐
No. or percent positive tubes reported	☐	☐
Interpretation made	☐	☐

RECORDS
- Records and Reports ☐ Satisfactory ☐ Unsatisfactory
- Worksheet for tests ☐ No ☐ Yes
- Worksheet and report combined ☐ No ☐ Yes
- Separate report form ☐ No ☐ Yes
- Laboratory records retained and available for reference _____ yrs.
- References in laboratory
  - Standard Method ☐ No ☐ Yes, _____ edition
  - Other _____

USE REVERSE FOR REMARKS

(Rev. 8-24-60) Form LAB-

COLLEGE OF AMERICAN PATHOLOGISTS

COLLEGE OF AMERICAN PATHOLOGISTS

COMMISSION ON INSPECTION AND ACCREDITATION

INSPECTION CHECKLIST

SECTION I

LABORATORY GENERAL

CAP—I & A No:_____

Name of Laboratory_____ QEP No:_____

CLIA No:_____

Address_____ Medicare No:_____

City_____ State_____ Zip_____

AEC No:_____

Name of Director_____ AABB No:_____

Name of Inspector:_____ JCAH No:_____

FDA No:_____

HOSPITAL LABORATORIES State No:_____

Name of Hospital_____

Name of Administrator_____

Name of Chief of Staff_____

INSTRUCTIONS:

1. This section must be completed for every inspection. All questions must be answered as "yes", "no", or not applicable. ("N/A")
2. Questions printed in red will be answered by the laboratory. Questions printed in black will be completed by the inspector.
3. Each question is assigned a "phase" category. A **phase 0** question is "for information only". A **phase I** question refers to a minor deficiency. Phase I deficiencies will not prevent accreditation but should be corrected if possible. **A phase II question refers to a major deficiency and must be corrected for accreditation.** As a general rule, a phase II deficiency is one which could affect test results, and therefore could affect patient care, or could affect the health and safety of hospital and laboratory personnel.
4. Certain questions marked phase I* or II* will be a phase I or phase II only for laboratories or departments accepting specimens in interstate commerce and using CAP accreditation in lieu of federal licensure.

INSTRUCTIONS FOR INTERSTATE LABORATORIES

Laboratories accepting *any* specimens in interstate commerce must comply with the rules and regulations promulgated under the CLIA 1967. If less than 100 specimens are received per year in any one category, the laboratory may apply for exemption from licensure. If more than 100 specimens are received per year in any one category, the laboratory must either be licensed by CDC or accredited by the CAP. Laboratories which are exempt from licensure based on CAP accreditation MUST still meet all of the legal requirements of CLIA 1967.

Certain questions in the check list are designated "II°" and are for interstate laboratories only. A "no" or "N/A" answer for one of these questions represents a Phase II deficiency for an interstate laboratory but may only be a "I" or "O" for a non-interstate laboratory.

False information:

Laboratories using CAP accreditation in lieu of federal licensure must verify the accuracy of information given and sign a statement to that affect. False information given in the questionnaire, check list, or in the reply to the recommendation (corrective action statements) is considered to be perjury and is subject to fine and penalty under federal law.

Documentation is *essential* for the following items:

1) Number of specimens received, per category per year.
2) Subscription and participation in the appropriate Survey program.
3) Qualification of *all* supervisory personnel.
4) Documentation of *all* quality control activities and procedures.

The original and underlying objectives of both the Inspection and Accreditation Program and the Clinical Laboratory Improvement Act is the improvement in the quality of laboratory services. The legal requirements for laboratories involved in interstate commerce must be met by the laboratory and by the College, as far as it is realistically possible to do so. Exceptions to the letter of the law are possible, but must be justified and documented. Conflicts or disputes over regulations and standards will be considered but flagrant disregard of the law may result in legal actions by federal authorities. The College will take all possible steps to avoid or resolve such conflicts, but the primary responsibility for complying with the law lies with the laboratory director.

ABBREVIATIONS used in Checklist:

AABB	AMERICAN ASSOCIATION OF BLOOD BANKS
AEC	ATOMIC ENERGY COMMISSION
BSP	BROMSULPHALEIN
CAP	COLLEGE AMERICAN PATHOLOGISTS
CDC	CENTER FOR DISEASE CONTROL
CLIA	CLINICAL LABORATORY IMPROVEMENT ACT
CSF	CEREBRAL SPINAL FLUID
CV	COEFFICIENT OF VARIATION
JCAH	JOINT COMMISSION ON ACCREDITATION OF HOSPITALS
KOH	POTASSIUM HYDROXIDE
MT(ASCP)	MEDICAL TECHNOLOGIST (AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS)
NBS	NATIONAL BUREAU OF STANDARDS
OR	OPERATING ROOM
OPD	OUT PATIENT DEPARTMENT
PAS	PERIODIC ACID SCHIFF
PT	PROTHROMBIN TIME
PTT	PARTIAL THROMBOPLASTIN TIME
PVA	POLYVINYLALCOHOL
QEP	QUALITY EVALUATION PROGRAM (SURVEY)
RBC	RED BLOOD CELL
SD	STANDARD DEVIATION
WBC	WHITE BLOOD CELL

Extent of services provided by the laboratory:

	PHASE	CIRCLE ONE			
Hematology	0	Yes	No	N/A	1.001
Chemistry	0	Yes	No	N/A	1.002
Urinalysis	0	Yes	No	N/A	1.003
Microbiology	0	Yes	No	N/A	1.004
Blood Bank	0	Yes	No	N/A	1.005
Diagnostic immunology and syphilis serology?	0	Yes	No	N/A	1.006
Nuclear medicine	0	Yes	No	N/A	1.007
Anatomic pathology	0	Yes	No	N/A	1.008
Cytology	0	Yes	No	N/A	1.009

Referred specimens:

Are all referred specimens sent to a laboratory which is either accredited by the College of American Pathologists or licensed under CLIA '67?	II	Yes	No	N/A	1.011
Is the name of the laboratory actually performing the test indicated on the final report?	II	Yes	No	N/A	1.012

Quality Control:

The Quality Control programs should be under constant surveillance by the laboratory supervisor (chief technologist) or by the different section or department supervisors, and should be reviewed at intervals by the laboratory director.

Is there a procedure manual for the quality control program to define policies, procedures, tolerance limits, corrective actions and related information?	II	Yes	No	N/A	1.020
Are the quality control programs organized to permit regular review?	II	Yes	No	N/A	1.021
Is there evidence of periodic review of the quality control programs by the laboratory director?	II	Yes	No	N/A	1.022
Are all procedure manuals reviewed periodically by the laboratory director?	II	Yes	No	N/A	1.023
Are all changes in procedures written, dated, and initialled by the supervisor or laboratory director?	II	Yes	No	N/A	1.024
Are quality control records retained for at least two years?	II	Yes	No	N/A	1.025

Physical Facilities

Allocation and arrangement of space. Is sufficient space provided for the following? Are related facilities conveniently located for optimum communication, work flow, transportation of specimens, supplies and reports?

Offices for:	SUFFICIENT SPACE? PHASE	CIRCLE ONE				CONVENIENTLY LOCATED? PHASE	CIRCLE ONE			
Laboratory director	I	Yes	No	N/A	1.031	I	Yes	No	N/A	1.032
Residents (anatomic)	I	Yes	No	N/A	1.033	I	Yes	No	N/A	1.034
Clerical staff (anatomic)	I	Yes	No	N/A	1.035	I	Yes	No	N/A	1.036
Pathologists (clinical)	I	Yes	No	N/A	1.037	I	Yes	No	N/A	1.038
Residents (clinical)	I	Yes	No	N/A	1.039	I	Yes	No	N/A	1.040
Chief Technologist	I	Yes	No	N/A	1.041	I	Yes	No	N/A	1.042
Section supervisors	I	Yes	No	N/A	1.043	I	Yes	No	N/A	1.044
Patient Service Function:										
Outpatient waiting room	I	Yes	No	N/A	1.051	I	Yes	No	N/A	1.052
Outpatient reception area	I	Yes	No	N/A	1.053	I	Yes	No	N/A	1.054
Area for venipuncture	I	Yes	No	N/A	1.055	I	Yes	No	N/A	1.056
Lavatories (specimen collection)	I	Yes	No	N/A	1.057	I	Yes	No	N/A	1.058
Other functions: (examination, phlebotomy, transfusion, bone marrow)	I	Yes	No	N/A	1.059	I	Yes	No	N/A	1.060
Administrative and Clerical Function:										
Anatomic (autopsy) pathology	I	Yes	No	N/A	1.061	I	Yes	No	N/A	1.062
Surgical pathology	I	Yes	No	N/A	1.063	I	Yes	No	N/A	1.064
Cytology	I	Yes	No	N/A	1.065	I	Yes	No	N/A	1.066
Clinical Laboratory (general)	I	Yes	No	N/A	1.067	I	Yes	No	N/A	1.068
Laboratory Personnel Facilities:										
Library	I	Yes	No	N/A	1.071	I	Yes	No	N/A	1.072
Conference room	I	Yes	No	N/A	1.073	I	Yes	No	N/A	1.074
Personnel lounge	I	Yes	No	N/A	1.075	I	Yes	No	N/A	1.076
Personnel lockers	I	Yes	No	N/A	1.077	I	Yes	No	N/A	1.078

	PHASE	SUFFICIENT SPACE? CIRCLE ONE				PHASE	CONVENIENTLY LOCATED? CIRCLE ONE			
Personnel lavatories	I	Yes	No	N/A	1.079	I	Yes	No	N/A	1.080
Drinking fountains	I	Yes	No	N/A	1.081	I	Yes	No	N/A	1.082

Personnel Policies

Is there a manual outlining personnel policies?	I*	Yes	No	N/A	1.091
Are records maintained on all current employees?	I*	Yes	No	N/A	1.092
Do personnel records include:					
Resume of training and experience?	I*	Yes	No	N/A	1.093
Formal certification or license?	I*	Yes	No	N/A	1.094
References?	I	Yes	No	N/A	1.095
Date of employment?	I	Yes	No	N/A	1.096
Description of duties?	I*	Yes	No	N/A	1.097
Record of continuing education?	I*	Yes	No	N/A	1.098
Record of advancement?	I	Yes	No	N/A	1.099
Health record?	I	Yes	No	N/A	1.201
Microbiology: include chest X-ray	I	Yes	No	N/A	1.202
Nuclear Medicine: include record of radiation exposure	I	Yes	No	N/A	1.203
Periodic evaluation of performance?	I	Yes	No	N/A	1.204
Incident or disciplinary action record?	I	Yes	No	N/A	1.205
Are technologists tested for color blindness?	II	Yes	No	N/A	1.208

*A "NO" answer is a Phase II deficiency for Interstate Laboratories

Communications within the laboratory:

Are telephones conveniently located?	I	Yes	No	N/A	1.211
Can calls be transferred easily?	I	Yes	No	N/A	1.212
Is there an interdepartmental intercom?	I	Yes	No	N/A	1.213
Does the laboratory have a direct outside line for emergency use?	I	Yes	No	N/A	1.214

Inventory and storage of supplies:

Is there an inventory control system to minimize shortages and eliminate emergency requisitions?	I	Yes	No	N/A	1.215

	PHASE	CIRCLE ONE			
Is the main laboratory storage area sufficient?	I	Yes	No	N/A	1.216
Is the storage area well organized and free of clutter?	I	Yes	No	N/A	1.217
Is refrigerated storage adequate?	I	Yes	No	N/A	1.218
Is the refrigerator storage area checked for temperature control?	II	Yes	No	N/A	1.219
Is deep freeze storage adequate?	I	Yes	No	N/A	1.220

Labeling and dating of supplies:

Are all reagents (purchased or prepared), kits, and biologicals dated on receipt?	II	Yes	No	N/A	1.221
Are all reagents (purchased or prepared), kits, and biologicals dated when prepared, opened or when placed in service?	II	Yes	No	N/A	1.222
Are all biological reagents stored properly (refrigerated if necessary) prior to being placed in service?	II	Yes	No	N/A	1.223
Are outdated reagents disposed of?	II	Yes	No	N/A	1.224

Bulk storage of flammables:

Are flammable liquids stored in a safety room with explosion-proof switches and an automatic fire door, or in a fire proof cabinet?	II	Yes	No	N/A	1.231

NOTE: If the total volume of flammable liquid is greater than 5 gallons, a safety cabinet or room must be used. Small quantities may be stored on open shelves.

Are storage areas and/or rooms where volatile solvents are used adequately ventilated?	I	Yes	No	N/A	1.232
Are safety cans used for highly volative liquids?	I	Yes	No	N/A	1.233

Environment:

Is the temperature adequately controlled during all seasons?	I	Yes	No	N/A	1.241
Is the humidity adequately controlled during all seasons?	II	Yes	No	N/A	1.242
Is the noise level acceptable in all areas?	I	Yes	No	N/A	1.243
Are noisy instruments shielded?	I	Yes	No	N/A	1.244

Housekeeping—general:

Are passage ways free of clutter?	I	Yes	No	N/A	1.250
Are floors adequately cleaned and maintained?	I	Yes	No	N/A	1.251

	PHASE	CIRCLE ONE			
Are walls and ceilings clean and well maintained?	I	Yes	No	N/A	**1.252**
Are bench tops and sinks clean and well maintained?	I	Yes	No	N/A	**1.253**
Are bench tops free of unnecessary clutter and trash?	I	Yes	No	N/A	**1.254**
Is broken glass disposed of in a separate container (marked to avoid injury to custodial personnel)?	I	Yes	No	N/A	**1.255**
Are contaminated specimens and materials properly labeled and disposed of?	II	Yes	No	N/A	**1.256**

Glassware washing:

Is the glassware washing area convenient to work areas serviced?	I	Yes	No	N/A	**1.261**
Is sufficient space provided for washing and drying?	I	Yes	No	N/A	**1.262**
Are utilities (water, drains, drying ovens or racks) adequate?	I	Yes	No	N/A	**1.263**
Are there written procedures for handling and cleaning of special glassware (cuvets, micopipets)?	I	Yes	No	N/A	**1.264**
Are contaminated items sterilized or disinfected prior to washing? (glassware from bacteriology)	I	Yes	No	N/A	**1.265**
Inspect recently processed glassware. Are water spots present?	I	Yes	No	N/A	**1.266**
Are items tested for detergent removal (BSP dye, pH paper, other indicator)?	I	Yes	No	N/A	**1.267**
Is the supply of purified water (distilled or deionized) sufficient for rinsing glassware?	I	Yes	No	N/A	**1.268**
Are chipped and scratched items of glassware discarded?	I	Yes	No	N/A	**1.269**

Fire safety—general:

Policies and procedures:

Are procedures and regulations written?	II	Yes	No	N/A	**1.271**
Are procedures and regulations posted or readily available to all personnel?	I	Yes	No	N/A	**1.272**
Are evacuation routes diagramed and posted?	I	Yes	No	N/A	**1.273**
Are all personnel familiar with safety policies and procedures?	I	Yes	No	N/A	**1.274**

Evacuation procedures:

Are fire drills held periodically?	I	Yes	No	N/A	**1.281**

	PHASE	CIRCLE ONE			
Are fire escape routes (fire exits) convenient to the laboratory?	I	Yes	No	N/A	1.282
Do all rooms in which major hazard exists have direct access to the hall or second exit for fast exit?	I	Yes	No	N/A	1.283
Are rooms with major hazards supplied with fire extinguishers and a fire blanket?	I	Yes	No	N/A	1.284
Have all personnel been instructed in the proper use of the fire blanket (i.e., to smother clothing fire AND/OR to use as a protective cover in escaping through an area blocked by fire)?	I	Yes	No	N/A	1.285
Is there a fire alarm station in or near the laboratory?	I	Yes	No	N/A	1.286
Is the fire bell or alarm system audible in the laboratory?	I	Yes	No	N/A	1.287

Fire fighting procedures and protective measures:

Is smoking prohibited in all areas in which volatile solvents are in use?	I	Yes	No	N/A	1.291
Is there a safety shower in each high hazard area (chemistry, histology)?	I	Yes	No	N/A	1.292
Are asbestos gloves available in high hazard areas?	I	Yes	No	N/A	1.293
Is sand or other nonflammable absorbent material available for control of burning liquids in high hazard areas?	I	Yes	No	N/A	1.294
Is there at least one properly placed fire extinguisher in or near each high hazard area?	I	Yes	No	N/A	1.295
Are they of the right type (CO_2 or dry chemical)?	I	Yes	No	N/A	1.296
Have personnel been instructed in the use of extinguishers?	I	Yes	No	N/A	1.297
Have personnel been instructed **not** to use water or soda-acid types of extinguishers on liquid and/or electrical fires?	I	Yes	No	N/A	1.298

Toxic and caustic materials—policies and procedures:

Is an emergency shower convenient to areas where caustic materials are used (reagent preparation, acid cleaning of glassware and other high risk areas)?	I	Yes	No	N/A	1.301

Handling of corrosive and caustic materials:

Have personnel been instructed in the safe handling of corrosive and caustic materials (i.e., handle only one bottle at a time, use of carts or carriers for transporting, use of transfer devices and safety procedures)?	I	Yes	No	N/A	1.302

	PHASE	CIRCLE ONE			
Are mechanical pipetting or transfer devices available for use with caustic and toxic materials?	I	Yes	No	N/A	1.303
Are fountain type eye washers available in areas where caustic materials are used?	I	Yes	No	N/A	1.304
Are safety glasses available and are personnel required to wear them when handling caustic materials (acid cleaning of glassware, reagent preparation, auto analyzers pumping acids under pressure)?	I	Yes	No	N/A	1.305
Are acid bottle carriers used for all large containers (over 500 ml)?	I	Yes	No	N/A	1.306
Are all containers of corrosives, acids, and caustic materials properly labeled with a warning as to the toxic content?	I	Yes	No	N/A	1.307

PURITY OF WATER

Method of purification:

Distillation?	0	Yes	No	N/A	1.311
Deionization?	0	Yes	No	N/A	1.312
Deionization and ultrafiltration?	0	Yes	No	N/A	1.313
Other?	0	Yes	No	N/A	1.314

Purity checks:

Is a system in use for checking purity of water?	II	Yes	No	N/A	1.315
Are procedures written?	II	Yes	No	N/A	1.316
Are records of checks maintained?	II	Yes	No	N/A	1.317
Is the resistance greater than 0.1 meg-ohms (100,000 ohms) or conductance less than 4 ppm expressed as NaCl?	I	Yes	No	N/A	1.321
Is the pH between 6.0 and 7.0?	I	Yes	No	N/A	1.322
Are tests for "total hardness" negative?	I	Yes	No	N/A	1.323
Is sodium less than 0.1 mg/L?	I	Yes	No	N/A	1.324
Is ammonia less than 0.1 mg/L (0.2 ppm)?	I	Yes	No	N/A	1.325
Are cultures and colony counts negative (or show minimum growth)?	I	Yes	No	N/A	1.326

	PHASE	CIRCLE ONE			
Water usage:					
Is reagent grade water used for preparation of all standards, reagents, and dilutions of samples? (For example, specimens run on flame or atomic absorption spectrophotometers, reconstitution of lypholyzed materials)	II	Yes	No	N/A	**1.331**
Is reagent grade water used for reconstitution of lypholized materials used for standards, controls and surveys?	II	Yes	No	N/A	**1.332**
Specimen collection:					
Is the area clean and well maintained?	I	Yes	No	N/A	**1.341**
Are disposable needles and lancets used?	I	Yes	No	N/A	**1.342**
Are disposable needles destroyed and disposed of in a safe manner (separate container, adequately marked to avoid injury to custodial personnel)?	I	Yes	No	N/A	**1.343**
Are syringes and needles stored (and disposed of) in such a manner to be reasonably inaccessible to unauthorized persons?	I	Yes	No	N/A	1.344
Specimen collection procedures:					
Is there a procedure manual for the proper collection and handling of specimens?	II	Yes	No	N/A	**1.345**
Does it include pertinent information when necessary regarding:					
Preparation of the patient?	I	Yes	No	N/A	**1.346**
Type of specimen to be collected?	I	Yes	No	N/A	**1.347**
Need for special timing for collection of specimens?	I	Yes	No	N/A	**1.348**
Need for preservative or anticoagulant?	I	Yes	No	N/A	**1.349**
Need for special handling between time of collection and time received by the laboratory (i.e., refrigeration, immediate delivery)?	I	Yes	No	N/A	**1.350**
Instructions for proper labeling?	I	Yes	No	N/A	1.351
Need for clinical data (age, sex, type of test, diagnosis)?	I	Yes	No	N/A	**1.352**
Distribution of specimen collection manual:					
Hospital laboratories: Is the specimen collection manual distributed to all nursing stations (floors, OR, OPD) and other locations where specimens are collected?	II*	Yes	No	N/A	**1.353**

	PHASE	CIRCLE ONE			
Non-hospital laboratories: Are instructions for the proper preparation of patients and collection of specimens supplied to all specimen collection areas and physician clients?	II*	Yes	No	N/A	1.354

*One must be answered "yes" or it is a Phase II deficiency.

Specimen receipt procedures:

	PHASE	CIRCLE ONE			
Are all specimens received by the department recorded in an accession book, day book, worksheet, computer, or other comparable record?	II	Yes	No	N/A	1.361
Are unlabeled or improperly labeled specimens rejected?	II	Yes	No	N/A	1.362
Are specimens from patients with known or suspected hepatitis labeled accordingly?	I	Yes	No	N/A	1.363
Are specimens containing radioactive materials labeled accordingly?	I	Yes	No	N/A	1.364
Are all specimens accompanied by an adequate requisition?	II	Yes	No	N/A	1.365

Does the requisition form include:

Name of patient?	II	Yes	No	N/A	1.371
Identifying number (hospital or laboratory number)?	II	Yes	No	N/A	1.372
Name of physician or person ordering test?	II	Yes	No	N/A	1.373
Type of test to be performed?	II	Yes	No	N/A	1.374
Time and date of specimen collection?	II	Yes	No	N/A	1.375
Time and date of receipt by the laboratory?	I	Yes	No	N/A	1.376
Are there written criteria for rejection of unacceptable specimens?	II	Yes	No	N/A	1.381

Reports of results of laboratory tests:

Is the report form adequate in regard to design, space and information?	II	Yes	No	N/A	1.391

Does the report form include:

Name of patient?	II	Yes	No	N/A	1.392
Identifying number (hospital or laboratory)?	II	Yes	No	N/A	1.393
Name of physician ordering the test?	II	Yes	No	N/A	1.394
Name of test to be performed?	II	Yes	No	N/A	1.395

	PHASE	CIRCLE ONE			
Date or time of collection of specimen?	I	Yes	No	N/A	**1.396**
Date and time of release of report?	I	Yes	No	N/A	**1.397**
Normal values, indicated when necessary?	I	Yes	No	N/A	**1.398**
Are results legible?	II	Yes	No	N/A	**1.401**
Are results reviewed for clerical errors and authenticated prior to release from the laboratory?	II	Yes	No	N/A	**1.402**
Are duplicate copies of reports retained by the laboratory and filed in a manner to permit easy retrieval of information if necessary?	II	Yes	No	N/A	**1.403**