



DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

15 CFR Part 285

Docket No: [110125063-1687-02]

RIN 0693-AB61

National Voluntary Laboratory Accreditation Program; Operating Procedures

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Final Rule.

SUMMARY: The Director of the National Institute of Standards and Technology (NIST), United States Department of Commerce, is issuing a final rule amending the regulations pertaining to the National Voluntary Laboratory Accreditation Program (NVLAP).

Regulations concerning the establishment of laboratory accreditation programs (LAPs)

within NVLAP are being amended to clarify the original intent of this section and to improve the readability and understanding of the agency's regulations.

DATES: This rule is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: David F. Alderman, Acting Chief, National Voluntary Laboratory Accreditation Program, National Institute of Standards and Technology, 100 Bureau Drive, Stop 2140, Gaithersburg, MD 20899-2140.

FOR FURTHER INFORMATION CONTACT: David F. Alderman, Acting Chief, National Voluntary Laboratory Accreditation Program, National Institute of Standards and Technology, 100 Bureau Drive, Stop 2140, Gaithersburg, MD 20899-2140; telephone number: (301) 975-4019; e-mail address: david.alderman@nist.gov; NVLAP website: [www.nist.gov/nvlap](http://www.nist.gov/nvlap).

SUPPLEMENTARY INFORMATION:

### Background

Title 15 Part 285 of the Code of Federal Regulations sets out procedures and general requirements under which the National Voluntary Laboratory Accreditation Program (NVLAP) operates as an unbiased third party to accredit both testing and calibration

laboratories. NVLAP establishes laboratory accreditation programs (LAPs) in response to legislation or requests from government agencies and private sector entities.

The NVLAP procedures were first published in the Federal Register on February 25, 1976, and have been revised several times. In 2001, major revisions to the procedures were published to ensure their consistency with certain international standards and guidance documents, and to reorganize and simplify Part 285 for ease of use and understanding. While the existing regulations were accurate, the language was complex and difficult to understand; therefore, the procedures were rewritten in plain English and their subparts consolidated in order to make the regulations more user friendly.

#### Description and Explanation of Change

The purpose of this rule is to amend section 285.4, *Establishment of laboratory accreditation programs (LAPs) within NVLAP*, so that it conforms to the intent of the 2001 revisions to Part 285 of Title 15 of the CFR and makes the regulations easier to understand. NIST is amending the last sentence in section 285.4 as follows: change the third instance of the word “and” to “or,” and add the words “to ensure open participation” after the phrase “other means.”

As a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), NVLAP complies with the requirements of ISO/IEC 17011, *Conformity assessment – General requirements for accreditation bodies accrediting*

*conformity assessment bodies.* The change will allow NVLAP more flexibility in determining how to best fulfill the requirements for impartiality found in ISO/IEC 17011, 4.3.2, by assuring a balanced representation of interested parties when evaluating the need for a requested LAP.

The original intent of the last sentence of section 285.4 was to allow NVLAP the flexibility to employ the most appropriate means to ensure open participation of stakeholders; however, the use of the word “and” may be misinterpreted to mean that a public workshop is required for each and every LAP request. There are numerous means by which consultation with interested parties may be accomplished exclusive of a workshop, which include, but are not limited to meeting with government and individual industry stakeholders on a frequent basis, attending consortia and conferences at which regulators, specifiers, and requesters are in attendance, and soliciting public comments via public notices, electronic communications, and news articles. Further, the use of the word “or” does not preclude the use of both workshops and other means to collect the necessary information.

#### Summary of Comments

On March 29, 2011, the National Institute of Standards and Technology published a notice of proposed rulemaking and request for comments in the Federal Register (76 FR 17367) pertaining to the proposed amendment to section 285.4 of Part 285 of Title 15 of the CFR. The comment period closed on April 28, 2011. No comments were received and there is no

other reason to believe that any alteration to the proposed rule is necessary; therefore, NIST will implement the rulemaking as proposed.

### Classification

#### *Executive Order 12866*

This rule is not a significant rule for the purposes of Executive Order 12866.

#### *Executive Order 12612*

This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

#### *Regulatory Flexibility Act*

The Chief Counsel for Regulation, Department of Commerce, certified to the Chief Counsel for Advocacy, Small Business Administration, at the proposed rule stage, under the provisions of the Regulatory Flexibility Act (5 U.S.C. 605(b)), that this rule will not have a significant economic impact on a substantial number of small entities for the following reasons: (1) the regulation is procedural and has no impact on any entity unless that entity chooses to participate, in which case, the cost to the participant is the same cost for any size participant; (2) access to NVLAP's accreditation system is not conditional upon the size of a laboratory or membership of any association or group, nor are there undue financial conditions to restrict participation; and (3) the technical criteria, against which individual

laboratories are assessed, are not changed by this rule. No comments were received on this certification; therefore no regulatory flexibility analysis is required and none was prepared.

*Paperwork Reduction Act*

This rule does not involve a new collection of information subject to the Paperwork Reduction Act (PRA). The collection of information for NVLAP has been approved by the Office of Management and Budget (OMB) under control number 0693-0003.

Notwithstanding any other provision of the law, no person is required to comply, nor shall any person be subject to penalty for failure to comply with, a collection of information, subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number.

*National Environmental Policy Act*

This rule will not significantly affect the quality of the human environment. Therefore, an environmental assessment or Environmental Impact Statement is not required to be prepared under the National Environmental Policy Act of 1969.

List of Subjects in 15 CFR Part 285

Accreditation, Business and industry, Calibration, Commerce, Conformity assessment, Laboratories, Measurement standards, Testing.

For the reasons set forth in the preamble, title 15 of the Code of Federal Regulations is amended as follows:

PART 285—NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM

1. The authority citation for 15 CFR Part 285 continues to read as follows:

Authority: 15 U.S.C. 272 *et seq.*

2. Section 285.4 is amended by revising the last sentence to read as follows:

§ 285.4 Establishment of laboratory accreditation programs (LAPs) within NVLAP.

\* \* \* For requests from private sector entities and government agencies, the Chief of NVLAP shall analyze each request, and, after consultation with interested parties through public workshops or other means to ensure open participation, shall establish the requested LAP, if the Chief of NVLAP determines there is need for the requested LAP.

Dated: December 8, 2011

Willie E. May  
Associate Director for Laboratory Programs

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