

Statement at the Public Meeting  
Concerning the NIOSH Testing and Certification  
Programs (July 28-30, 1980)

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Good morning, ladies and gentlemen. My name is John W. Locke. I am the Coordinator of the U.S. Commerce Department's National Voluntary Laboratory Accreditation Program - the letters of the acronym being spelled "N", "V", "L", "A", "P", and pronounced "nav-lap."

My purpose for coming here today is to acquaint NIOSH with the services available under NVLAP, should NIOSH decide to pursue the third alternative for the respirator testing and certification program as described in the June 18th notice of this meeting; I quote:

"Implement a program whereby NIOSH would certify, alone or jointly, private laboratories for the actual testing and certification of respirators using performance standards specified by NIOSH."

We noted in the consultant's report entitled "Evaluation of the NIOSH Certification Program," dated November 21, 1979 that NVLAP was mentioned as a possible alternative to explore "...in the event the certification program is expanded to include outside labs." The consultants cited Title 15, Part 7a of the Code of Federal Regulations. Part 7a covers NVLAP's general procedures. However, NVLAP also has optional procedures covered by Title 15, Part 7b and Part 7c. The optional Part 7b procedures, which were published on March 9, 1979, are for use by Federal agencies in requesting a laboratory accreditation program under NVLAP. These Part 7b procedures could be of particular interest to NIOSH.

But, before I discuss how the Part 7b procedures work, I'd like to share with you some of the background and philosophy under which the Department of Commerce operates NVLAP. Hopefully, this will answer some of your questions.

We define laboratory accreditation as a formal recognition that a testing laboratory is competent to carry out specific tests or specific types of tests. This definition essentially conforms with the ASTM definition and the International Standards Organization definition. It does not include the development and promulgation of test methods or standards. NVLAP procedures specifically prohibit the development or modification of product standards or test method standards.

Laboratory accreditation also does not include the act of certifying that a product meets a standard. We define certification as the process of assuring that a product meets quality, performance, or safety requirements. Defined in this way, certification inherently includes three distinct functions:

- 1) Developing and promulgating product standards and test methods which specify what requirements are to be met and how the products are to be tested;
- 2) Testing the product, using the appropriate test methods, to determine if the product tested does, in fact, meet all of the conditions stipulated in the standards; and
- 3) Certification processing (often simply called certification) which defines how many products in a group of products must be tested to reach the desired level of assurance that each product meets the desired characteristics of quality, performance, or safety.

Certification processing may provide the degree of assurance desired either by using a statistical selection from the group of products to be tested or by making use of the manufacturers' quality control system which typically includes such statistical selection procedures in evaluating the components and materials from which the product is made. Certification processing often includes provisions for recordkeeping and product labeling.

Laboratory accreditation addresses only - the testing of the product. Laboratory accreditation systems have been developed because significant sections of the community of commerce, as well as government, have an interest in ensuring that laboratory test results can be relied upon and are obtained in an efficient manner.

It is for this reason that NVLAP was established by the Department of Commerce. The major purpose of NVLAP is to provide the nation with a source of nationally recognized, competent testing laboratories. Among the objectives of NVLAP are:

- o To initiate new accreditation programs as needed;
- o To provide an accreditation procedure which others can use in lieu of developing new systems; and
- o To reduce the number and frequency with which different agencies and groups evaluate the same laboratory by coordinating accreditation activities.

NVLAP was formally established with the publication of the general procedures in February, 1976 - the same Part 7a procedures I mentioned earlier. These Part 7a procedures are lengthy and somewhat cumbersome. From experience, we've found that it takes about two years to establish a program under the Part 7a procedures. This was true for our first program covering thermal insulation materials test methods and our second program covering concrete test methods. That's primarily why two sets of optional procedures (Part 7b and Part 7c) were established in 1979. The optional procedures substantially reduce the time it takes to establish a laboratory accreditation program.

In order to start a program using the general Part 7a procedures, a written, formal request, that can be submitted by anyone, must be made to the Secretary of Commerce to establish a program for a specific product or testing area. The request must include identification of the specific standards and test methods to be included in the program. There can be no program without a well established, valid set of test methods.

The requestor must describe the need for a program by first, estimating the number of laboratories that may want to become accredited and second, estimating the number of users of testing laboratories which may desire services of accredited laboratories. Once the market is defined, four questions must be answered:

- 1) Why would NVLAP accreditation of laboratories benefit the public;
- 2) What is the national need for laboratory accreditation that is not now served by existing programs;

- 3) Is it feasible and practical to accredit laboratories under NVLAP; and
- 4) Why should the Federal government be involved?

If these questions are answered satisfactorily, a preliminary finding of need is published in the Federal Register. After the 60-day public comment period, the Department decides, based upon the comments, whether to make a final finding of need - thus establishing the program - or to withdraw the preliminary finding of need.

Under the optional Part 7b procedures for use by Federal agencies, any agency may make a request for a program. No separate finding of need is made by the Department of Commerce since it is the requesting agency's legislative or regulatory prerogative to determine the need. The Department of Housing and Urban Development is the first agency to make use of this option. In May 1979, HUD requested that NVLAP accredit laboratories that conduct tests as part of the HUD certification program for carpet. The availability of the carpet program was announced in January of this year. The application deadline was this May. We are currently assessing the applicant laboratories and plan to announce accreditation determinations by October of this year. Based on this experience, we believe that it should not take more than one year after a request from a Federal agency is received to begin accrediting laboratories.

The qualifications and requirements that a laboratory must meet in order to become accredited are called criteria. Under the general Part 7a procedures, criteria are developed through recommendations of an advisory committee composed of equal numbers of private and government interests. We have committees for the insulation program and the concrete program, both of which have recommended criteria. The final criteria for these programs were also published in January of this year.

Under the optional Part 7b procedures, the requesting Federal agency has the option of recommending criteria or requesting that an advisory committee be formed to develop recommendations. HUD chose to recommend criteria for the carpet program.

Based on the recommendations received, the Department of Commerce proposes criteria for evaluating the laboratories in the Federal Register for public comment. After the comments are resolved, final criteria are published in the Federal Register. Once a program is established and criteria are published, any laboratory whether it be private or public, independent or in-house, domestic or foreign, may seek accreditation.

Fees paid by the applicant laboratories are tailored to each accreditation request. The fees depend upon the number and type of test methods for which accreditation is sought as well as the number of programs applied for. Significant discounts are incorporated into the fee formula for those laboratories applying under more than one program.

The National Bureau of Standards is responsible for the evaluation of applicant laboratories. NBS draws on in-house expertise and hires technical experts to conduct evaluations.

An evaluation is based upon three inputs:

- 1) The information provided as part of the application package;
- 2) An on-site examination of the laboratory; and
- 3) The results of any proficiency testing that may be required for some of the test methods.

NBS recommends the granting or denying of accreditation to the Department of Commerce which makes the accreditation decision. Deficiencies uncovered are fed back to the laboratory and ample time is provided for corrective action before NBS recommends any denials. Nevertheless, if the Department proposes to deny accreditation, the laboratory may appeal through formal administrative procedures. Accreditation decisions are published in the Federal Register.

A review of each laboratory's accredited status is made annually based on periodic on-site examinations and proficiency test results. The frequency of on-site visits is from one to two and one-half years depending on the particular needs of each program. Proficiency testing is typically scheduled about every six months, however, this may vary depending upon the type and complexity of the test methods and the nature of the product.

Accreditation criteria currently used by NVLAP are broken into two categories, which we call general criteria and specific criteria. The general criteria focus on the overall laboratory operation and address:

- o Organization structure, management and technical direction;
- o Professional and ethical business practices; and
- o the laboratory's quality control system.

The specific criteria are stated in fairly universal terms and derive their name from the fact that they apply specifically to each test method for which accreditation is sought.

The specific criteria address:

- o Personnel competence, training, and qualifications;
- o Equipment, facilities, and procedures including calibration, maintenance, test plans, etc., and
- o Recordkeeping including new data, test reports, audits, specimen handling, document availability, etc.

The specific criteria are tailored to each test method by, what we call, "supplemental information." The supplemental information indicates how the specific criteria are to be interpreted and implemented for each test method or groups of test methods.

I believe I've spoken enough about NVLAP. Further details about our program are covered in the documents I am submitting in conjunction with my comments today. These documents include NVLAP annual reports for 1978, 1979 and 1980, the Part 7a and Part 7b procedures, as well as the criteria and fees for accrediting laboratories under the insulation, concrete, and carpet programs. Hopefully, I've indicated in general terms how NIOSH could utilize NVLAP and design its certification program to include the use of NVLAP accredited laboratories. Let me make it clear we are not expert in the problems of respirators and we are not suggesting that the implementation of alternative three, using NVLAP, is the proper course to choose - that is for NIOSH to decide. However, we do know something about laboratory accreditation and product certification. We willingly offer our services under NVLAP if NIOSH deems it appropriate.

At this point, I'll be happy to answer any questions you may have.