FINAL REPORT
of the
COMMITTEE ON NATIONAL ACCREDITATION OF ENVIRONMENTAL LABORATORIES

September 1992

EXECUTIVE SUMMARY

In July 1991, the Committee on National Accreditation of Environmental Laboratories (CNAEL) was chartered at the request of EPA Deputy Administrator F. Henry Habicht II, and held the first of four meetings. The CNAEL was charged with determining the need and advisability of a national environmental laboratory accreditation program, alternatives to such a program, and the role of EPA in any program. CNAEL is composed of members from the laboratory and regulated industry communities, academia, other federal agencies, the states, public environmental interest groups, and private accrediting bodies.

CNAEL identified and prioritized numerous issues which were of concern to each of the affected parties and reached agreement on an overall problem statement: to achieve data o needed quality in a cost effective manner. Fifteen alternative solutions were proposed and evaluated in relation to the problem statement. Multiple options for operation of program were identified and ranked. In addition, the scope of a program was defined in terms of environmental regulations, which laboratories should be included, and which activities/tests should be included. Finally, CNAEL identified the elements of a national environmental laboratory accreditation program for purposes of clarity. At the conclusions of its deliberations CNAEL made a primary and secondary recommendation for the technical alternatives and one implementation plan as follows:

1. A national program for accreditation of environmental laboratories, which includes the key elements of on-site audits, performance evaluation testing, and data audits.

2. A program of performance evaluation testing combined with a laboratory process and quality assurance certification program, which would include on-site audits.

3. The implementation plan for either of these programs would enlist the states and/or third parties to perform the accrediting function with oversight of the accrediting bodies by a federal agency or interagency group.

The conclusions and recommendations of CNAEL were presented to Deputy Administrator Habicht on August 14, 1992 and to the Environmental Monitoring Management Council on October 6, 1992.

INTRODUCTION AND BACKGROUND

The Committee on National Accreditation of Environmental Laboratories is an outgrowth of the Environmental Monitoring Management Council (EMMC). EMMC was chartered by EPA Deputy Administrator F. Henry Habicht II in February of 1990 to develop and recommend policy on matters related to environmental monitoring. Among the issues which were examined was the feasibility and advisability of a national environmental laboratory accreditation program. EMMC consists of senior management officials representing all EPA programs. Under their direction, an Ad Hoc Panel was established to investigate the feasibility and advisability of a laboratory accreditation program.

The first interim report of the Ad Hoc Panel summarizes its findings and recommendations. The Panel identified numerous benefits of a national program, including benefits to the states, the laboratory

community, and the regulated community. In particular, a national program that achieves reciprocity among state certification programs would eliminate the duplication that currently exists among public and private programs. The EMMC concluded that CNAEL was needed in order to achieve full participation by all affected interests in characterizing the needs of the user community and examining a preliminary program design.

EPA's charge to CNAEL, was: 1) to determine if there was a need for an environmental laboratory accreditation program and what advantages would be derived from establishing a program; 2) to identify options for operating a national program; 3) to identify other alternatives to a national program which would address the needs of the affected groups; and 4) to recommend an appropriate role for EPA in developing or implementing any program. Each group represented on CNAEL presented their perspectives which included descriptions of the various accreditation (or evaluation) programs currently operated by the states, federal agencies, industry, and private accrediting bodies.

Initial Perspectives

Many federal agencies are both generators and users of environmental monitoring data. For example, the Department of Defense is prepared to operate without a national program but believes that the work could be accomplished more efficiently and at lower cost to the government if a national program were established.

Industry favors the establishment of a national program because of the lack of readily available information and current accreditation programs, the increased costs which are passed on to the consumers, and the disappointments industry has experienced with some of the existing programs.

The laboratory community also supports national accreditation for the benefits which might accrue to the laboratory under such a system: fewer but more comprehensive audits, fewer redundant performance evaluation samples, upgrading of quality assurance programs in all laboratories providing a level playing field in the economic are and nationwide recognition of performance capabilities.

The private laboratory accreditors prefer a national program which is consistent among all states and private parties because there are major differences in the thoroughness of existing programs. As a result private industry or other laboratory users are forced to conduct their own evaluations. The limited scope of existing programs further exacerbates this problem. A uniform national program should also ensure that U.S. laboratories are accepted throughout the world.

States originally began establishing independent accreditation programs because there was no other source. One reason for the inconsistencies among states programs is, in part, that n guidance existed at the time most of the programs were established. The cooperation of the states is needed to assure a successful national program.

PROCESS FOR SELECTING AND EVALUATING ALTERNATIVES AND OPTIONS

CNAEL established four subcommittees to accomplish the following: 1) examine the existing problem and to assess the needs of all parties, 2) identify and evaluate potential alternatives to a national accreditation program, 3) define the elements of a national accreditation program, and 4) identify the full range of environmental media, types of testing, and environmental statues that should be accounted for by any program.

The first subcommittee outlined the needs, taking into consideration work already conducted by EPA and other groups. The needs assessment consisted of a review of the existing literature and as analysis of

comments and information provided by CNAEL members and the public. Based on this work CNAEL established a set of criteria for evaluating the alternatives using a Total Quality Management approach to reaching a consensus. In a brainstorming session, the needs of the various groups were defined, consolidated, and prioritized into a comprehensive list of goals. CNAEL distilled the defined needs in a problem statement that encompassed the large majority of the needs: To obtain data of needed quality in a cost effective manner.

A second subcommittee identified and evaluated potential alternatives to national laboratory accreditation, including certification of analysts, bonding/insuring laboratories, certification of laboratory products, establishment of reciprocity agreements among existing state programs, maintaining the status quo, among others. A list of fifteen alternatives was generated. CNAEL used the aforementioned list of goals for purposes of evaluating how each of the alternatives considered, eliminated, or addressed the goals. In addition, the states represented on CNAEL presented a summary of the principles they believed were critical in state acceptance of a national accreditation program.

Some of the alternatives were combined with one another in order to obtain the most advantageous solution. Using a multi-voting technique, the number of alternatives was reduced to four. CNAEL divided into four groups to develop the advantages and disadvantages for these remaining alternatives.

A third subcommittee defined the elements of a national accreditation program which were based on existing programs and guidelines. CNAEL accepted, with minor modifications, the elements of a program outlined by the International Standards Organization (ISO) Guides on accreditation.

A small fourth subcommittee defined the scope of a program in terms of the types of laboratories, methods/tests, and the environmental programs. The subcommittee used Federal environmental statutes as a starting point for defining the purpose of accreditation. Accommodations for technological advances or changes in measurement technology were considered to be pivotal in establishing a system which would be flexible enough to serve parties. Agreement was reached that a national program should be applicable to laboratories performing tests related to Federal environmental statutes, including public, private, and academic laboratories.

CNAEL identified seven different options for administering a program. These ranged from a completely centralized federal program to one owned and operated by the private sector with no federal or state participation. Presentations on current systems of operation were provided by the American Association of Laboratory Accreditation (a private accrediting body), the California state program and the National Institutes of Standards and Technology programs for Weights and Measures and the Fastener Quality Act. A subcommittee narrowed the list to three options taking into consideration governmental resource constraints and the goal of achieving state reciprocity.

CNAEL developed a questionnaire on costs for the laboratories undergoing accreditation/evaluation and for the accrediting bodies, i.e., states, private companies, and the regulated industry. Upon completion of these surveys by the CNAEL members and their constituents, the data was analyzed by an EPA economist. Results were discussed with CNAEL members, and a few modifications were made based on comments from members.

CNAEL invited speakers to present their perspectives and experience in laboratory accreditation. The EPA National Enforcement Investigations Center discussed its viewpoint, the EPA Office of Air Quality Planning and Standards made a presentation on the work it had done on accreditation, and the EPA Office of Wastewater Enforcement and Compliance discussed its perspective of a national program. CNAEL also heard from a laboratory which is regulated under the Clinical Laboratory Improvement Act of the National Health Care Finance Administration program for accreditation of clinical laboratories.

Comments were also solicited from the general public and many written comments were received as well as oral comments during each of CNAEL meetings.

The members of CNAEL representing the states presented a statement to the Committee on their views of a national laboratory accreditation program. This position paper supported laboratory accreditation and specified the administrative option which would be acceptable to them. In their opinion this position would be adopted by the large majority of all states.

The top alternatives and administrative options were then evaluated by CNAEL. Again a multi-voting technique each member of CNAEL voted for their top two choices.

EVALUATION ALTERNATIVES

The fifteen alternatives identified by CNAEL in the order of preference (after evaluation against the goals described below) were:

- National Laboratory Accreditation
- Performance Evaluation Testing
- Federal Pre-emption
- Laboratory Process Certification
- Quality Assurance Systems Certification
- National Guidelines
- Reciprocity
- Resident Inspectors
- Training
- Analyst Certification
- Product Certification
- Fraud Audits
- Laboratory Manager Certification
- Performance Bonds
- Status Quo

These alternatives were evaluated against the goals which were developed and prioritized in relation to overall need of obtaining data of needed quality in a cost effective manner. The goals were as follows:

- Facilitate reciprocity
- Standardize sampling, analytical methods and quality control
- Provide an objective evaluation of laboratory performance in various sample matrices, including provision of materials
- Establish a comprehensive and flexible program
- Eliminate redundancy and inconsistency in the current system
- Promote communication between user and provider
- Identify and prosecute fraud quickly and justly
- Allow for improved/new techniques in a timely manner
- Establish a program which is practical in all aspects
- Establish uniform inspections/audits
- Produce data of known, legally defensible quality
- Require uniform standards for analysts
- Assist data users to select laboratories
- Assist laboratories in identifying and correcting problems
- Provide timely technology transfer on methods and quality control requirements

The first seven goals received a larger number of votes than the others and, therefore, were double weighted in the evaluation of the alternatives.

A subset of the alternatives was agreed upon to be carried forward in the analysis. These were selected because CNAEL members agreed that each can stand alone as a viable alternate e. Members noted that training should be a part of any program, and should be considered as an essential element. Members also noted that many of the alternatives were components of others and that several could be combined to create separate and viable alternatives. Federal pre-emption was eliminated as an alternative because it was of a practical solution in the light of states rights. National guidelines was considered the context of an administrative option, rather than as both an administrative option and a program alternative. CNAEL then identified ten combinations t would serve as more complete and practical solutions. Three of the combined alternatives were selected over the individual solutions. The subset of selected alternatives was as follows:

- National Environmental Laboratory Accreditation
- Performance Testing + QA Systems Certification + Lab Process Certification + National Guidelines
- Performance Testing + QA Systems Certification + Lab Process Certification
- Performance Testing + QA Systems Certification + Product Certification

In a later analysis the alternative which includes national guidelines was considered in the context of an administrative option, rather than as both an administrative option and a program alternative. A cost analysis was conducted on the remaining three alternatives. For the purposes of characterizing the technical aspects of the alternatives, agreed that the alternatives as listed above are in order of decreasing stringency. For the cost analysis, Performance Testing + QA Systems Certification + Lab Process Certification should be assumed to include an on-site audit; Performance Testing + QA Systems Certification + Product Certification should not be considered to involve an on-site audit. CNAEL considered that, for purposes of the cost analysis, the first two alternatives should be treated as equivalent because the technical differences are to substantial enough to be detected by the cost analysis.

In addition CNAEL narrowed the list of administrative options to be considered in the economic analysis to:

- Oversight by the federal government with non-federal implementation;
- Federal guidelines; and
- Administration by a private sector organization with federal and state government cooperation.

In making its selections, the subcommittee concluded that federal operation would be infeasible (largely due to resource constraints); that achieving state reciprocity without federal intervention is difficult but achievable (currently New Jersey, New York and California are working cooperatively); and that, although a program operated entirely by the private sector without federal or state government participation is possible, such a program is not likely to be accepted by the majority of states and, therefore, would do little to change the status quo. The status quo was deemed to be unsuitable due to its inherent problems. CNAEL agreed to the following refinements to two of the three administrative options:

- The option for federal guidelines should be assumed to involve some Federal oversight for implementation of the guidelines, and
- The option for federal government oversight with non-federal implementation should be assumed to include the possibility of delegating the oversight authority to a private sector accrediting organization. State representatives on CNAEL expressed concern of oversight of states programs by a non-federal organization.

- The option for federal government oversight with non-federal implementation should be assumed include the possibility of the states delegating the accrediting function to a private sector accrediting organization.

COST ANALYSIS

A program of national laboratory accreditation may result in significant cost changes for both environmental laboratories and the accrediting bodies that currently administer environmental laboratory certification programs. This analysis explores the potential effects of national laboratory accreditation. It is based upon survey data about accreditation co is from individual environmental laboratories and accrediting bodies, as well as other sources in the published literature, and insights provided by laboratory operators. Based on the data provided all estimates were made with the following confines: only private commercial laboratories were considered, and only analyses of drinking water, waste water, and hazardous waste were included.

Under the current system, environmental laboratories operating in a particular media in more one state are required to be accredited in the same media by multiple jurisdictions, often with different analytical requirements. Each state or federal program establishes their own set of requirements for certification, which in some cases force individual laboratories to repeat analytical exercises. Even in instances where the laboratories are owed to use the analytical element of another certification program to fulfill their analytical requirements, the costs of paperwork and application to an additional program are often substantial. Finally, many environmental laboratories are currently subject to private review of their analytical skills by companies that conduct business with these laboratories, which would be unnecessary under a consistent and well-monitored national accreditation program. Permit applicants and defendants in environmental law suits may continue to verify the ability of a given laboratory to deliver accurate analyses.

A national accreditation program would require each laboratory to fulfill the analytical requirements for each media only once, thereby reducing the costs of accreditation for those laboratories currently maintaining multiple accreditations by media. Laboratories who are currently accredited by only one location would become free to pursue clients in other jurisdictions. The analytical requirements for national accreditation would likely be more stringent than the current analytical requirements of most accrediting bodies. In particular, the frequency of on-site audits would be increased to one a year, and each audit would require more staff from the accrediting body.

Currently, the accreditation system for drinking water, waste water, and hazardous waste is estimated to cost the accrediting bodies between $4 million and $7 million per year. An additional $2 million per year is spent by non-accrediting bodies to test the proficiency of environmental laboratories. Laboratories themselves must pay between $11 and $19 million for on-site audit costs, and analytical testing. The total cost of the present system of laboratory accreditation is between $17 to $28 million each year.

Under national laboratory accreditation, the cost to those environmental laboratories who participate in hazardous waste, waste water, or drinking water certification programs is estimated at between $6 million and $7 million, for performance evaluation testing, paperwork, and on-site audits. Since national accreditation will be self-funding, the program will also charge a significant administrative fee, which is estimated to be between $5 million and $7 million.

An additional cost of any form of national laboratory accreditation program will be a standard setting conference, estimated to be $500,000 annually. One option may be an annual conference, modeled after the National Conference on Weights and Measures sponsored by the National Institutes of Standards and Technology. Other options may include an expansion and extension of the CNAEL (or similar

committees) or some other neutral consensus forum. A decentralized system will require some sort of a national oversight organization, estimated to require 25 FTE's and $100,000 of budget used mostly for travel. The annual cost of this oversight board is estimated at $2 million per year. The projected total costs for a national program are between $13.5 million and $15.5 million.

It is important to note that the changes in cost to laboratories will not be uniform over the entire laboratory industry. Our projections indicate that the large laboratories who are currently accredited by multiple accrediting bodies are most likely to see a significant reduction in their total costs of accreditation, despite the increased analytical requirements of a program. Smaller laboratories, who are currently only accredited by one accreditation body, will face more testing requirements than they currently do. Therefore, accreditation costs will not decrease as sharply and may actually rise for these small laboratories. The impact on smaller laboratories can be reduced by a properly structured program such as a tiered approach based on types of analyses, media, and/or volume of business.

A national accreditation program may take one of the two following forms: a centralized organization that accredits all environmental laboratories, or a decentralized national system where each state will be responsible for accrediting the environmental laboratories based in its state according to national standards, and any accredited laboratory can conduct business in any state. The cost of administering national accreditation with a centralized organization is estimated at roughly $7 million per year, which can be passed on the laboratories in the form of accreditation fees. It is important to note that this cost estimate for a centralized program does not include the start-up costs associated with establishing a national program, which may be quite high.

The difference in the costs between a centralized national laboratory accreditation program and a centralized national laboratory accreditation program is determined by the higher efficiency of regional accreditation bodies compared to a national accreditation program. At the present time, we are unable to project how costs might change under a decentralized system. However, a decentralized system will require some kind of national oversight organization.

In conclusion, the total cost of accreditation of environmental laboratories is likely to be reduced under a national system. The costs faced by an individual laboratory will depend on the number of accreditations that a laboratory has and the amount of the accreditation costs that are passed on to the laboratory. Under a centralized system, a new organization must be put into place, while under a decentralized system, current accreditors must adjust accreditation norms to national standards.

CONCLUSIONS AND RECOMMENDATIONS

A uniform set of criteria developed to evaluate the various alternatives highlighted the fact that an effective solution must contain the following:

- simplify the current system of multiple laboratory accreditation programs by:
    - promoting reciprocity and leveling the differences between the various state programs;
    - promoting uniform standards for all aspects of laboratory performance;
    - ensuring consistent laboratory audits; and
    - ensuring uniform national performance evaluation testing,
- minimize negative effects on the operation of existing state laboratory accreditation programs,
- provide reliable, uniform information concerning laboratory performance to data users, and
- require minimal outlay of federal or state funds and operate through a self-supporting mechanism.

The cost analysis pointed out the high cost of the current system. Any alternative which does not replace the current system will only lead to additional expense. The adoption of a national uniform system with significant reciprocity is critical to reducing the expenses to both the laboratories and the accrediting bodies. There is no discernible difference in the costs for the final two alternatives. The second option provides more flexibility to the laboratory in the area of personnel, reporting, record keeping, and health and safety.

Consequently, CNAEL agreed to recommend, as a first option, the establishment of a national environmental laboratory accreditation program that has federal oversight and is implemented by the states and/or third parties. The second recommended option is a program of Performance Evaluation Testing, Quality Assurance System Certification, and Laboratory Process Certification which would be implemented in an identical fashion.