UNITED STATES DEPARTMENT OF COMMERCE
The Assistant Secretary for Productivity, Technology, and Innovation
Washington, D.C. 20230
(202) 377-~~3111~~ 2054

DOCKET NUMBER
PROPOSED RULE PR-20 (45)
(45 FR 20493)

June 27, 1980

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Secretary:

We are writing in response to a March 28, 1980 Federal Register advance notice of rulemaking to improve the accuracy in personnel dosimetry. This notice announces NRC's intent to develop a "processor certification" program to address the problem of poor performance of personnel dosimetry processors. As we understand it, the contemplated design of this program provides for one or more "testing laboratories" which would certify processors. NRC would require its licensees to use certified processors. Four alternatives are considered for the identification of the testing laboratory or laboratories.

In response, we would like to make you aware of the Department of Commerce's National Voluntary Laboratory Accreditation Program (NVLAP) as another alternative for identifying competent testing laboratories. NVLAP was established in late 1973 as a result of a request by the American Society for Testing and Materials to establish a national, testing laboratory examination service over a broad range of testing fields whenever a need was identified. The original NVLAP procedures were adopted on February 25, 1976 (15 CFR Part 7a). When a need has been identified, NVLAP accredits laboratories for their competence to perform in accordance with nationally recognized standards and test methods. Under NVLAP's optional procedures for Federal agencies (15 CFR Part 7b), a laboratory accreditation program for a particular field (or product area) of testing can be established whereby the requesting Federal agency determines the need for the program and recommends criteria for evaluating the competence of applicant laboratories.

Participation by laboratories in NVLAP is voluntary. Fees are paid by applicants commensurate with the costs of assessment. On-site examinations are scheduled every one to two years depending upon the need and the complexity of the test methods. Proficiency testing is required depending upon the particular needs for assuring competence in the performance of each test method. Published criteria are used for making the accreditation decision.

Enclosed is a reprint of the January 23, 1980 Federal Register notice of NVLAP criteria and fees for accrediting laboratories that test thermal insulation materials, freshly mixed field concrete, or carpet. Also, enclosed for your information are two documents of the International Organization for Standardization (ISO), Guide 2-1980(E), "General Terms and Their Definitions Concerning Standardization and Certification" and "Report from the ISO/STACO Ad Hoc Group on Definitions Required for Laboratory Accreditation Purposes." We suggest that a set of definitions in the preamble of your proposal would avoid possible confusion and misunderstanding of the terms used in your proposed program.

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We believe that the role which you suggest for NBS (i.e., to monitor the technical competence of the "testing laboratory or laboratories") could be performed by NVLAP. However, we are not suggesting that the use of NVLAP is the proper course which NRC should follow. That is for NRC to decide. Rather, we are offering NVLAP as an alternative approach for your consideration.

If you wish more information about NVLAP, please contact us.

Very truly yours,

John W. Locke

John W. Locke
Coordinator, NVLAP
Office of Product Standards Policy

Attachment

Reprinted from Federal Register Volume 45, Number 16
Wednesday, January 23, 1980 (pages 5572-5600)

federal register

Wednesday
January 23, 1980

Part VI

Department of Commerce

Office of the Secretary

Laboratories That Test Thermal Insulation Materials, Freshly Mixed Field Concrete, or Carpet; Accrediting Criteria; Fees

DEPARTMENT OF COMMERCE

Office of the Secretary

National Voluntary Laboratory Accreditation Program; Final Criteria for Accrediting Laboratories That Test Thermal Insulation Materials, Freshly Mixed Field Concrete, or Carpet

AGENCY: Assistant Secretary of Commerce for Science and Technology.

ACTION: Announcing the final general and specific criteria that must be met by laboratories that test thermal insulation materials, freshly mixed field concrete, or carpet in order to be accredited under the National Voluntary Laboratory Accreditation Program

SUMMARY: In conformance to the procedures of the National Voluntary Laboratory Accreditation Program (NVLAP) (15 CFR Part 7a and Part 7b), this notice contains the text of the final general and specific criteria to be used by the Department of Commerce (DOC) in accrediting testing laboratories that voluntarily request accreditation. DOC is offering three laboratory accreditation programs (LAPs) covering test methods for thermal insulation materials, freshly mixed field concrete, and carpet. These final criteria to be used for all three LAPs are based upon criteria proposed in the **Federal Register** on September 28, 1979 (44 FR 56230–56261), and include modifications to the prodposed criteria in response to comments from the public. The evaluation of these public comments and the recommendations of the National Laboratory Accreditation Criteria Committee for Thermal Insulation Materials, the National Laboratory Accreditation Criteria Committee for Freshly Mixed Field Concrete, and the Department of Housing and Urban Development (HUD) submitted to the Assistant Secretary of Commerce for Science and Technology, provided valuable guidance in arriving at the final criteria. These final criteria do not differ from the proposed criteria in any significant way.

DATES: These final criteria shall go into effect on March 7, 1980. Each laboratory which requests an application package by February 29, 1980, and which submits a completed application by April 11, 1980, will be included among the initial group of laboratories to be evaluated for NVLAP accreditation during the current round of accreditation actions. Laboratories that submit completed applications after April 11, 1980, will be included in a subsequent group of laboratories to be evaluated six months to one year later. A form for requesting an application is included in Appendix 4 of this notice.

FOR FURTHER INFORMATION CONTACT: Dr. Howard I. Forman, Deputy Assistant Secretary for Product Standards, Room 3876, Department of Commerce, Washington, D.C. 20230; (202) 377–3221.

SUPPLEMENTARY INFORMATION:

Background

The National Voluntary Laboratory Accrediation Program (NVLAP) was established by notice in the **Federal Register** on February 25, 1976 (41 FR 8163–8168, 15 CFR Part 7 which has been recently redesignated 15 CFR Part 7a). That notice, amended by optional procedures published in the **Federal Register** on March 9, 1979 (44 FR 12982–12990 designated 15 CFR Part 7b), describes the procedures used for developing the three LAPs currently being implemented by this notice as follows:

(1) *Insulation LAP.* The first LAP (NVLAP–01 or the insulation LAP) is for accrediting laboratories that test thermal insulation materials. A final finding of need for this LAP was published on October 12, 1977 (42 FR 55020–55024). Subsequently the National Laboratory Accreditation Criteria Committee for Thermal Insulation Materials (NLACC–01 or the insulation LAP committee) was formed and met on several occasions to develop and recommend general and specific criteria to the Secretary. These recommendations were submitted to the Secretary on August 3, 1978 and formed the basis for proposed criteria on September 29, 1978 (43 FR 45290–45298). Comments received from the public were reviewed by the insulation LAP committee which made recommendations on how to incorporate certain of the comments into the criteria. Final general and specific criteria to be used in evaluating the capability of laboratories to test thermal insulation materials were published on January 18, 1979 (44 FR 3886–3906). In a **Federal Register** notice, October 17, 1979 (44 FR 60052–60054), the Department of Commerce (DOC) announced the accreditation of 30 testing laboratories, effective October 12, 1979.

As a result of experience gained in applying the criteria in the evaluation of these laboratories and because of different recommendations being developed by a second criteria committee (described in a succeeding paragraph), the insulation LAP committee was asked to meet again to consider recommending revised criteria to the Secretary. A report entitled, "Recommendations for Revision One of the Criteria for Accrediting Laboratories Which Test Thermal Insulation Materials" was prepared and submitted to the Secretary on August 9, 1979.

The final criteria published herein replace, as of March 7, 1980, the criteria issued in the **Federal Register** on January 18, 1979, for accrediting laboratories that test thermal insulation materials. However, the accreditation granted to the 30 laboratories in October 1979 will remain in effect until October 11, 1980, when the term of accreditation for each of the 30 laboratories expires.

(2) *Concrete LAP.* Parallel to the foregoing effort on insulation, a second LAP (NVLAP–02 or the concrete LAP) for accrediting laboratories that test freshly mixed field concrete was established with a final finding of need published on December 13, 1978 (43 FR 58223–58226). A second criteria committee, the National Laboratory Accreditation Criteria Committee for Freshly Mixed Field Concrete (NLACC–02 or the concrete LAP committee), was formed and met on four occasions to develop and recommend criteria to the Secretary. These recommendations were submitted to the Secretary on August 2, 1979.

(3) *Carpet LAP.* On May 17, 1979, the Department of Housing and Urban Development (HUD) requested that the Secretary establish a third LAP (NVLAP–03 or the carpet LAP) to accredit laboratories that test carpet according to the requirements set forth in the HUD Use of Materials Bulletin, UM–44c. This request was made on the basis that the LAP be developed using optional NVLAP procedures for use by Federal agencies (15 CFR Part 7b) published in the **Federal Register** on March 9, 1979 (44 FR 12982–12990). In accordance with these optional procedures, HUD has determined the need for such a LAP and, on August 15, 1979, forwarded recommended criteria to the Secretary to be used to accredit laboratories that test carpet.

One Set of Criteria

NVLAP was developed to provide national recognition of the capability of laboratories qualified to perform tests in product areas where such recognition is needed. DOC believes that the criteria used in conferring this national recognition should be identical or as consistent as possible among various product areas for which accreditation is granted. It is generally understood that there are certain fundamental elements relative to facilities, equipment, personnel, and quality control practices that all laboratories should possess. These new criteria reflect the basis of those fundamental elements as they

apply to LAPs for insulation, concrete, and carpet. The consistent criteria for these three LAPs are expected to be applicable to future LAPs in other product areas. The use of consistent criteria will tend to assure that NVLAP accredited laboratories have been uniformly evaluated regardless of the product area. Similarly, laboratories seeking accreditation in more than one area will be less likely to be faced with different and possibly conflicting criteria. From an operational point of view, consistent evaluation criteria, regardless of the number of LAPs or test methods for which a laboratory may seek accreditation, are desirable in order to minimize accreditation costs to the laboratories and the likelihood of confusion in administering the program.

Basis of Final Criteria

The recommendations from the insulation LAP committee, the concrete LAP committee, and HUD formed the basis for the proposed criteria announced on September 28, 1979 in the **Federal Register** (44 FR 56230–56261). On the same day in a separate **Federal Register** notice (44 FR 56262–56263), DOC issued the proposed schedule of fees that laboratories would be charged if they formally apply for accreditation. Information on fees was provided to enable a laboratory to more thoroughly assess the proposed criteria.

Persons desiring to comment on the proposed criteria were invited to submit their comments to the Assistant Secretary of Commerce for Science and Technology on or before November 27, 1979. The written statements submitted during the comment period are part of the public record and are available for inspection and copying in DOC's Central Reference and Records Inspection Facility, Room 5317, Main Commerce Building, 14th Street between Constitution Avenue and E Street, NW., Washington, D.C. 20230.

Persons desiring to present views at an informal hearing were invited to request such a hearing. One request was received and, accordingly, an informal, public hearing was held on November 28, 1979. A transcript of the hearing testimony is also available for inspection and copying in DOC's Central Reference and Records Inspection Facility.

The issues raised by the oral and written comments in response to the notice of proposed criteria were addressed by the insulation LAP committee and the concrete LAP committee in open meetings held on December 18, 1979. The suggestions and ideas of the committee members, including their evaluation and recommendations with respect to these comments, were presented to the Assistant Secretary of Commerce for Science and Technology in the minutes of the meeting dated January 14, 1980, and are likewise available for inspection and copying in DOC's Central Reference and Records Inspection Facility.

Evaluation of Comments

Twelve written comments and one oral comment were received in response to the proposed criteria. These comments have been carefully considered and evaluated, and a report has been prepared entitled, "Summary and Analysis Report of Public Comments Received in Response to Proposed Accrediting Criteria for Laboratories That Test Thermal Insulation Materials, Freshly Mixed Field Concrete, or Carpet." This report and a copy of the comments are part of the public record and are available for inspection and copying in DOC's Central Reference and Records Inspection Facility. Some issues relate directly to the criteria for accrediting laboratories. Other issues relate to the operating or accreditation process of NVLAP, including the content of the appendices of the proposal which is not part of the criteria. Revisions to the appendices may be necessary as the three LAPs are administered. When such revisions are developed, they will be published in the **Federal Register** and made effective immediately upon publication. DOC's consideration of the public comments as well as the recommendations of the insulation LAP and concrete LAP committees and HUD with respect to these comments follows. The comments are discussed below according to the issue addressed or the major section of the criteria to which the comment applied.

(1) *Typographical Errors.* Two significant typographical errors were identified by a number of the commenters. In exhibit 2A the short title for ASTM C173 should have read, "Air Content of Freshly Mixed Concrete by the Volumetric Method." Under the title "Data Analysis Method" section of the between laboratory program of Appendix 2, the standard deviation formula under step (5) was incorrect and has been corrected.

(2) *The Need For These Laboratory Accreditations Programs (LAPs). One commenter supported the need for a LAP for concrete testing laboratories but believed that criteria as set forth are so complex and costly that few testing laboratories would try to become accredited. Another commenter expressed concern about the additional paperwork and costs which would affect the HUD carpet certification program, possibly causing some manufacturers, particularly small businesses, to drop out of the program. Concern was also expressed about added control by government over everyday laboratory procedures used in evaluating carpet. A third commenter also questioned the credibility of the HUD rationale contained in its statement of need, particularly as related to minimization of cost to both industry and government. (The statement of need is in HUD's request for a carpet LAP which was published by DOC in a* **Federal Register** notice on June 18, 1979 (44 FR 35000)). This commenter was supportive of a national accreditation program for carpet testing laboratories only if the program was broadened to include additional test methods serving needs other than those of HUD.

The need for the LAP for concrete was formally established after public review under the original procedures (15 CFR Part 7a) in a separate finding as stated in the **Federal Register** of December 13, 1978 (43 FR 58223–58226) and no new issue has been raised which would warrant reopening the matter. The determination of need for the carpet LAP, having been established under the optional procedures (15 CFR Part 7b) in which the Federal agency which requests a LAP makes its own finding of need, is the responsibility of HUD. DOC's NVLAP program is intended to provide national recognition of testing laboratories which voluntarily seek such status. How HUD or any other Federal agency utilizes the DOC accredited status of laboratories to suit their own needs is a matter for them to determine.

DOC is sensitive to the costs associated with the program. The key is to provide an evaluation thorough enough that the capability of a laboratory can reliably be attested to, yet not so stringent as to cause undue expense to or disruption at the laboratory. Reaching a proper balance between these two objectives is, of course, a matter of judgment which is expected to improve with experience in DOC's administration of the program. NVLAP stresses evaluation of a laboratory in a three-phased approach: (1) Evaluation of written information; (2) on-site examination and evaluation of the laboratory; and (3) evaluation of proficiency tests performed by the laboratory. These evaluations, along with the requirement to periodically re-evaluate the laboratory, are believed to be more extensive than has been required up to now in accreditation programs administered under the HUD certification program. DOC is of the

view that the credibility of the NVLAP depends upon reasonably stringent criteria, and each of the LAPs has had that objective as a principal goal. Notwithstanding this posture, it is of interest to note that other comments have been received, to be addressed later under the scope of the criteria section, which suggest that DOC has made compromises that may diminish the credibility of the originally established accreditation process.

DOC is also sensitive to the desirability of including all appropriate test methods in a LAP, once the need for that LAP has been determined. This subject will be discussed in the next section.

(3) *Test Methods Included in the LAPs. Concrete.* One commenter suggests that the concrete LAP should be expanded to include preparation of design mixes and testing of aggregates as required in ASTM E329. This subject was originally discussed in the final finding of need for the LAP as set out in the **Federal Register** on December 13, 1978 (43 FR 58223–58228) and was discussed at subsequent meetings of the concrete LAP committee. The resulting decision has been to limit the LAP to freshly mixed field concrete. The list of test methods shown in the proposed criteria resulted. DOC concludes that since the product specified in the finding of need was expressly limited to freshly mixed field concrete, the standards and test methods in the LAP should be limited to those directly related to that product. Nevertheless, if there is a sufficient demand from the public for a LAP covering an expanded group of concrete products, DOC will be responsive and establish such a LAP. Under the NVLAP procedures such a demand can only be evidenced after a formal request to the Secretary of Commerce. In response to such a request, DOC will publish it in the **Federal Register** and call for comments to determine whether a need exists which would justify establishment of the proposed LAP. As a practical matter, rather than encouraging initiation of a formal request to make a finding of need at this time, DOC suggests that such a request be submitted after some experience with the accreditation of laboratories under the current concrete LAP has been obtained.

Another comment suggests that ASTM C192 should be eliminated from the LAP. This test method, which deals with the preparation of concrete test specimens in the laboratory, was thought to be important because the proficiency test phase for the LAP originally envisioned distribution of materials from which the laboratory was to make samples for comparison testing. Since the proficiency testing program which has evolved no longer requires the preparation of concrete test specimens in the laboratory, DOC concurs with the commenter that this test method is no longer appropriate for inclusion in the program.

One commenter suggested that ASTM C173 should not be optional because it is widely used in measuring air content of lightweight concrete structures. DOC believes, however, that some testing laboratories, particularly those specializing in tests related to road construction projects, rarely if ever test lightweight concrete, and that ASTM C173 should continue to be optional at the request of the laboratory seeking accreditation.

Two commenters addressed the issue of test method grouping. One suggested that no laboratory is likely to perform only the field tests, and an accredited laboratory should include all tests, both field and laboratory. This commenter did point out that an owner or engineer might wish to do only field testing but that he/she would not likely seek accreditation. However, DOC understands that many laboratories determine compressive strength of cylindrical concrete specimens (ASTM C39) made by others, and that the making of the specimens may account for a significant portion of testing errors. Therefore, DOC believes that accreditation of laboratories for field tests only will be a valuable service. The second commenter suggested that in order to be accredited a laboratory should be capable of performing the entire set of tests in the "field" test method group. That is the intent of the LAP.

Carpet. A number of commenters have pointed out that some of the test methods included in the carpet LAP are generally being replaced by newer test methods, and that the old methods should be replaced in the program by the newer methods. These commenters also suggest that the so-called "pill test" required by the Consumer Product Safety Commission (CPSC) to be performed on representative samples of all carpet manufactured or sold in the United States should be included in the program.

A review of the NVLAP procedures indicates that they are silent regarding the possible need for, or the method by which, standards and test methods may be added to an existing LAP. This could imply that in order to add test methods under Part 7a procedures, a new finding of need would have to be established, and the advisory committee would have to recommend criteria to evaluate the laboratories performing the additional tests. Under Part 7b procedures, the Federal agency originally requesting the LAP could request that DOC include any additional standards or test methods. HUD which requested the carpet LAP under Part 7b procedures has advised that it is not in a position to request new methods which are not now required in its program or which, as in the "pill" test, are enforced by another agency, CPSC.

After thoroughly reviewing the requests and the history of the NVLAP program, DOC has concluded that NVLAP should be responsive to requests to add standards and test methods when such desires are made known as a result of a request for comments on a LAP as published in the **Federal Register**, or if such standards and test methods are pertinent to the specific product for which the LAP was established. Having reached this conclusion, DOC decided to propose an amendment to NVLAP procedures so that in appropriate cases additions of standards and test methods to LAPs can be made. Accordingly, DOC published a proposed amendment to the NVLAP procedures in the **Federal Register** on December 28, 1979 (44 FR 76810–76811). DOC is prepared to add ASTM E648 and FF 1–70 to the carpet LAP, as requested by a number of commenters, based on the provisions stated in that proposed amendment. However, assuming that no adverse comments are received which are of such nature as to cause DOC to drop the proposed amendment, the effective date of the amendment cannot occur until February 26, 1980, the expiration date of the period for public comment. In the event that public comment convinces DOC to withdraw the proposed amendment, DOC will not be able to include the additional test methods requested for the carpet LAP.

DOC is not prepared to delete ASTM E84 or UL 992 from the carpet LAP at this time, since those test methods were explicitly requested by HUD. If no laboratory were to apply to be accredited for those two test methods, then conceivably in the interest of program efficiency, DOC may delete them sometime in the future. Under NVLAP procedures, DOC is precluded from making changes to the standards or test methods, or from judging their efficacy. However, DOC may find a test method too subjective for adequate evaluation, and therefore elect not to include such a test method in a LAP. NVLAP is designed to recognize the capabilities of laboratories which voluntarily request such recognition. It

is not intended in any way to establish new standards or test methods for a product.

Another commenter, a carpet trade association, suggested that the ASTM D418 be broken into three separate tests, that tests for dry crocking and wet crocking be added to the program, and that tests for carpet with attached cushion, described in HUD Standard UM 44c Addendum 3, be added to the program. DOC has reviewed these comments in depth and examined the methods in detail, and has added and grouped test methods accordingly as shown in Appendix 3. The test methods have been added, subject to the condition that they may have to be withdrawn before actual assessment of the laboratories begins if the amendment to the procedures described earlier for adding test methods to LAPs is not made final.

(4) *Scope of the Criteria.* One commenter reviewed the proposed criteria and reorganized the information in a way thought more understandable to laboratories interested in applying for accreditation. DOC has taken note of these suggestions, implemented them in a number of instances, and wishes to express its appreciation for these suggestions.

Another commenter suggested that trying to adapt the laboratory accreditation criteria to two new product areas, concrete and carpet, would "* * * provide for the degradation of the originally established accreditation process." This commenter further suggested that widely diverse input from industry groups, testing laboratories, regulators, and users of products or services involved will likely lead to further conciliations and compromises such that the consolidated criteria would represent a "least common denominator" approach to accreditation which, if left unchecked, would eventually relegate the accreditation process to ineffectiveness.

DOC is continually faced with decisions about the adequacy of the criteria in its proposals. It does not believe that these new criteria weaken the program. In fact, almost all elements in the original criteria are addressed in a similar way in these criteria. The simplification referred to in the proposal deals more with the format by which the criteria are now presented and not the content of the criteria. For instance, in the original criteria there was confusion and overlap between the required content of the quality control manual and the responses necessary to fulfill the requirements of the specific citeria. These new criteria eliminate much of this confusion but do not materially weaken the requirements. In fact, in the sections dealing with personnel, the criteria have been materially strengthened.

DOC believes that the criteria will continue to evolve as new programs are added. This will not come from an attempt to use the "least common denominator" approach, but rather from experience gained in applying the criteria in actual practice and from ideas generated by knowledgeable persons focusing on the content of the criteria. The concrete LAP committee brought many new insights to the criteria because of the members' long association with the Cement and Concrete Reference Laboratory (CCRL) program under which laboratories have been examined for over 50 years.

DOC does not believe that persons involved in any one testing area necessarily have a unique insight into what is necessary to provide adequate criteria in that area. Very few laboratories test only in one specific product area. Normally, laboratory management must be capable of assuring that it will obtain accurate, reliable data in a number of product areas. In a similar sense, an accreditation program should be able to determine the capability of a laboratory testing in a number of areas in a reasonably consistent manner with criteria which are compatible to multifaceted operations. This is not to say that the criteria can always be uniform. For example, if NVLAP became involved in a LAP requiring bioassay or other biological test systems, significant additions to the criteria may be required relative to laboratory practices in the handling of laboratory animals, certain facilities, and experimental design to assure adequate data.

This leads into two comments related to the use of "supplemental information" in implementing the criteria. The criteria describe specific requirements that a laboratory must satisfy for each test method for which accreditation is sought. A test method describes how a laboratory is to perform a particular test. The "supplemental information" simply adapts the requirements of the criteria to the requirements of each test method. For instance, section S2.2.2 of the criteria states that calibration and verification records must be maintained on the testing equipment. A test method identifies the test equipment that should be calibrated. The "supplemental information" simply states what calibration and verification records must be maintained for each piece of equipment identified in the test method. This mechanism for implementing the accreditation process was chosen by DOC because it was felt that detailed information as to how to implement the criteria for a given test method would not change the intent or substantive effect of any requirement of the criteria, as established through notice and comment procedures in the **Federal Register**. Thus, it is not necessary to follow those procedures before deciding on specific items of "supplemental information." Furthermore, DOC believes that publication of criteria specifically adapted to each of the more than 80 test methods in the program would also be impracticable; it would take hundreds of pages in the **Federal Register**, be unnecessarily redundant, require re-publication in the **Federal Register** each time a test method is changed or revised, and would possibly submerge the overall concept being proposed—namely, the determination of whether a laboratory is capable of becoming accredited.

While DOC recognizes that there is some interpretation required to establish the "supplemental information," it still believes that notice and comment procedures (in addition to those already used in issuing the criteria) are unnecessary because the degree of interpretation in most instances is "de minimus," i.e., too small to be of any significance. Given the existing constraints of the criteria and the test methods, DOC believes that most reasonable persons who are versed in the technical aspects of operating testing laboratories would agree with the decision reached in relating the requirements of the test methods to the requirements of the criteria. Nevertheless, the National Bureau of Standards (NBS), which is responsible for preparing the "supplemental information", is in constant contact with knowledgeable people versed in the procedures and economics for testing each product. Much guidance is obtained from the standards organization which contributed to the development of the test method. Furthermore, the concrete LAP committee appointed a subcommittee to advise on the preparation of the "supplemental information" for the concrete LAP. In response to one comment questioning the nature of HUD's participation, it may be stated that HUD was asked to provide technical support under Part 7b procedures to develop the "supplemental information" for the carpet LAP. However, this information has been developed under the general guidance of the NBS technical staff and

with interaction with the affected testing community.

(5) *Requesting Accreditation.* One commenter has suggested that the "supplemental information" should be made available to laboratories interested in accreditation before the formal application is submitted. The proposal stated that an application would be published in the **Federal Register** with the final criteria and that any interested laboratories could apply for accreditation for the test methods of interest. The "supplemental information" for all test methods of interest would then be supplied to the laboratory, after which the laboratory could withdraw or modify its request if it did not wish to proceed with the accreditation for certain of the test methods. In this case the application would also require information about the laboratory relative to the general criteria. In response to this comment, and in considering that such a detailed application form may seek information which would not be used if the laboratory decided against seeking accreditation after reviewing the "supplemental information," DOC has revised the application procedures so that a laboratory interested in possible accreditation would fill out a very simple request form (Appendix 4 of this notice) listing the laboratory name and address and checking off the test methods in which it might be interested, and send it to NVLAP. In response, a formal application package will be sent to the laboratory along with a copy of the "supplemental information" for each test method checked. This formal application package includes an application form that will require the information in response to the general criteria.

When a completed application form is received, a site visit preparation form will be sent to each applicant. The site visit preparation form elicits information regarding laboratory operations as related to the specific criteria and individual test methods for which accreditation is sought. Its purpose is to provide advance information to the on-site examiner so that an efficient and cost-effective evaluation of the laboratory may be accomplished during the on-site visit. Both the insulation LAP committee and concrete LAP committee recommended that the paperwork involved in the accreditation process be reduced. The evaluation methodology used with the first round of applicant laboratories was based on gathering extensive written information for off-site evaluation by a peer evaluation at NBS, followed by verification at the laboratory by a non-peer examiner. Based on the recommendations of the two committees and the NBS experience with the initial evaluations, the methodology employed for these LAPs is being shifted to emphasize a peer on-site review. Hence, there is no longer a need for the extensive questionnaires that applicant laboratories were required to fill out for the first round of evaluations. However, the information requested in the site visit preparation form is deemed necessary to acquaint the on-site peer evaluator of what to expect in the visit to the laboratory. In the future the evaluation methodology may be shifted depending upon the experience gained and the particular evaluation needs of future LAPs.

Another commenter expressed concern that applications for accreditation would be accepted only once a year, as was the case in the insulation LAP, and that during that year accreditation would not be granted for any additional test methods available in the LAP. DOC believes that these limitations may continue to be necessary in the near term until the scope and breadth of the NVLAP program becomes large enough to sustain a diverse core of examiners and evaluators. The intent in the long term is to respond more rapidly to the new needs of laboratories accredited under the program, and to make the program available to new laboratories on a more timely basis. As soon as possible, DOC will try to make access to the program available more frequently than annually.

(6) *Basic Conditions of Accreditation.* One of the basic conditions for accreditation contained in the NVLAP procedures is that each testing laboratory that desires to participate in the program must agree to "avoid reference by itself and forbid others utilizing its services from referencing its accredited status in consumer media and in product advertising or in product labels, containers and packaging or the contents therein." Two commenters have objected strenuously to this provision indicating that, if an organization has incurred the expense of accreditation, it should receive the additional benefit associated with recognition of that accreditation. One commenter suggested that certain code groups are increasingly promulgating requirements with respect to the status of the laboratories performing tests, including provisions regarding communications of their accreditation status to inspectors, contractors, etc. Their fear is that an entirely separate and redundant accreditation program would have to be established, if vendors could not appropriately communicate the accreditation status of the laboratory they have retained to respond to testing requirements.

DOC recognizes that the process, which should lead to a credible statement that a product meets a standard, requires at least three distinct steps. First, a standard and a test method must be available by which evidence can be produced that verifies the fact that the product does indeed meet the standard. Second, some organization must perform the test. Third, unless every item of production is tested, the product upon which a test has been made must be reasonably representative of the product being offered to the consumer. The statement that a product meets a given standard is called certification. To make such a statement, the certifier must be knowledgeable of the variability in the product which could be attributed to the production process, and the variability which could be attributed to the test method. None of these ingredients is included in the NVLAP program. A testing laboratory typically has little information about the variability of a given product with the possible exception of when it is responsible for operating a certification system.

Laboratory accreditation is the process wherein a determination is made that a laboratory is *capable* of performing a test properly. There is nothing in this determination which guarantees or even states that a laboratory will always perform the test method properly. There is no formal determination of the range of values an accredited laboratory may obtain in performing a specific test although information from proficiency tests for certain test methods does enter into the evaluation of a laboratory. A laboratory need have no information about the variability in the product being tested in order to be accredited under NVLAP procedures.

A hangtag or label on a product tends to assure the consumer that a product meets a standard. This is the typical object of a certification program, not a laboratory accreditation program. A laboratory accreditation program identifies laboratories which have been examined and are found to be capable of performing the test methods properly. Such a program will assist manufacturers seeking capable laboratories to test their products periodically so that the manufacturer can credibly assert or self-certify that its product meets a standard. An accreditation program is also useful to third party certification bodies, such as

trade associations, which have products tested periodically by a capable laboratory so that the certifying body can conclude that a product meets a standard.

Recognizing these distinctions and limitations, it would be appropriate for an accredited laboratory to advertise its accredited status to manufacturers and certification bodies which would have use of the laboratory's services. It would also be appropriate for manufacturers and certifiers to notify code officials that their product has been tested by an accredited laboratory, as long as the sampling conditions, which the manufacturer or certifier used in selecting the sample tested, are also specified. The mere fact that a laboratory has performed a test on a sample of a product at some point in time, and found that the sample met the standard, is no basis for certifying that a specific product sold to a consumer meets a standard. Advertising the fact of accreditation to consumers, or labeling products to this effect, is not appropriate unless there is some way (such as a certification program) which will more precisely indicate what the results of such testing mean. It is for these reasons that the limitation on advertising and labeling were included in the procedures in the first place, and why DOC sustains those provisions.

The insulation LAP and concrete LAP committees reviewed this issue extensively. On the one hand, it was clear to the members that NVLAP accreditation should not be used in such a way that government approval of a product might be implied. On the other hand, the committees felt strongly that more clarification of this issue is needed, and asked in their recommendations that DOC prepare a position statement more clearly describing how the fact of accreditation can be properly publicized. The statement that appears in the criteria is taken directly from the NVLAP procedures (41 FR 8163–8168) and is not subject to revision except by revising the procedures. DOC believes much can be accomplished by clarifying the conditions of use, by giving examples, and by exploring a wide range of ideas which might be employed to improve recognition of the meaning and significance of NVLAP. DOC is preparing a position statement and a program for improving the recognition of NVLAP accredited laboratories.

(7) *Organizational Structure (G1).* One commenter questioned the purpose of securing the name of the parent organization and the names and positions of the principal officers and board of directors of the laboratory (sections G1.1.2 and G1.1.3). DOC believes that this information is fundamental to the legal identification of a laboratory. Also, this information is important if allegations involving ethical practices are received by DOC against any NVLAP accredited laboratory. This same commenter questioned the need for submitting a statement of changes in a laboratory's organizational structure. This provision requires that a laboratory submit a statement of any *fundamental* changes. Changes in the name, address, facilities, or management of a laboratory's ownership are fundamental to that laboratory's accredited status and should be reported to DOC. The insulation LAP committee and concrete LAP committee recommended no changes to these provisions but suggested that, for identification of the parent organization, one organizational level above the laboratory was sufficient. DOC plans to make this clear in the application form.

(8) *Policy Statements (G2).* A number of comments addressed the policy statements under the professional and ethical business practices section of the general criteria. One commenter suggested that DOC should not "dictate" a laboratory's policy. The provision does not preclude a laboratory from having other policies or changing the wording of the policies suggested. It simply requires that, "as a minimum," the laboratory should abide by certain ethical business practices. The policy statements listed under this section of the criteria are meant to apply to the test methods for which a laboratory is accredited. DOC believes that NVLAP accredited laboratories should conduct those testing operations for which they are accredited in accordance with these ethical practices.

One commenter suggested that the requirements of the original criteria to submit documentary evidence showing that the laboratory complies with certain ethical practices should not be relaxed. DOC does not believe that this change is a "relaxation" of the criteria. Securing agreement to policy statements gives DOC a uniform standard for judging noncompliance. Under the original criteria each laboratory's documented evidence was different and cumbersome to analyze, thus making a judgment of compliance with the criteria far more complex and difficult.

Three different comments were expressed regarding the provision that requires a laboratory to treat test data as proprietary information (section G2.1.4). One commenter suggested that this provision be dropped because at times test data have to be promptly reported to third parties and transmittal cannot wait for paperwork. Another commenter endorsed the DOC position saying it should be the manufacturer's not the laboratory's decision to release test data. A third commenter suggested that the phrase, "unless the client agrees in writing to the release of such information" was not needed and should be deleted. The insulation LAP committee and concrete LAP committee endorsed this view and recommended that this phrase be deleted. DOC agrees and section G2.1.4h as been revised to read: "Treat test data, records, and reports as proprietary information."

Two commenters questioned the practicality of the provision for return of the certificate of accreditation if an accredited laboratory should find itself unable to conform to any of the criteria (section G2.1.8). Their concern focused on the situation where an accredited laboratory loses capability to perform one or more of the test methods for which it is accredited, but retains capability for the other test methods for which it is accredited. It was suggested that that section, G2.1.8, be revised to indicate that DOC would issue an amended certificate to cover this type of situation. DOC agrees with this suggestion and, accordingly, the language of G2.1.8 now reads, "Return to DOC its certificate of accreditation should it become unable to conform to any of these general and specific criteria for accreditation for possible revision or other action."

One of the commenters suggested that DOC circulate the latest versions of test methods to the accredited laboratories to facilitate the implementation of the change. DOC intends to periodically communicate with accredited laboratories, and informing them of revisions to the test methods would be part of such communications.

One commenter suggested that advice be secured from interested parties as changes in test methods are incorporated as part of a LAP. DOC anticipates that, when changes are made to any test methods of a given LAP, their implementation will depend upon any new requirements that the test method changes entail. DOC will seek the advice of technical experts on these matters when it is necessary.

One commenter suggested that accredited laboratories be required to identify the version of the test method used for each of its tests. DOC believes that the provision S3.1.1(f), "Identification of the test method, procedure, or specification," requires the identification of the version used.

One commenter expressed concern that in-house laboratories would be subject to discriminatory provisions of certifiers using NVLAP accredited testing services. As alluded to earlier, NVLAP is not a certification program. NVLAP accreditation is, rather, a formal recognition of competence of a laboratory to perform certain tests. Certification involves other functions and requirements beyond the testing function. How certification programs use NVLAP accredited laboratories or place additional requirements on them is not within DOC's control. DOC is governed by procedures which state that no action will be taken or criteria developed that would prohibit the accreditation of a testing laboratory solely on the basis of that laboratory's association or non-association with manufacturing, distributing, or vending organizations, or because the testing laboratory is a foreign firm.

(9) *Quality Control System (G3).* One commenter questioned the purpose of a quality control or laboratory operations control manual. The recommendations of both the insulation LAP committee and concrete LAP committee included provisions for some type of manual, suggesting that a manual was an essential element in the effective operation of a laboratory. DOC concurs with this position.

One commenter suggested that the manual should be submitted for a more in-depth analysis rather than evaluating it during the on-site examination. The first round of laboratory evaluation activities under the insulation LAP involved an in-depth analysis of submitted manuals. The exercise of reviewing the laboratories' manuals without prior knowledge of the environment in which they were used was not always meaningful. The problem of reviewing submitted manuals was made more difficult by confusion created in the original criteria regarding the expected content of the manuals. The submitted manuals varied considerably in content and style and in some cases were difficult to analyze for compliance. DOC believes that these new criteria and changes in the application procedure will now afford a more effective evaluation of a manual's content by an on-site examiner who would review certain areas of the manual to verify that it satisfies the requirements of the criteria. The changes, which are incorporated in the part of this notice entitled, "Accreditation Process," will save the laboratory time in preparing for the site visit and will assure an accurate representation of laboratory operations at the time of review for accreditation.

One commenter suggested that DOC develop a series of "uniform protocols" which could be adopted by a laboratory seeking accreditation in the preparation of its quality control and operations control manual. DOC believes that this concept has some merit. However, it has some distinct disadvantages also. By providing uniform protocols, DOC would be, in effect, prescribing one way to write the manual which may erroneously be interpreted as the best way. There may not necessarily be a *best* way to write a manual. The manual should be a clearly written document that can guide laboratory personnel in the operation of tests in the laboratory. It has to be tailored to each particular laboratory and to the preferences of the laboratory's management. DOC believes that a manual prepared by the laboratory's management would be a far more effective tool than having DOC's idea of a manual "imposed" on a laboratory. The criteria state what the manual should contain as a minimum, not how the language of the manual should read.

(10) *Technical Staff (G1.1.5 and F1).* One commenter suggested that the personnel requirements of ASTM E329 should be adopted for the concrete LAP. The concrete LAP committee discussed the issue thoroughly and concluded that such requirements were not appropriate because ASTM E329 would shortly be revised. Both the insulation LAP committee and concrete LAP committee discussed the issue of recommending minimum requirements for education, experience, and technical society activity for the laboratory's technical director and testing staff. Both committees, in general, recommended against having specific requirements listed in the criteria at this time, but believed that for the technical staff the key is demonstrated competence. Consistent with those committee recommendations, no specific requirements are stated in the criteria at this time. However, DOC will monitor standards development activities relative to testing laboratory personnel qualifications for possible adoption in the future.

One commenter suggested that closed-book examinations serve no purpose and that technicians should not be expected to memorize the test methods but should have the ASTM books available as a continual reference. DOC agrees that in most cases memorizing the test method is impractical and continual reference to the text of the test method is desirable. However, for some simple test methods conducted at field sites where access to the text of the test methods is not normally available and supervision is limited, a technician should have the test method memorized. In such a case, a closed-book examination is appropriate. The field test methods of the concrete LAP are examples of test methods where a closed-book examination is appropriate.

One commenter suggested that the re-examination period of one year was too frequent and should be changed to every two years. DOC believes that an annual reaffirmation of a technician's competence to perform certain test methods or parts of test methods is important and does not entail much paperwork. In most cases all that is required is: (1) An annual observation by the supervisor of the actual performance of all the test methods or parts of test methods that each technician is assigned to perform; and (2) A written statement signed by the supervisor and filed with the laboratory's personnel records attesting that each technician is competent to perform, as of the observation date, those test methods or parts of test methods that the technician is assigned to perform.

One commenter suggested that the criteria should explicitly recognize that the division of labor within each testing laboratory will vary. In some laboratories, a single individual may perform all aspects of a particular test method. In another laboratory, a different individual might well be responsible for certain aspects of a test method. DOC does recognize this division of labor. The criteria do not prohibit any division of labor nor do they prescribe what the division should be for a particular test method. In order to clarify the intent of the relevant criterion, two sections have been changed. The first sentence of section S1.1 has been changed to require that the laboratory shall attest to the competence of each relevant staff member "in the performance of each test method or part thereof that each member is assigned to perform." Section S1.3(a) has been revised to read, "A record, including dates and results, of the observation or examination of performance for each test method or part thereof for which each staff member is assigned to perform."

(11) *Equipment, Facilities, Procedures (S2).* Some commenters expressed concern that many provisions of criterion S2 were not required for certain test methods. Requirements such as maintaining schematics, drawings,

diagrams, or photographs of equipment or facilities, and keeping elaborate calibration records were not necessary. DOC agrees that for certain test methods such provisions are inappropriate. That is why the phrase, "as applicable" is inserted in provisions, S2.1, S2.2.1, S2.2.2, and S2.3, and S2.4. The "supplemental information" for each test method indicates where such provisions are applicable.

One commenter questioned the need for test plans, claiming that the text of the test methods are sufficient for a technician to carry out the test methods. DOC believes that test plans are necessary to guide a technician in using the test method with the particular equipment and facilities available in the laboratory. The text of test methods in many cases does not clearly indicate how certain functions such as equipment maintainance and verification checks; specimen selection, handling and disposal; and data collection, analysis, and reporting are carried out. In addition, a laboratory may have particular ways of carrying out such functions which are not clearly prescribed by the text of the test methods.

One commenter suggested that provision S2.3(a), "Equipment maintenance and verification checks;" should be deleted since it is redundant with S2.2.1. It is DOC's position that these two provisions are not necessarily redundant. S2.3(a) specifically pertains to the test plan and should be guidance to the technician regarding checks of the equipment that should be made before conducting a test or series of tests. S2.2.1 is a more general provision requiring a description of the procedures for calibrating, verifying, and maintaining the laboratory's test equipment and facilities. Such procedures would be part of a laboratory's routine for checking equipment independent of the performance of specific tests.

One commenter suggested that those non-critical parts of test methods which could be done by unaccredited subcontractors (S2.3(e)) needs to be identified. DOC agrees that identification of parts that can be handled by unaccredited subcontractors is desirable. However, by specifying what parts are appropriate for subcontractors and what parts are not, DOC may preclude some unforeseen case where it is actually appropriate. Identification of such parts, where it is practical or where experience has been gained, will be handled as part of the "supplemental information." DOC desires, however, to remain flexible to make judgments on a case-by-case basis using its technical experts until more experience is gained as to what parts are appropriate for unaccredited subcontractors and what are not.

(12) *Records (S3).* In the proposed criteria document, comments on the length of time that records should be retained by accredited laboratories were specifically requested. The proposed criteria were silent on this issue. One commenter recommended that no change be made at this time with respect to maintenance of records. Another commenter suggested that there was no reason for retention of records beyond the point of each successive reaccreditation. DOC believes that for accreditation purposes records should be retained by accredited laboratories for at least that period of time which occurs between successive on-site examinations. There is no reason why accredited laboratories should not retain records for longer periods of time, particularly those time periods that may be imposed by Federal, State, or local government requirements, or other contractual requirements.

Accordingly, provision S3.5, has been added to read, "The laboratory shall retain records required by these general and specific criteria for a minimum of three years or for any longer period of time specified by Federal, State, or local government requirements, or other contractual requirements."

One commenter questioned the need for a written complaints file and expressed concern that DOC should not be entitled to examine or remove the documents contained in such a file. The criteria require that a laboratory maintain a file of written complaints and disposition thereof (S3.4). The on-site examiner would merely verify that such a file existed at the laboratory and would not require copies or removal of the file's contents.

In light of this comment, DOC reviewed the provisions relative to the responsibility of participating laboratories to provide DOC access to records and other documents required by the criteria. Accordingly, language has been added after the list of basic conditions for accreditation that requires the laboratory to permit the on-site examiner to review and examine such documents. In addition, if a hearing under 5 U.S.C. 556 has been instituted at the laboratory's request, the laboratory is required to permit DOC to review and copy such documents for possible use as evidence to be presented at such a hearing.

(13) *Proficiency Testing (Concrete LAP).* Three commenters provided many suggestions regarding the within-laboratory and between-laboratory proficiency testing programs for the concrete LAP. One commenter requested clarification of the administration of a within-laboratory program. Such a program is intended to be an on-going monitoring system for the accredited laboratory's own use in identifying problems that may arise with its testing. A laboratory, in order to maintain its accreditation, is expected to continuously administer such a program of the kind outlined in Appendix 2. In response to this comment and at the recommendation of the concrete LAP committee, DOC has revised the requirements to submit a copy of the within-test variation table of figures for five consecutive weeks rather than three weeks as originally proposed.

Two commenters made specific suggestions related to the requirements of the between-laboratory program. One commenter suggested that the 28-day test on cylindrical specimens would provide more significant results than the 7-day test. DOC agrees but believes for the purpose of making comparisons between laboratories that the 7-day test is sufficient. One commenter suggested that the interval to detect testing problems would be too long if the comparison is made every six weeks as it takes six consecutive comparisons to be significant. He suggested that one solution would be to make at least one comparison during the operating season of 6–10 sets of specimens. Another commenter suggested that the frequency of comparison be every 3 weeks instead of 6 weeks. Another commenter suggested that it would be useful to compare the coefficient of variations of the comparison tests with the coefficient of variation obtained from the laboratory's within-laboratory program. The concrete LAP committee considered these suggestions and recommended that the laboratory be allowed to use either the 7-day or 28-day test, that the 6-week frequency of comparisons be retained, and that the calculation of the coefficient of variation for the comparison tests not be required because it would not be meaningful. DOC agrees with the committee's views and has implemented them in Appendix 2. In response to one comment at the recommendation of the concrete LAP committee, one editorial revision was made to improve the readability of step number 9 of the data analysis method for a between-laboratory program.

(14) *Proficiency Testing (Carpet LAP).* A number of comments addressed the proficiency testing requirements of the carpet LAP outlined in Appendix 3. One commenter suggested that proficiency testing should be required for ASTM E84

and UL 992. DOC does not agree that these additional proficiency tests should be required because anticipated participation is not sufficient to make the test results statistically meaningful and useful for determining the capability of the participating laboratories to perform those tests.

One commenter suggested that proficiency tests are needed for ASTM E648, the flooring radiant panel test, as well as test methods for weight, compression set, and compression resistance included under addendum 3 of HUD Use of Materials Bulletin, UM 44c, if these test methods are added to the carpet LAP. These suggestions have been accepted as indicated in Appendix 3.

Two commenters objected to the publications of desired precision figures for test methods where no industry-wide figures have been established, for two reasons: (1) Such "desired precision" figures suggests that a determination has been made that a properly operating laboratory should obtain results within the specified intervals; and (2) such figures, if published, will inevitably be used by third parties as the basis for concluding that laboratories should be able to perform the specified tests within the published "precision" figures. The original intent of publishing "desired precision" figures was to give a laboratory guidance for its own internal quality control checks. However, DOC agrees that such publication may be misleading and indeed may be cited as mandatory by other authorities. Therefore, "desired precision" figures are being deleted until such time that valid data are available.

The frequency of proficiency testing was addressed by two commenters. One commenter urged that the frequency of testing be at least twice a year. Another commenter suggested that the frequency be reduced to once a year at least subsequent to the third proficiency test round in order to reduce costs. At the present time, DOC believes that proficiency testing two times a year is the most desireble frequency for the test methods in the carpet LAP. However, changes may be made at some future date should they be deemed appropriate. All efforts will be made to reduce the costs of proficiency testing wherever possible by combining samples, reducing mailings, etc.

(15) *Examination and Audit Procedures (Concrete LAP).* One commenter suggested that the concrete LAP be implemented in two phases: (1) The first phase would emphasize the training and actual performance of technicians to conduct the tests methods, and (2) the second phase would emphasize the required documentation such as the manual and record keeping provisions of the criteria. DOC believes that NVLAP accreditation should be based on all provisions of the criteria. Some provisions may be emphasized more than others during the early stages of implementing the concrete LAP. Then, after some experience has been gained, the emphasis can be adjusted accordingly. However, no provisions of the criteria can or should be ignored. If changes to the criteria became necessary to encourage greater participation, such changes will be considered at the appropriate time.

(16) *Examination and Audit Procedures (Carpet LAP).* A number of comments addressed the proposed examination and audit procedures for the carpet LAP. One commenter suggested that the frequency of the on-site examinations for the carpet LAP occur once per year for the first two years. Because the on-site examination is the most significant factor of cost to the carpet LAP and since greater frequency would significantly increase costs, DOC believe that a frequency of every two years is adequate for the nature of the carpet LAP test methods and should be retained.

One commenter stated that the functions of the on-site examiner were unclear, but should include the witnessing of the laboratory's ability to perform the test methods as well as evaluation of equipment, manuals, etc. DOC believes that an actual demonstration of the test methods is important in determining the capability of a laboratory to conduct tests, but is aware that some complex tests are so long and involved that such witnessing is not suitable. Accordingly, the on-site examiner will witness the conduct of tests as appropriate. The other functions of the on-site examiner will be to verify compliance with provisions of the general and specific criteria including a review of the quality control or laboratory operations control manual, test equipment, procedures, and record-keeping at the laboratory.

One commenter expressed concern that the LAPs lacked a simple means of rectifying deficiencies, particularly the types which occur during the initial accreditation process. DOC plans to provide ample opportunity for applicant laboratories to correct deficiencies before any recommendation to deny accreditation is prepared. In those cases where deficiencies are identified, the applicant laboratory will be notified of those deficiencies during the on-site examination and in a subsequent letter to the laboratory. The laboratory will be asked to certify in writing, and to document, where applicable, that the deficiencies have been corrected. The correction of the deficiencies may be further confirmed by an unannounced visit. If after a specified length of time a laboratory fails to rectify deficiencies or meet other requirements of the program, DOC will send a letter to that laboratory proposing to deny accreditation. The laboratory may appeal such a proposed denial by requesting in writing a hearing under the provisions of 5 U.S.C. 556.

One commenter expressed concern that the unannounced visits could be used as a tool for harassment of accredited laboratories and suggested that DOC specifically renounce such use of unannounced visits. It is DOC's policy not to use unannounced visits as a tool for harassment. Unannounced visits will be carried out either in a random manner or because there is a clear indication that a laboratory is having problems in complying with the criteria. Since NVLAP is intended to enhance the overall quality of testing, both announced and unannounced visits will be used constructively to identify deficiencies where they may exist and to aid in improving the laboratory's operations.

(17) *Examiner Qualifications.* One commenter indicated that the on-site examiner qualifications were not actually stated under the section on examiner qualifications. Accordingly, this section has been revised and incorporated as part of the description of the NVLAP accreditation process presented in later sections of this notice.

(18) *Costs & Fees.* A number of comments addressed the cost of accreditation to participating laboratories. One commenter wanted to know whether two fees are required for two plant laboratories under a single department head. Generally, separate fees are required for laboratories that have different people, different equipment, and separate and distinct facilities. However, if the physical location of the plant laboratories are adjacent or within a few blocks of each other, they may be considered as one laboratory with one fee, particularly if they share resources (i.e., same people, etc.). Since the major cost involved in the evaluation and accreditation of laboratories is the on-site visit, two laboratories in the same location which are integrally operated may be examined at one time thus reducing the costs.

Two commenters indicated that the fee structure is unrealistic and does not totally reflect the actual costs of becoming accredited. DOC recognizes

that the cost to a laboratory to apply for accreditation is greater than the fees paid because of the internal costs of preparing the documentation and performing the operations necessary to be accredited. However, DOC also recognizes that in most cases a well-operated laboratory already has documentation, such as a quality control or laboratory operations control manual, used to guide its operations. For those laboratories the additional cost is minimal. Laboratories that do not have a manual but desire accreditation generally will find that the process of preparing a manual is beneficial because it will force the laboratory's management to carefully review its procedures and operations. During such a review, deficiencies may be found, and improvements can be made which lead to the overall upgrading of the laboratory. Then, too, most laboratories regularly employ internal quality control checks which are similar to those required by the criteria. Integration of the accreditation into the routine quality control checks will minimize these costs.

One commenter suggested that the "economies of scale" built into the fee structures are not applicable to carpet testing laboratories since these laboratories would not be interested in participating in the other LAPs. DOC believes that there are some laboratories interested in accreditation under both the carpet and insulation LAPs. In order to accommodate such laboratories the fee structure provides a reduction in the fixed charge for each additional LAP under which the laboratories desire to participate.

Instructions for Making Application

Any laboratory interested in being accredited under NVLAP should fill out the request for application form attached at the end of this notice and address it to: NVLAP Coordinator, Room 3876, U.S. Department of Commerce, Washington, D.C. 20230.

The request letter should identify the laboratory accreditation programs (LAPs) and the specific test methods under each LAP in which the laboratory is interested. No commitment by the laboratory will be implied by such a request. Likewise, the Department of Commerce will only send an application package, and will take no further action unless a formal application for accreditation is submitted by the laboratory by the date specified in the application package. The laboratory will receive an application package tailored to its request.

All requests for application postmarked by February 29, 1980 will be considered with the next group of laboratories to be examined for accreditation. The application packages will be sent out on or about March 7, 1980. All laboratories submitting applications postmarked by April 11, 1980 and accompanied by the requisite fee or purchase order will be scheduled for their on-site examination. Applications received after this date will be included in subsequent groups of laboratories to be considered for accreditation six months to one year later.

A description of the NVLAP accreditation process and laboratory accreditation criteria for the three LAPs are provided below.

Dated: January 18, 1980.

Jordan J. Baruch,

Assistant Secretary for Science and Technology.

Accreditation Process

The accreditation process of the National Voluntary Laboratory Accreditation Program (NVLAP) is comprised of four elements: (1) Requesting accreditation, (2) the on-site examination, (3) proficiency testing, and (4) the evaluation and accreditation.

(1) Requesting Accreditation

Any testing laboratory interested in becoming accredited under NVLAP should fill out the request for application form in Appendix 4 at the end of this notice and address it to: NVLAP Coordinator, Room 3876, U.S. Department of Commerce, Washington, D.C. 20230.

The request letter should identify the laboratory accreditation programs (LAPs) and the specific test methods under each LAP in which the laboratory is interested. No commitment by the laboratory will be implied by such a request. Likewise, the Department of Commerce will only send an application package, and will take no further action unless a formal application for accreditation is submitted by the laboratory by the date specified in the application package. The NVLAP Coordinator will acknowledge each request and forward it to the National Bureau of Standards (NBS) which will assemble an application package tailored to those LAPs and specific test methods for which the laboratory is interested.

Each application package will include—

(a) Instructions describing the steps to follow for becoming accredited;

(b) An application form and test method selection list,

(c) A fee schedule,

(d) Laboratory accreditation criteria, and

(e) "Supplemental information" relevant to each test method or group of test methods for which the laboratory seeks accreditation.

The application form elicits information relative to the laboratory accreditation criteria.

The fee schedule provides the applicant laboratory with the information needed to calculate the fees required in accordance with the list of test methods for which accreditation is sought. Intent to pay the applicable fees, as evidenced by the submittal of a check or purchase order in the appropriate amount, must be demonstrated before any evaluation work can be undertaken. All fees must be paid before a certificate of accreditation can be issued. In a separate notice appearing in the Federal Register today, DOC announced the issuance of the fee schedule which shows how the fees will be calculated.

The criteria employed for determining whether an applicant laboratory merits accreditation are divided into two types: general and specific. The general criteria relate to general characteristics commonly found in, and generally expected of, any reputable testing laboratory. The specific criteria are those requirements for accreditation that relate specifically to individual test methods. The specific criteria are designed so that they may be applied to all test methods in any NVLAP activity without having to be changed each time a test method is added or revised. Because "universal" language is used, some portions of the criteria may not be applicable to all test methods. This is why the words, "as applicable," are used several places in the criteria.

The "supplemental information" indicates how each section of the specific criteria relates to each test method or group of test methods. It identifies those sections of the specific criteria that are not applicable, indicates how the sections which are applicable are to be interpreted and implemented, and describes how a laboratory's compliance will be assessed. In essence, the "supplemental information" tailors the specific criteria to the particular characteristics of individual test methods. It will not extend the criteria into new areas and will be revised, as necessary, each time any test method is revised.

In order for a laboratory to be accredited under the NVLAP procedures, it shall agree in writing to the following basic conditions:

(1) Be examined and audited, initially and on a continuing basis;

(b) Pay accreditation fees and charges;

(c) Avoid reference by itself and forbid others utilizing its services from referencing its accredited status in consumer media and in product advertising or on product labels, containers, and packaging or the contents therein;

Note.— A NVLAP accredited laboratory may advertise its accredited status on its letterhead, brochures, and test reports as well as in trade publications and other laboratory services advertsing media.

(d) Maintain compliance with applicable general and specific criteria;

(e) Participate in proficiency testing programs that may be required for maintaining accreditation.

The laboratory shall permit the on-site examiner to review and examine any records or other documents required by the criteria. Also, if a hearing under 5 U.S.C. 556 has been instituted at the laboratory's request, the laboratory shall permit DOC personnel to review and copy any records or other documents required by the criteria.

In addition, each applicant laboratory should be aware that compliance with the general and specific criteria and accreditation by the Secretary of Commerce will in no way relieve the laboratory from the necessity of observing and being in compliance with existing Federal, State, and local statutes, ordinances, and regulations, including consumer protection and antitrust laws, which may be applicable to the operation of the laboratory.

(2) On-site Examination

Upon receipt of a completed application form, NBS will send a site visit preparation form that elicits information regarding the applicant laboratory's operation as related to the specific criteria and individual test method for which accreditation is sought. Its purpose is to provide advance information to the on-site examiner so that an efficient and cost-effective evaluation of the laboratory may be accomplished during the on-site visit. This advance information will also be used to acquaint the different on-site examiners with the breadth and scope of operations at the laboratories so that the accreditation criteria may be more uniformly applied from laboratory regardless of the examiner.

Once an applicant laboratory has submitted a complete site visit preparation form, NBS will arrange a visit of the on-site examiner(s) to the laboratory. The on-site examiner(s) will confirm information supplied by the laboratory and will check conformance to the specific criteria applicable to each test method or group of test methods for which the laboratory seeks acreditation. The visit may last from one to three days or even longer depending upon the number and complexity of the test methods for which accreditation is sought. The on-site examiner(s) will conduct an exit interview with the laboratory's management at the conclusion of the on-site examination to summarize the examiner(s) findings.

A scheduled on-site examination and a complete reassessment of a laboratory's compliance with the criteria will be accomplished for each LAP as follows:

(a) Insulation LAP—approximately once a year for the first two years and approximately every two years thereafter.

(b) Concrete LAP—approximately every two and one-half years.

(c) Carpet LAP—approximately every two years.

In addition to regularly scheduled laboratory visits, unannounced visits may occur at any time. These visits may be initiated by the use of a random selection scheme or in response to a specific need because in the opinion of DOC the laboratory appears to have testing problems. In general, a complete review of the laboratory is not comtemplated for the unannounced visits. In the case of randomly selected visits, key items in the laboratory will be checked. In the case of visits due to an apparent problem, items relating to the problem will be checked. Failure of the laboratory to cooperate with the DOC representatives will be grounds for revocation of accreditation.

The on-site examiners will be government employees of NBS contract employees. NBS will be responsible for the professional and technical performance of all on-site examiners. On-site examiners will receive from NBS guidelines and materials for conducting the initial and periodic on-site examinations in a consistent manner from test method to test method and from laboratory to laboratory.

(3) Proficiency Testing

Proficiency testing is an integral part of the NVLAP accreditation process. Of utmost importance to the user of laboratory services is information as to whether or not a testing laboratory consistently obtains reliable results. The existence of facilities, equipment, and personnel, verified by a laboratory's ability to meet the criteria, establishes the capability for obtaining such results. An analysis of actual test results is necessary to determine if these ingredients do in fact produce the desired results. Each LAP has specific proficiency testing requirements. Implementation of these requirements may depend on the number of laboratories applying for each testing area covered, since in some cases a sufficient number of participants are necessary to reach statistically valid conclusions about test results obtained by each participant.

Insulation LAP. Laboratories applying for accrediation must expect to participate in proficiency tests where such tests are designated in Appendix 1. It may be that fewer than a statistically significant number of laboratories will request accreditation for one or more of the test methods requiring proficiency testing. In such a case, the requirement to conduct proficiency tests for that test method may be waived, and the evaluation for accreditation will be based only on the information submitted by laboratory and on the on-site examiner's assessment.

Values for the desired precision and accuracy for the test methods under the insulation LAP are shown in Appendix. 1. For test methods requiring proficiency testing, the precision and accuracy figures represent the values required for demonstrating "good" laboratory performance and the desired degree of proficiency. Approximately 95 percent of the laboratories should be able to achieve this level of proficiency. Limits approximately 50 percent greater are used to define "acceptable" performance for accreditation purposes. The frequency of proficiency testing is also shown in Appendix 1.

Concrete LAP. The concrete LAP committee carefully considered distribution of a proficiency sample. However, because of the complexity of preparing the sample and the uncertainty about reaching statistically valid conclusions regarding the test results, such distribution was not recommended. A somewhat different approach to proficiency testing is required for the concrete LAP.

The proficiency testing requirement consists of two programs: (1) A within-laboratory program; and (2) a between-laboratory program. Implementation of the between-laboratory program will not be required for the first year of accreditation under this LAP. However, all laboratories applying for initial or renewed accreditation under this LAP after the first year of accrediation will be required to establish a between-laboratory program.These two programs are intended to give a laboratory a relatively simple means of checking the reliability of its test results. The procedures for conducting a within-laboratory program and a between-

laboratory program described in Appendix 2 are minimum guidelines (i.e., any laboratory may use a more sophisticated program or statistically rigorous analysis).

The minimum scope of these two proficiency programs required for laboratories requesting accreditation under the concrete LAP is as follows:

A laboratory applying for accreditation for the field test methods group only shall—

(a) Monitor the within-test variation of compressive strength test results on cylindrical concrete specimens made from the same sample of field concrete by its personnel using compressive strength test data produced by the compression testing facilities which normally break these specimens for the applicant laboratory (the within-laboratory program); and

(b) Compare with at least one other laboratory on a periodic basis compressive strength test results for cylindrical concrete specimens made by each laboratory from the same sample of field concrete (the between-laboratory program). (Note that after initial curing, a pair of cylindrical concrete specimens made by each cooperating laboratory will be transported to a single compression testing facility for completion of curing, capping, and testing.)

A laboratory applying for accreditation for the field and laboratory test methods group shall—

(a) Monitor the within-test variation of compressive strength test results on cylindrical concrete specimens made and tested by its personnel from the same sample of concrete (the within-laboratory program); and

(b) Compare with at least one other laboratory on a periodic basis compressive strength test results for cylindrical concrete specimens made and tested by each laboratory from the same sample of field concrete (the between-laboratory program).

Carpet LAP. Proficiency tests are proposed for the test methods shown in Appendix 3. Although it is intended that proficiency must be demonstrated for all of these test methods, that may not be feasible if an insufficient number of laboratories request accreditation for a given test method. In such a case, the accreditation would be based only on the information submitted by the laboratory and the on-site examiner's assessment.

Because there are no industry-wide recognized precision and accuracy values for many of the carpet tests, the adequacy of a laboratory's performance will be based on a statistical analysis of the returned proficiency test data. Laboratories exhibiting extreme test data in the statistical analysis will be subject to closer examination during the on-site examination and may be required to perform additional proficiency testing at their cost, or may be denied accreditation.

The frequency of testing for those those test methods requiring proficiency tests is shown in Appendix 3.

(4) Evaluation and Accreditation

An evaluation by NBS of the written information supplied by the laboratory, the on-site examiners' assessment, and any proficiency testing data will form the basis for DOC's decision to accredit an applicant laboratory. NBS evaluators will review the submitted information, the on-site examination report, and the results of any proficiency testing, and make an evaluation of the laboratory for the purpose of recommending the approval, denial, or revocation of accreditation. Each evaluator will be a technical expert in those fields of testing covered by one or more LAPs. For each LAP there will be at least one evaluator thoroughly knowledgeable about the specific test methods included in that LAP and in performing day-to-day laboratory operations. The evaluators will be government employees or NBS contract employees. NBS will be responsible for the professional and technical performance of all evaluators and one of its key considerations in selecting evaluators and on-site examiners will be to minimize potential conflicts of interest.

DOC will make the final accreditation decision based upon the recommedations of NBS and such other considerations as may be appropriate. When the decision is favorable, DOC will issue a certificate of accreditation to the applicant laboratory. Laboratories will be granted accreditation for one year. The yearly accreditation fee must be paid before accreditation can be renewed.

Laboratory Accreditation Criteria

The final general and specific criteria to be used to accredit laboratories that test thermal insulation materials, freshly mixed field concrete, or carpet under the National Voluntary Laboratory Accreditation Program (NVLAP) of the U.S. Department of Commerce (DOC) are set forth below. These criteria have been developed in compliance with the NVLAP procedures (15 CFR Part 7a and Part 7b) and form the basis for accrediting testing laboratories that voluntarily reques this accreditation. These criteria are believed to be appropriate for use in accrediting laboratories which test many other kinds of products should NVLAP be requested in the future to provide such accreditation.

General Criteria

General criteria include characteristics that should be found in reputable testing laboratories. They include general information about a laboratory (e.g., name, address, ownership, management structure); conditions that must be met for accreditation (e.g., agreement to adopt certain policies); and the maintenance of a quality control or a laboratory operations control manual (e.g., written procedures and information addressing the control of staff, physical plant, operational processes, testing control procedures, and quality assurance) for use by laboratory staff in the laboratory.

The minimum information to be included in a laboratory's manual is identified in the specific criteria. In responding to the provisions of the specific criteria, an applicant laboratory develops the minimum written procedures and information necessary for its manual.

For initial and continued accreditation, each applicant shall provide, in writing, information in response to the following provisions:

Criterion G1. *The laboratory has a legally identifiable organizational structure that enables it to develop and maintain a testing capability to perform satisfactorily the functions for which accreditation is sought.*

G1.1 The laboratory shall submit a description of its organization including—

G1.1.1 The name and full address of the laboratory which is seeking accreditation;

G1.1.2 If the laboratory is part of a larger organization, the complete legal name and address of that larger organization;

G1.1.3 Ownership and amanagement structure of the laboratory, including the names and positions of its principal officers and board of directors;

G1.1.4 An outline or organizational chart identifying all key management and supervisory positions in each relevant operation, support, and service unit in the laboratory's functional organization, and defining at least those reporting relationships that are relevant to this accreditation request;

G1.1.5 Position description, including the required qualifications, of the person who has technical responsibility for the laboratory in the testing area(s) for which accreditation is sought; and

G1.1.6 A general description of the laboratory, including its facilities and scope of operation.

G1.2 The laboratory shall submit a statement of any fundamental changes related to the provisions of G1.1 within 30 calendar days of such changes.

Criterion G2. *The laboratory is operated in accordance with generally accepted professional and ethical business practices.*

G2.1 The laboratory shall agree in writing that as a minimum it will be its policy to—

G2.1.1 Perform the tests for which accreditation is sought in accordance with the designated test methods, and to report and explain deviations from those test methods in its test reports;

G2.1.2 Assure that reported values accurately reflect measured data;

G2.1.3 Limit test work to that for which competence and capacity are available;

G2.1.4 Treat test data, records, and reports as proprietary information;

G2.1.5 Respond to and attempt to resolve complaints contesting test results;

G2.1.6 Be capable of performing each test for which it is accredited according to the latest version of each test method within one year after publication or within another time limit specified by the Department of Commerce (DOC);

G2.1.7 Maintain an independent decisional relationship between its clients, affiliates, or other organizations, so that the laboratory's capacity to render test reports objectively and without bias is not adversely affected; and

G2.1.8 Return to DOC its certificate of accreditation, should it become unable to conform to any of these general and specific criteria for accreditation, for possible revision or other action.

Note.—Compliance with criterion G2 will be assessed when a complaint or other evidence, which is received by DOC, questions the accredited laboratory's compliance with this criterion.

Criterion G3. *The laboratory maintains a quality control system to help assure the technical integrity of its work.*

G3.1 The laboratory's quality control system must include a quality control manual or a laboratory operations control manual containing written procedures and information in response to the applicable requirements of the specific criteria. The procedures and information may be explicitly contained in the manual or may be referenced so that their location in the laboratory is clearly identified. The written procedures and information must be adequate to guide a testing technician (who is deemed qualified by the National Bureau of Standards (NBS) or by an NBS contractor) in conducting the tests in accordance with the test methods for which accreditation is sought.

G3.2 The laboratory shall have a current copy of its quality control manual or laboratory operations control manual available in the laboratory for use by laboratory personnel and shall make the manual available for DOC review and audit.

Note.—For NVLAP purposes the terms "quality control manual" and "laboratory operations control manual" are understood as follows. A quality control manual consists of general guidelines for the quality control of the laboratory's method of operation. Specific information is provided for portions of individual test methods whenever specifics are needed to comply with the criteria or otherwise support the laboratory's operations. A laboratory operations control manual consists of specific procedures and information for each test method responding to the applicable requirements of the specific criteria.

Specific Criteria

Specific criteria are those requirements for accreditation which relate specifically to individual test methods. The specific criteria are designed so that they may be applied to all test methods in any NVLAP activity without having to be changed each time a test method is added or revised. Because "universal" language is used, some portions of the specific criteria may not be applicable for all test methods. This is why the words, "as applicable," are used in several places in the specific criteria. For the test methods for which accreditation is sought, "supplemental information" will be sent to each applicant laboratory showing how the specific criteria relate to each of those test methods. The "supplemental information" identifies those sections of the specific criteria that are not applicable, indicates how those sections which are applicable are to be interpreted and implemented, and describes how a laboratory's compliance will be assessed. In essence, the "supplemental information" tailors the specific criteria to the particular characteristics of individual test methods. It will not extend the criteria into new areas and will be revised, as necessary, each time any test method is revised.

The provisions of the specific criteria are the following:

Criterion S1. *The laboratory is staffed by personnel who are competent to perform the tests for which accreditation is sought.*

S1.1 The laboratory shall assure the competency of its staff through the observation and/or examination of each relevant staff member in the performance of each test method or part thereof that each member is assigned to perform. Staff members who perform relatively simple tests at field locations with limited on-site supervision must annually pass an examination supplied by DOC. The observations at the laboratory must be conducted at intervals not exceeding one year by one or more individuals judged qualified by the person who has technical responsibility for the laboratory. In lieu of an annual observation or examination, current approval of staff members by DOC-recognized certification or licensing organizations in areas of competence encompassing these test methods is acceptable.

S1.2 The laboratory shall make available the description of its training program for assuring that new or untrained staff will be able to perform tests properly and uniformly to the requisite degree of precision and accuracy.

S1.3 The laboratory shall maintain in its personnel files—

(a) A record, including dates and results, of the observation or examination of performance for each test method or part thereof for which each staff member is assigned to perform;

(b) Certification of competence, if any, from recognized outside agencies; and

(c) A listing of training courses completed.

Criterion S2. *The laboratory's facilities, equipment, and procedures are appropriate for accreditation.*

S2.1 The laboratory shall maintain a list of its facilities and equipment required for each test method for which accreditation is sought, and, as applicable, a description of those facilities and equipment including—

(a) Sufficient identification of test instruments to allow correlation with calibration records;

(b) Schematics, drawings, diagrams or photographs of equipment and facilities for demonstrating conformance with the requirements of the test method; and

(c) A description of environmental or sample conditioning equipment and facilities showing how compliance with the requirements of the test method is measured and maintained.

S2.2 The laboratory shall provide evidence of the calibration, verification, and maintenance of the facilities and equipment specified for each test method for which accreditation is sought, through the following:

S2.2.1 A description of the procedures used in calibrating, verifying,

and maintaining the test equipment and facilities, including, as applicable—

(a) Calibration and verification equipment or services used;

(b) Reference standards and materials used;

(c) Measurement assurance, collaborative reference, or other programs in which the laboratory participates;

(d) Routine maintenance; and

S2.2.2 Calibration and verification records including, as applicable—

(a) Equipment description or name;

(b) Name of manufacturer;

(c) Model, style, and serial number, or other identification;

(d) Equipment variables subject to calibration and verification;

(e) Range of operation and range of calibration and verification;

(f) Resolution of the instrument and allowable error to tolerances on readings;

(g) Calibration or verification schedule (intervals);

(h) Date and result of last calibration or verification and date of the next calibration or verification;

(i) Name of laboratory person or outside service providing the above calibration or verification; and

(j) Traceability to NBS or other authority as required.

S2.3 The laboratory shall maintain a test plan supplementing each test method for which accreditation is sought which includes, as applicable, instructions for—

(a) Equipment maintenance and verification checks;

(b) Specimen selection, handling, and disposal;

(c) Data collection, analysis, and reporting;

(d) Quality control checks and audits; and

(e) Any subcontractors performing part of the test and a description of how the laboratory assures the required precision and accuracy.

Note.—The intent of this provision, S2.3(e), is to allow subcontractors to perform common repetitive tasks (such as making slides or taking pictures) which are required by certain test methods. However, only laboratories having the measuring equipment by which final test data are obtained can be accredited. If data obtained using one test method in this accreditation program are used as input data for a second test method, or if the test procedures for one test method affects the results obtained in a second test method, a laboratory seeking accreditation for the second method must also be accredited for the first method. An accredited laboratory may not present final test data to a client as data from an accredited laboratory unless the final test data actually were obtained from an accredited laboratory.

S2.4 The laboratory shall maintain, as applicable, documented evidence that no degradation of performance results from the use of equipment, facilities, or procedures which are not in strict conformance with each test method for which accreditation is sought.

Criterion S3. *The laboratory maintains records of its operations.*

S3.1 The laboratory shall maintain records of those testing activities associated with each test method for which accreditation is sought, including the following:

S3.1.1 Test reports containing, as applicable—

(a) Name and address of the laboratory;

(b) Pertinent dates and identifying numbers;

(c) Name of client;

(d) Description and identification of the specimen (including, as necessary, location of the batch, lot, or project of the sampled material from which the specimen was taken);

(e) An appropriate title;

(f) Identification of the test method, procedure, or specification;

(g) Known deviations, additions to, or exclusions from the test method;

(h) Measurements, examinations, derived results, and identification of test anomalies;

(i) If necessary, a statement as to whether or not the test results comply with the requirements of product or project specifications;

(j) Signature of person having technical responsibility for the test report; and

(k) All items required by the test method.

Note.—The laboratory shall make available to DOC, upon request, a typical completed test report with the name of the client and source of any product deleted.

S3.1.2 Data generated during testing if not included in the test report, such as raw data, calculations, tables, graphs, sketches, and photographs; and

S3.1.3 Specimen control forms which document the receipt, handling, storage, shipping, and testing of specimens or a written description of the procedures and separate records that are maintained to control these operations.

S3.2 The laboratory shall have copies of applicable standards and other documents referred to or used in performing each test method for which accreditation is sought.

S3.3 The laboratory shall maintain records of its quality control checks and audits for monitoring its test work including—

(a) Records of audit sampling of the test results; and

(b) Records of detected errors and discrepancies and actions taken subsequent to such detection.

S3.4 The laboratory shall maintain a file of written complaints and disposition thereof.

S3.5 The laboratory shall retain records required by these general and specific criteria for a minimum of three years or for any longer period of time specified by Federal, State, or local requirements or other contractual requirements.

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Appendix 1: Insulation LAP (NVLAP-01)

Operational Information

List of Methods, Performance Guidelines and Proficiency Testing Requirements.

The test methods and performance guidelines for this LAP for thermal insulation materials are shown in Exhibit 1. The tests are the latest versions applicable and are identified by a NVLAP Code Number, a recognized test method number, and a short title. Performance guidelines are given in the column titled, "Desired Precision and Accuracy."

Test methods which require proficiency testing are identified in the column titled, "Test Frequency (Times Per Year)." Samples for these tests will be distributed at the frequency shown. The distribution of samples and analysis of resulting data will be handled by NBS.

The performance guidelines are expressed in terms of repeatability (R), which is a measure of the ability of a laboratory to repeat its own test result on the same or essentially identical samples, and accuracy (A), which is a measure of the ability of a laboratory to obtain a test result in agreement with the "true" or target test result. The limits specified in Exhibit 1 for precision and accuracy are for "good" performance. Approximately 95% of the laboratories should be able to achieve this. Limits approximately 50% wider are used to define "acceptable" performance for accreditation purposes. The limits presented in this Exhibit are for laboratory accreditation purposes only and should not be interpreted as setting specification limits on products.

Values for precision and accuracy are listed in Exhibit 1 for some test methods even though a proficiency test is not required for those tests. This information is given as a guide to the laboratory for assessing its own testing capability in lieu of a proficiency sample. This also represents the level of capability expected by NVLAP of the laboratories performing those tests.

The column labeled "Complexity" showing the letter B followed by the subscript 1, 2 or 3 indicates the complexity of the test method for examination purposes. These are used to determine examination costs and are explained in a separate Federal Register notice describing accreditation fees.

The last column identifies footnote comments listed at the end of Exhibit 1 which pertain to individual test methods.

Exhibit 1

NVLAP Code/ Test Method Number	Complexity	Short Title (property) Subtitle (if applicable)	Desired Precision and Accuracy	Test Frequency (Times per Year)	Comments
01/C01 ASTM C739 (para. 7.7 in 77 version)	B_2	Corrosiveness; Cellulosic fiber (loose-fill)	Non-quantitative test		
01/C02 HH-I-515 (para. 4.8.5 in D version Amendment 1)	B_2	Corrosiveness; Cellulosic fiber (loose-fill)	Non-quantitative test		
01/D01 ASTM C136	B_1	Sieve or screen analysis	R = 4% aggregate A = 4.4% aggregate		
01/D02 ASTM C167	B_1	Thickness and density Blanket & batt	Thickness: A=1/16 in. (1.0 mm) Density: A = 2%		
01/D03 ASTM C209 (para. 6 in 72 version)	B_1	Thickness Board (cellulosic fiber)	A = 0.1 mm		
01/D04 ASTM C209 (para. 13 in 72 version)	B_1	Water absorption, 2 hour Board (cellulosic fiber)	A = 25% of percent water absorption	2	A
01/D05 ASTM C209 (para. 13 in 72 version) by D1037 (para.100-106 in 72 version)	B_1	Water absorption, 24 hour Board (cellulosic fiber)	A = 25% of percent water absorption	2	A
01/D06 ASTM C209 (para. 13 in 72 version) by D1037 (para. 107-110 in 72 version)	B_2	Linear expansion Board (cellulosic fiber)	A = 0.1% expansion		
01/D07 ASTM C272	B_1	Water absorption Core materials	A = 25% of percent water absorption	2	A
01/D08 ASTM C302	B_1	Density Preformed pipe insulation	Thickness: A = 1 mm Density: A = 2%		
01/D09 ASTM C303	B_1	Density Preformed block insulation	A = 2%		
01/D10 ASTM C355	B_2	Water vapor transmission Thick materials Desiccant method	A = 25%	2	

NVLAP Code/ Test Method Number	Complexity	Short Title (property) Subtitle (if applicable)	Desired Precision and Accuracy	Test Frequency (Times per Year)	Comments
01/D11 ASTM C356	B_1	Linear shrinkage Soaking heat Preformed high temperature insulation	R = 0.5% linear shrinkage A = 0.5% linear shrinkage		
01/D12 ASTM C411	B_1	Hot-surface performance High temperature insulation	Warpage: A = 1 mm		
01/D13 ASTM C519	B_2	Density Loose-fill (fibrous)	A = 2%		
01/D14 ASTM C520	B_2	Density Granular loose-fill	A = 2%		
01/D15 ASTM D756	B_2	Weight and shape changes Accelerated service (Proc. A) Plastics	A = 0.5% weight change A = 0.5% linear dimension change A = 1.5% volume change		
01/D16 ASTM D756	B_2	Weight and shape changes Accelerated service (Proc. B) Plastics	Same as for 01/D15		
01/D17 ASTM D756	B_2	Weight and shape changes Accelerated service (Proc. E) Plastics	Same as for 01/D15		
01/D18 ASTM D1622	B_2	Apparent density Rigid cellular plastics	A = 4%		
01/D19 ASTM D2126	B_2	Response to thermal and humid Aging (Proc. B) Rigid cellular plastics	A = 0.5% weight change A = 0.5% linear dimension change		
01/D20 ASTM D2126	B_2	Response to thermal and humid Aging (Proc. D) Rigid cellular plastics	Same as 01/D19		
01/D21 ASTM D2126	B_2	Response to thermal and humid Aging (Proc. E) Rigid cellular plastics	Same as 01/D19		
01/D22 ASTM D2126	B_2	Response to thermal and humid Aging (Proc. F) Rigid cellular plastics	Same as 01/D19		
01/D23 ASTM D2842	B_2	Water absorption Rigid cellular plastics	A = 1.0% absorption (by volume)	2	
01/D24 ASTM C739 (para. 7.5 in 77 version)	B_2	Moisture absorption Cellulosic fiber (loose-fill)	A = 25% percent water absorption	2	B
01/D25 HH-I-515 (para. 4.8.3 in D version Amendment 1)	B_2	Moisture absorption Cellulosic fiber (loose-fill)	A = 25% percent water absorption	2	B

NVLAP Code/ Test Method Number	Complexity	Short Title (property) Subtitle (if applicable)	Desired Precision and Accuracy	Test Frequency (Times per Year)	Comments
01/026 HH-I-515 (para. 4.8.1 in D version Amendment 1)	B_2	Settled density Cellulosic fiber (loose-fill)	A = 3%	2	
01/F01 ASTM D777 as modified by Federal Specification H-H-B-1008	B_1	Flammability Paper and paperboard	Char length: R = 3.6% A = 9.0% Fire Resistance permanence: R = 6% increase in char length A = 10% increase in char length		
01/F02 ASTM E84	B_3	Surface burning characteristics Building materials	Flame spread classification: A = 20% Smoke classification: A = 40%	2	
01/F05 ASTM E136	B_1	Behavior of Materials in a Vertical Tube Furnace	Primarily a non-quantitative test		
01/F06 ASTM C739 (para. 10.4 in 77 version)	B_3	Flame resistance permanency cellulosic fiber (loose-fill)	A = 20% flame spread		
01/F07 HH-I-515 (para. 4.8.7 in D version Amendment 1)	B_3	Critical radiant flux Radiant Panel (cellulosic fiber, loose-fill)	A = 14% R = 20%	2	
01/F08 HH-I-515 (para. 4.8.8 in D version Amendment 1)	B_2	Smoldering combustion cellulosic fiber (loose-fill)	A = 20% R = 20%	2	
01/S01 ASTM C165	B_2	Compressive properties Thermal Insulation Proc. A	A = 4%	2	
01/S02 ASTM C203	B_2	Breaking load/flexural strength Preformed block insulation	Breaking load: A = 2% Flexural strength: A = 10%	2	
01/S03 ASTM C209 (para. 9 in 72 version)	B_2	Transverse strength Board (cellulosic fiber)	A = 4%		C
01/S04 ASTM C209 (para. 10 in 72 version)	B_2	Deflection at specified load Board (cellulosic fiber)	A = 0.2 mm		D

NVLAP Code/ Test Method Number	Complexity	Short Title (property) Subtitle (if applicable)	Desired Precision and Accuracy	Test Frequency (Times per Year)	Comments
01/S05 ASTM C209 (para. 11 in 72 version)	B_2	Tensile strength Parallel to surface Board (cellulosic fiber)	A = 15%		
01/S06 ASTM C209 (para. 12 in 72 version)	B_2	Tensile strength Perpendicular to surface	A = 4%		
01/S07 ASTM C273	B_2	Shear test Sandwich construction	A = 25%		
01/S08 ASTM C446	B_2	Breaking load/modulus of rupture Preformed pipe insulation	Breaking load: A = 2%		
			Modulus of rupture: A = 5%		
01/S09 ASTM D781	B_2	Puncture Test Paperboard and fiberboard	R = 7.3% A = 8.0%		
01/S10 ASTM D828	B_2	Tensile breaking strength Paper and paperboard	R = 5% A = 11%	6	
01/S11 ASTM D1621	B_2	Compressive properties Rigid cellular plastics Proc. A - Crosshead	A = 6%		E
01/T01 ASTM C177	B_3	Thermal transmission properties Low-temperature guarded hot plate	R = 1% A = 4%	2	F
01/T04 ASTM C236	B_3	Thermal conductance Guarded hot box	A = 4%	1	
01/T05 ASTM C335	B_3	Thermal conductivity Pipe insulation	A = 4%	2	
01/T06 ASTM C518	B_3	Thermal transmission properties Heat flow meter	R = 1% A = 4%	2	G
01/T02 ASTM C653	B_2	Thermal resistance (Rec. Practice) Blanket (mineral fiber)	See 01/T01 and 01/T06		H
01/T10 ASTM C687	B_2	Thermal resistance (Rec. Practice) Loose-fill (fibrous)	See 01/T01, 01/T04 and 01/T06		H
01/V02 ASTM D591	B_1	Starch in paper Qualitative test	Non-quantitative test		
01/V03 ASTM D2020	B_1	Mildew (fungus) resistance Paper and paperboard	Non-quantitative test		
01/V04 ASTM E96	B_2	Water vapor transmission Thin sheets Proc. A	R = 19% A = 25%		
01/V05 HH-I-515 (para. 4.8.6 in D version Amendment 1)	B_1	Fungus, Cellulosic fiber (loose-fill)	Non-quantitative test		
01/V06 HH-I-515 (para. 4.8.9 in D version Amendment 1)	B_1	Starch, Cellulosic fiber (loose-fill)	Non-quantitative test		

Footnotes:

A - Accreditation for one or more of 01/D04, 01/D05 and 01/D07 requires proficiency testing in only one of these tests.

B - Accreditation for 01/D24 and 01/D25 requires proficiency testing in only one of these tests.

C - Both 01/S01 and 01/S02 proficiency tests are required for accreditation of any one or all 01/S03, 01/S04, 01/S05, 01/S06, 01/S07 and 01/S08.

D - Eligible for accreditation only if accredited for 01/S03.

E - Accreditation for 01/S11 requires proficiency testing in both 01/S01 and 01/S02.

F - Proficiency test not required if performing proficiency test in 01/T06.

G - Proficiency test not required if performing proficiency test in 01/T01.

H - Eligible for accreditation only if laboratory is accredited for 01/T01, 01/T04 or 01/T06.

Appendix 2: Concrete LAP (NVLAP-02)

Operational Information

List of Test Methods and Test Method Grouping.

The test methods included in this LAP for freshly mixed field concrete are shown in Exhibit 2. The tests are the latest versions applicable and are identified by a NVLAP Code Number, a recognized test method number, and a short title. Because of the interrelationship among test methods, accreditation is granted for two groups of test methods rather than on an individual test method basis. Laboratories may seek accreditation for a Field Group (02/G01) or for a Field and Laboratory Group (02/G02) as identified in Exhibit 2. Each laboratory must have the capability of performing all of the tests in the group selected. ASTM test method C173 (NVLAP 02/A02) is optional and is not required for accreditation in either group. Evaluation of ASTM C173 is available and may be elected at no extra cost.

Exhibit 2

NVLAP Code/ Test Method Number	Short Title	Test Method Group NVLAP Code: Field 02/G01	Test Method Group NVLAP Code: Field and Laboratory 02/G02
02/M01 ASTM C31	Making and Curing Concrete Test Specimens in the Field	X	X
02/M03 ASTM C172	Sampling Fresh Concrete	X	X
02/P01 ASTM C143	Slump of Portland Cement Concrete	X	X
02/W01 ASTM C138	Unit Weight, Yield, and Air Content (Gravimetric) of Concrete	X	X
02/A01 ASTM C231	Air Content of Freshly Mixed Concrete by the Pressure Method	X	X
02/S01 ASTM C39	Compressive Strength of Cylindrical Concrete Specimens		X
02/A02 ASTM C173	Air Content of Freshly Mixed Concrete by the Volumetric Method		

On-Site Examination.

On-site examination for this LAP will be performed by an examining organization selected and appointed by NBS. The Cement and Concrete Reference Laboratory (CCRL) which is sponsored by the American Society for Testing and Materials (ASTM) has been recognized as such an examining organization. The CCRL which has provided inspection service to testing laboratories since 1929, reports its findings directly to the laboratories requesting this service. The CCRL inspection charge is customarily determined by ASTM. However, it is estimated that the cost will be $850 per inspection for the Field Test Method Group and $1000 per inspection for the Field and Laboratory Test Method Group. On-site examinations of NVLAP applicant concrete laboratories will be scheduled as part of the existing CCRL inspection tour. At the present time, the CCRL inspection tour covers all participating laboratories in about two and one half years. Accordingly, applicant laboratories may anticipate this approximate time frame for examination.

Each applicant laboratory inspected by the CCRL since March 1, 1978, will not require reexamination in order to be accredited under the first round of accreditation for the concrete LAP provided that it authorizes review of the recent CCRL inspection report by NVLAP personnel, certifies that any deficiencies noted in the report have been corrected, provides written information confirming compliance with NVLAP criteria, and pays the NVLAP administrative charge of $500 for the concrete LAP.

Those applicants not inspected by CCRL since March 1, 1978, will be contacted by CCRL concerning the scheduling of an on-site examination. All fees associated with the inspection will be collected for the CCRL by ASTM. The CCRL inspection report will be made available for review by NVLAP personnel. The NVLAP administrative charge of $500 for the concrete LAP will be collected separately.

Proficiency Testing Requirements.

The proficiency testing requirement for the concrete LAP is composed of a "within-laboratory program" and a "between-laboratory program" for the compressive strength test.

WITHIN-LABORATORY PROGRAM

Purpose. A within-laboratory program is designed to allow a laboratory to monitor the variability of its test results produced as a normal part of its operations. More specifically, the program provides a means for measuring the ability of a laboratory to repeat its own test result on cylindrical concrete specimens made from a sample of concrete taken from a single batch. This "repeatability" characteristic is commonly referred to in the concrete standards literature as within-test variation. A statistical measure of within-test variation is the coefficient of variation. The paragraphs which

follow outline procedures for calculating the coefficient of variation, and provide guidelines for interpreting the significance of the calculated values. The procedures are based on the Standard Recommended Practice for Evaluation of Strength Test Results of Concrete - American Concrete Institute (ACI) 214-77.

General Procedures. The procedures for carrying out a within-laboratory program are slightly different depending on whether a laboratory applies for accreditation for the Field Test Method Group or for the Field and Laboratory Test Method Group. For the Field Group, each applicant laboratory shall monitor the within-test variation of compressive strength test results on cylindrical concrete specimens made from the same sample of concrete by its personnel using compressive strength test data produced by the compression testing facilities which normally break these specimens for the applicant laboratory. For the Field and Laboratory Group, each applicant laboratory shall monitor the within-test variation of compressive strength test results on cylindrical concrete specimens made and tested by its personnel from the same sample of concrete.

Data Analysis Method. The following method for monitoring within-test variation applies for both test method groups:

(1) Randomly select at least ten tests per week and calculate the difference between the lowest and highest values for the companion cylindrical concrete specimens for each test. If less than ten tests were made in a given week use as many tests as were conducted. A test, as defined by ACI 214, is the average strength of all specimens--usually two or three of the same age fabricated from a sample taken from a single batch of concrete.

(2) Calculate the coefficient of variation (V) for each test using the formula:

$$V = \frac{R \times 1/d_2 \times 100}{\bar{x}} \text{ percent}$$

where: R = difference between the lowest and highest values for the companion cylindrical concrete specimens

$1/d_2$ = conversion factor:
for two companion cylindrical concrete specimens, $1/d_2 = 0.886$
for three companion cylindrical concrete specimens, $1/d_2 = 0.591$

$\bar{x}$ = average strength for the companion cylindrical concrete specimens for each test.

(3) Identify all V's that exceed 10%. Values for the coefficient of variation over 10% should occur no greater than one in twenty tests. If the frequency is greater than one in twenty, the laboratory should check its operations for possible procedural aberrations.

(4) Calculate the average of the coefficient of variation ($\bar{V}$) for all the tests randomly selected each week, using the formula:

$$\bar{V} = \frac{\sum_{1}^{n} V}{n}$$

where: n = number of tests randomly selected for sampling for the week.

(5) Calculate a five week moving average ($\bar{\bar{V}}$) of the weekly averages of the coefficient of variation ($\bar{V}$) for the five most recent weeks, using the formula:

$$\bar{\bar{V}} = \frac{\sum_{x-4}^{x} \bar{V}}{5}$$

where: x = number of weeks that have elapsed since the beginning of the within-laboratory program.

(6) Rate each moving average coefficient of variation ($\bar{\bar{V}}$) as follows:

Rating	$\bar{\bar{V}}$ (%)
Satisfactory (SAT)	below 5.0
Unsatisfactory (UNSAT)	above 5.0

(7) Prepare a table showing at least the following information:

Week Ending	Approximate Number of Tests for Week	No. of Tests Sampled for Week	No. of $\bar{V}$'s Exceeding 10%	$\bar{V}$(%)	$\bar{\bar{V}}$(%)	Rating

This table provides a check on the variability of the laboratory's testing operations. Values for the five week moving average coefficient of variation should not be greater than 5 percent. If they are greater than 5 percent, the laboratory must investigate its operations to find the possible causes for

this wide variation and tighten its quality control accordingly. Actions taken to remove the causes of variation identified must be recorded and filed. Raw data used to compile the table for at least the five most recent weeks must be available for NVLAP audit. (Note: It is recognized that responsibility for within-test variations is shared when others test cylindrical concrete specimens.)

An example of a within-test variation table follows:

Week Ending	Approximate Number of Tests for Week	No. of Tests Sampled for Week	No. of $\bar{V}$'s Exceeding 10%	$\bar{V}$(%)	$\overline{\bar{V}}$(%)	Rating
3/3	85	10	0	4.0		
3/10	110	10	1	6.0		
3/17	100	10	0	3.0		
3/24	125	10	1	5.0		
3/31	115	10	0	3.0	4.2	SAT
4/7	90	10	1	7.0	4.8	SAT
4/14	140	10	3	11.0	5.8	UNSAT
4/21	130	10	1	8.0	6.8	UNSAT
4/28	145	10	1	5.0	6.8	UNSAT
5/5	120	10	0	3.0	6.8	UNSAT
5/12	140	10	0	2.0	5.8	UNSAT
5/19	160	10	0	4.0	4.4	SAT
5/26	180	10	0	2.0	3.2	SAT
6/2	170	10	0	2.0	2.6	SAT

Requirements. The following are the operational requirements for the within-laboratory program:

(1) The laboratory shall have its within-laboratory program implemented within 90 days after the date of application for accreditation.

(2) The laboratory shall document the procedures used to respond to problem areas of testing identified by unsatisfactory ratings under the within-laboratory program.

(3) The laboratory shall submit to NBS a copy of the within-test variation table of figures two times during its operating season with the minimum time between submissions not less than six weeks.

An on-site examiner will verify that the within-laboratory program is documented and operational. Evidence will be sought of timely action taken by the laboratory in responding to unsatisfactory ratings. The on-site examiner may verify the rating obtained by the laboratory by analyzing data sampled from the data pool used by the laboratory in its calculations. Differences in results may lead to the request for data and copies of pertinent documents for further analysis and evaluation at NBS.

BETWEEN-LABORATORY PROGRAM

Purpose. A between-laboratory program is designed to produce, for each cooperating laboratory, information related to the reliability of its test results. By periodically comparing the compressive strength test results obtained by each cooperating laboratory using the same sample of concrete tested at the same age, differences in the test results can be calculated. If such differences are too large (i.e., statistically significant), the cooperating laboratories may reasonably conclude that aberrations are present in the testing procedures of one or the other laboratory, or possibly both laboratories. In such a case, a close review of each cooperating laboratory's testing procedures is warranted so that any aberrations may be identified and corrected. The method outlined under the paragraph titled, "Data Analysis Method," provides a step-by-step procedure for calculating the differences and for interpreting the significance of such calculated values.

General Procedures. The procedures for carrying out a between-laboratory program are slightly different depending on whether a laboratory applies for accreditation for the field test method group or for the field and laboratory test method group (see Exhibit 2). For the Field Group, each applicant laboratory shall compare with at least one other laboratory on a periodic basis compressive strength test results for cylindrical concrete specimens made by each laboratory from the same sample of concrete. After initial curing, a pair of cylindrical concrete specimens made by each cooperating laboratory will be transported to a single compression testing facility for final moist curing, capping, and testing. For the Field and Laboratory Group, each applicant laboratory shall compare with at least one other laboratory on a periodic basis compressive strength test results for cylindrical concrete specimens made and tested by each laboratory from the same sample of concrete.

Each applicant laboratory shall arrange with another laboratory(ies) a periodic schedule for comparing compressive strength test results. For each comparison, the cooperating laboratories shall select a mutually convenient time and project site for obtaining concrete samples. Each sample selected must be large enough for each cooperating laboratory to make two companion cylindrical concrete specimens. The sample must be part of either laboratory's routine work. It is suggested that the laboratories alternate visits to each other's project sites so that the expense of extra trips can be equally shared. For each sample, each cooperating laboratory shall independently mold, cure, transport, ship, store, cap, and test at 7 or 28 days age its pair of cylindrical concrete specimens. The concrete should have a specified nominal compressive strength between 3,000 and 5,000 psi and a slump exceeding two inches.

Data Analysis Method. The following method for two cooperating laboratories making the comparison applies for both test method groups.

(1) Test the two cylindrical concrete specimens in accordance with ASTM C39.

(2) Calculate the average strength ($\bar{X}$).

(3) Calculate the difference, D, between each laboratory's results:

$$D = (\bar{X}_a - \bar{X}_b)$$

where: D = the difference between each laboratory's average strength

$\bar{X}_a$ = average strength of laboratory A's cylindrical concrete specimens

$\bar{X}_b$ = average strength of laboratory B's cylindrical concrete specimens

(Note: Always keep the laboratory identification the same since "D" may be either plus or minus.)

(4) Calculate the average difference of the current and previous 5 comparisons, or the total number of comparisons if fewer than six but more than three as follows:

$$\bar{D} = \frac{\sum D}{n}$$

where: $\bar{D}$ = average difference

$\sum D$ = algebraic sum of differences using the sign of each difference

n = number of differences.

(5) Calculate the standard deviation of "n" differences as follows:

$$S = \left[\left[(\sum D^2) - (\sum D)^2/n\right] \div (n-1)\right]^{1/2}$$

where: $\sum D^2$ = algebraic sum of squared differences.

(Note: These calculations are easily made on inexpensive hand-held calculators.)

(6) Calculate the significant difference, (sig. dif.) as follows:

$$\text{sig. dif.} = \{tS\} \div (n)^{1/2}$$

where: t = Student "t" statistic from Table 1 below.

Table 1. Values of Student "t" at $\alpha = .01$

n	t
3	9.92
4	5.84
5	4.60
6	4.03

(7) Compare the average difference $\bar{D}$ and the significant difference (sig. dif). Conclude that: the cooperating laboratories are probably obtaining significantly different results if the absolute value of $\bar{D}$ exceeds the significant difference (sig. dif.). (Note: $\bar{D}$ and S are recomputed each time a comparison is made and the consecutive values of $\bar{D}$ and S are not statistically independent or random. Therefore, significant differences will be indicated more often than once in 100 ($\alpha = .01$) when no real difference exists. Also, since the values are not statistically independent, there will be a tendency for the magnitude of $\bar{D}$ to exceed sig. dif. on consecutive comparisons.)

(8) Examine the sign of consecutive individual differences D and conclude: (a) that it is likely that the cooperating laboratories are obtaining different results if five consecutive differences have the same sign, and (b) that it is certain that the laboratories are obtaining different results if seven consecutive differences have the same sign.

(9) When new data (after the first six sets of data have been recorded) are obtained, examine each individual difference (D) in a group of seven consecutive differences (D_1 - D_7). If any one of the D values appears to be in gross error use the following method to check your assumption. Using six of the seven D values, not including the D under investigation, calculate the average D and the standard deviation S, as defined in step 5 for the six D values. If the D under investigation differs from the average D by more than 3S, then it can be concluded that a gross error has occurred. This value of D should be recorded but not used in future calculations.

(10) Tabulate the results as follows:

Item	Data
1.	Sample Description
2.	Class Concrete
3.	Lab A, $\bar{X}_a$
4.	Lab B, $\bar{X}_b$
5.	D
6.	$\bar{D}$
7.	S
8.	n
9.	sig. dif.
10.	3S
11.	Action required?

(11) When any excessive differences are detected using the methods in paragraphs 7 ($\bar{D}$ exceeding sig. dif.), 8 (5 to 7 consecutive values of D are the same sign), and 9 (D exceeding 3S), a careful review of each cooperating laboratory's testing procedures must be done to identify any aberrations that may be present. Generally, an additional between-laboratory comparison should be scheduled to verify that aberrations have been eliminated. However, no mandatory rules can be established since either or both laboratories may contribute to the difficulty and the cooperating laboratory may not be an accredited laboratory. In some instances the cause for an errant result may become clearly apparent such as an error in report transcription or an error in labeling a specimen.

"Other" Cooperating Laboratory Qualifications. Each applicant laboratory shall select its "other" cooperating laboratory(ies) which must meet at least one of the following qualifications:

(1) Be a NVLAP accredited laboratory.

(2) Be a nonaccredited commercial testing laboratory.

(3) Be a laboratory administered by a state, municipality, or other governmental agency.

(4) Be a laboratory operated by a representative of a contractor, engineer, architect, concrete producer, or other agency on a job.

(5) Consist of two different laboratories (one of which does the field tests and the other of which does the laboratory tests). The field tests consist of making the cylindrical concrete specimens, providing initial curing, and transporting the specimens to the laboratory. The laboratory tests consist of curing, capping, and testing the cylindrical concrete specimens.

In unusual circumstances under which no other qualified laboratory is available, different groups of employees of the same laboratory can perform as the "other" laboratory provided:

(a) The two groups are employed by different divisions of the same laboratory and report to persons other than those responsible for the supervision and operation of the laboratory seeking accreditation.

(b) The testing operations are carried out separately with initial curing, transporting, stripping, final curing, capping and testing being done by different personnel using facilities and equipment physically remote and clearly distinct from one another.

In circumstances where there is no laboratory with acceptable curing, capping, and testing facilities in a convenient geographical area, it may be necessary for the cooperating laboratories to carefully pack and ship or transport the specimens by truck, bus, or other means to a laboratory with appropriate facilities. Preliminary contacts with individual state highway and transportation departments have indicated that they may be receptive to requests for their participation as an agency to receive, cure, cap, and test cylindrical concrete specimens.

There is no mandatory requirement for the period of time the "other" cooperating laboratory should remain with the accredited laboratory. However, a minimum period of one year is recommended.

Requirements. The following are the operational requirements for the between-laboratory program:

(1) Each applicant laboratory shall implement the between-laboratory program before July 1, 1981.

(2) Each applicant laboratory shall be responsible for obtaining the "other" cooperating laboratory.

(3) Each applicant laboratory shall arrange a comparison test on an average of every six weeks of the laboratory's annual operating season with the maximum period between comparison tests not to exceed ten weeks.

(4) Each applicant laboratory shall submit to NVLAP a copy of the comparison test results table at least once every six months during its operating season. A minimum of two submissions per operating season is required with the minimum time between submissions not less than six weeks.

An on-site examiner will verify that the between-laboratory program is documented and operational. Evidence will be sought of timely actions taken by the laboratory to identify and correct any causes of aberrations. If questions arise regarding the validity of the between-laboratory program, copies of pertinent documents may be requested for further examination and evaluation at NBS.

Appendix 3: Carpet LAP (NVLAP-03)

Operational Information

List of Methods and Proficiency Testing Requirements.

The test methods for this LAP for carpet are shown in Exhibit 3. The tests are the latest versions applicable and identified by a NVLAP Code Number, a recognized test method number, and a short title.

Test methods which require proficiency testing are identified in the column titled, "Test Frequency (Times per Year)." Samples for these tests will be distributed at the frequency shown. The adequacy of a laboratory's performance will be based on a statistical analysis of returned proficiency test data. Laboratories exhibiting extreme test results will be subject to closer examination during the on-site examination and may be required to perform additional proficiency testing at their cost, or may be denied accreditation. The column labeled "Complexity" showing the letter B followed by the subscript 1, 2, 3 or 4 indicates the complexity of the test method for examination purposes. These are used to determine examination costs and are explained in a separate Federal Register notice describing accreditation fees.

Exhibit 3

NVLAP Code/ Test Method Number	Complexity	Short Title Subtitle (if applicable)	Test Frequency (Times per Year)
03/C01 AATCC 16E	B_2	Colorfastness to Light (Xenon Arc)	2
03/C02 AATCC 8	B_1	Colorfastness to Crocking	
03/D01 ASTM D418	B_2	Methods of Testing Woven and Tufted Pile Floor Coverings	
		Pile Weight - Uncoated (Para. 10-19)	
		Pile Weight - Coated (Para. 20-29) as modified by UM 44C	2
		Pile Thickness - (Para. 30-36)	2
		Tuft Height - (Para. 37-45) as modified by UM 44C	
03/D02 DDD-C-95A	B_1	Shrinkage	
03/S01 ASTM D1335 Federal Test Method Standard 191-5100	B_2	Tuft Bind of Floor Coverings Textile Test Method - Breaking Strength	2
191-5950		Textile Test Method - Delamination	2
03/E01 AATCC 134/ CRI 102	B_2	Electrostatic Propensity of Carpets	
03/F01 ASTM E84	B_3	Surface Flammability (Carpet)	x/A
03/F02 UL 992	B_3	Surface Flammability	
03/F03 DoC FF1-70	B_1	Methenamine Pill Test	
03/F04 ASTM E648	B_3	Radiant Panel (Carpet)	2
03/B01 UM 44C Addendum 3	B_3	Attached Cushion Tests	
03/B02 UM 44C Addenda 2 and 3	B_4	Attached Cushion Tests	

/A Proficiency testing requirements dependent on the number of LAPs in which laboratory is enrolled for this test.

Appendix 4: Request for Application

TO RECEIVE A NVLAP APPLICATION PACKAGE COMPLETE THIS FORM (OR A PHOTOCOPY) AND SEND TO:
NVLAP Coordinator
Room 3876
U.S. Department of Commerce
Washington, D.C. 20230

THE NVLAP APPLICATION PACKAGE INCLUDING SUPPLEMENTARY INFORMATION WHICH DESCRIBES REQUIREMENTS FOR NVLAP ACCREDITATION FOR EACH TEST METHOD SHOULD BE SENT TO:

Laboratory Name _____

Street _____

City _____ State _____ Zip Code _____

Attention: (Requestor's Name) _____

CHECK EACH ACCREDITATION PROGRAM AND TEST METHOD LISTED BELOW FOR WHICH INFORMATION IS DESIRED (refer to Appendices 1, 2, and 3 of this notice for the title of each test method). THIS REQUEST POSES NO OBLIGATION TO PARTICIPATE IN THE PROGRAM.

_____ NVLAP 01 - Thermal Insulation Materials

___01/C01	___01/D10	___01/D21	___01/F08	___01/S11
___01/C02	___01/D11	___01/D22	___01/S01	___01/T01
___01/D01	___01/D12	___01/D23	___01/S02	___01/T04
___01/D02	___01/D13	___01/D24	___01/S03	___01/T05
___01/D03	___01/D14	___01/D25	___01/S04	___01/T06
___01/D04	___01/D15	___01/D26	___01/S05	___01/T09
___01/D05	___01/D16	___01/F01	___01/S06	___01/T10
___01/D06	___01/D17	___01/F02	___01/S07	___01/V02
___01/D07	___01/D18	___01/F05	___01/S08	___01/V03
___01/D08	___01/D19	___01/F06	___01/S09	___01/V04
___01/D09	___01/D20	___01/F07	___01/S10	___01/V05
				___01/V06

_____ NVLAP 02 - Freshly Mixed Field Concrete

_____ Field Group - 02/G01 (ASTM C31, C172, C143, C138, C231)

_____ Field and Laboratory Group - 02/G02 (ASTM C31, C172, C143, C138, C231, C39)

_____ 02/A02 (ASTM C173)

_____ NVLAP 03 - Carpet

___03/C01	___03/D02	___03/F01	___03/F04
___03/C02	___03/S01	___03/F02	___03/B01
___03/D01	___03/E01	___03/F03	___03/B02

Signature _____ Phone _____ Date _____

TO BE INCLUDED IN THE UPCOMING ROUND OF ACCREDITATIONS, THIS FORM SHOULD BE MAILED BY FEBRUARY 29, 1980

[FR Doc. 80-2100 Filed 1-22-80; 8:45 am]
BILLING CODE 3510-13-C

National Voluntary Laboratory Accreditation Program; Fees To Accredit Laboratories That Test Thermal Insulation Materials, Freshly Mixed Field Concrete, and Carpet

In a separate notice appearing in this issue of the Federal Register, the Department of Commerce announced the issuance of criteria for accrediting testing laboratories which test thermal insulation materials, freshly mixed field concrete, and carpet. In conformance with paragraph (a) of both section 7a.10 and section 7b.10 of the Procedures for the National Voluntary Laboratory Accreditation Program (NVLAP) (15 CFR Parts 7(a) and 7(b)) and under a delegation of the Secretary of Commerce (41 FR 26593), notice is hereby given of the fees which have been established for the three laboratory accreditation programs (LAPs) (i.e., insulation LAP, concrete LAP, and carpet LAP).

Basis for Fees. The fees are based on the premise that all of the operational costs incurred by the National Bureau of Standards (NBS) in evaluating laboratories seeking accreditation are recovered from fees charged to the applicant laboratories. This includes the work-hours, travel, and per diem costs of examiners and evaluators used in the evaluation process. Administrative costs associated with preparing LAPs, establishing criteria, and developing examination procedures are not recovered from applicants' laboratory fees at this time but are paid from NVLAP's budget of appropriated funds.

The fees will vary depending on: (a) examiner time requirements caused by the complexity of the test methods and (b) the frequency with which the examiners must visit the laboratories in each of the LAPs. In the insulation LAP, for example, laboratory visits are required to be made once a year for the first two years, while for the concrete LAP visits are requird to be made, on the average, only once every two and one-half years. The fees also include a contingency factor to cover the costs associated with conducting unannounced additional visits for up to one-third of the participating laboratories. The purposes of these unannounced visits are to verify the effectiveness of the LAPs by randomly selecting laboratories for reexamination, and also to reexamine those laboratories which have received complaints concerning their performance.

Fees for Evaluating a Laboratory. The NVLAP fee model is composed of several components shown in the following equation:

$$F = A + B_1(N_1) + B_2(N_2) + B_3(N_3) + \ldots C + P$$

Some of these components do not apply for certain LAPs. For identification of those components that apply for every LAP, see Table 1, "Applicability of Cost Components by LAP."

Component A. Component A is a fixed charge that covers NVLAP travel expenses of on-site examiners and preliminary technical review and person-hour costs associated with the LAP operation. The value of the fixed charge A is dependent upon the particular LAP in which the laboratory is involved. For laboratories wishing accreditation for more than one LAP, see the section entitled, "Multiple LAP Enrollment." The values are:

A_1 = $750 per year (insulation LAP)
A_2 = $500 per year (concrete LAP)
A_3 = $350 per year (carpet LAP)

Component B. Component B is a variable charge which covers NVLAP examination and evaluation costs related to each test method for the complete technical review of written information submitted by the laboratory, on-site examination, and the integration of proficiency testing performance results for that test method.

Subscripts 1, 2, 3, and 4 for Component B represent the four levels of complexity into which the test methods fall when considered for examination purposes. The fee per method for the simpler test methods is represented as B_1. N_1 is the number of such test methods. B_2 is the fee per method for test methods of intermediate complexity and N_2 is the number of such test methods. The most complex test methods and the number of each are represented by B_3 and N_3, respectively. B_4 is a fee associated with groups of test methods. The values are:

B_1 = $50
B_2 = $100
B_3 = $150
B_4 = $200

The level of complexity for each test method in the insulation and carpet LAPs is shown in Exhibits 1 and 3 in the appendices to the Federal Register notice referenced in the first sentence of this notice.

Component C. Component C represents the charges associated with laboratory examinations performed by examining organizations selected by NBS. Usually, this cost will be payable directly to the examining organizations by the laboratories being examined. At the present time, the component C charge would be applicable only to the concrete LAP.

The Cement and Concrete Reference Laboratory (CCRL), which is sponsored by the American Society for Testing and Materials (ASTM), is an example of such an examining organization that may be used by NBS. The CCRL which has provided inspection service to testing laboratories since 1929, reports its findings directly to the laboratories requesting this service. NBS plans to use CCRL services for performing the on-site examination function for the concrete LAP. The CCRL inspection charge will ultimately be determined by ASTM. However, it is estimated that the cost will be $850 per inspection for the Field Test Method Group and $1,000 per inspection for the Field and Laboratory Test Method Group. NVLAP on-site examinations of applicant concrete laboratories will be scheduled as part of the existing CCRL inspection tour. At the present time, the CCRL nation-wide inspection tour covers all participating laboratories in about two and one-half years. Accordingly, applicant laboratories may anticipate this approximate time frame for examination.

Each applicant laboratory which has had a CCRL inspection since March 1, 1978 does not have to be reexamined in order to be accredited under the first round of accreditations for the concrete LAP provided that it:

(1) Submits the latest CCRL inspection report and certifies, in a letter from the technical director of the laboratory, or other person who is responsible for the technical operation of the laboratory and who is authorized to so certify, that any deficiencies noted in that report have been corrected;

(2) Provides written information; confirming compliance with NVLAP criteria;

(3) Pays the component A_2, annual NVLAP administrative charge of $500 for the concrete LAP.

Those applicants not inspected by CCRL since March 1, 1978, will be contacted by CCRL concerning the scheduling of an on-site examination. All fees associated with the inspections will be collected for the CCRL by ASTM. The CCRL inspection report will be made available for review by NVLAP personnel. The annual NVLAP administrative charge of $500 (component A_2) will be collected separately.

Component P. Component P represents the charges associated with proficiency testing. These charges cover the cost of samples and their distribution, the analysis of test data supplied by the applicant laboratory, and the reporting of results. Component

P charges are applicable only to the insulation and carpet LAPs.

Proficiency testing services may be provided by NBS itself or by an organization selected by NBS to carry out such services for NVLAP. When proficiency testing services are provided by an organization selected by NBS to carry out such tests for NVLAP, this cost is payable directly to that organization by the applicant laboratory. The NBS/CTS Collaborative Reference Program operated through Collaborative Testing Services, Inc. (CTS), a nonprofit corporation, is an example of such an organization which has been used to provide proficiency samples for the insulation LAP.

The costs associated with proficiency tests are a function of the cost to NVLAP for obtaining appropriate sample materials, distributing the samples, and analyzing test data. The costs in the past for the insulation LAP were $100 per year for each test method requiring proficiency testing. Exhibits 1 and 3 in the appendices of the **Federal Register** announcement cited in the first sentence of this notice identify those test methods for which proficiency testing is required.

Multiple LAP Enrollment. When a laboratory wishes accreditation for more than one LAP, component A, the fixed charge component, will be prorated since many of the administrative costs for each LAP cover the same operations as in other LAPs. The total fixed charge will be determined by selecting the largest component A value from the relevant LAPs and adding 20 percent of the remaining component A values for the other LAPs involved.

If a laboratory requests accreditation for a test method which is essentially the same in two different LAPs (e.g., ASTM E 84 in the insulation and carpet LAPs) there will be no additional cost, with the possible exception for proficiency tests, for the laboratory to be accredited for the test in the second LAP once it is accredited for that test in the first LAP. Component B, the variable charge component, will be applied only once. However, the laboratory must indicate at the time of its application that it wants accreditation for the test method in both LAPs and must be prepared to demonstrate for an on-site examiner the performance of the test for either product. Also, a separate test report for each product must be available (see Criterion S3.1.1 in the **Federal Register** notice cited in the first sentence of this notice). In addition, the laboratory must be prepared to participate in separate proficiency tests if such tests are specified.

Fee Summary. The fee structure distribution is demonstrated by Table 1 for the insulation, concrete, and carpet LAPs. The applicable cost components are shown by the letter X.

Table 1—Applicability of Cost Components

	Components			
	A	B	C	P
Insulation LAP	X	X		X
Concrete LAP	X		X	
Carpet LAP	X	X		X

Example Calculations. In order to illustrate the annual fees for accreditation, the following examples are provided:

Example 1: If a laboratory chooses to be accredited under the insulation LAP only for 5 simple test methods (B_1), 7 intermediate test methods (B_2), and 2 complex test methods (B_3), and if proficiency tests are required for 6 of these 14 test methods at a cost of $100 each per year, the annual fee (F) would be:

$$F = A_1 + B_1(N_1) + B_2(N_2) + B_3(N_3) + P$$

$$F = \$750 + \$50(5) + \$100(7) + \$150(2) + \$100(6) = \$2,600$$

Example 2: If a laboratory chooses to be accredited under the concrete LAP for the field and laboratory groups, the equivalent annual fee (F) would be:

$$F = A_2 + C$$

Where C is the pro-rata share of the CCRL inspection costs ($1,000 ÷ 2.5 = $400), and

$$F = \$500 + \$400 = \$900.$$

Example 3: if a laboratory chooses to be accredited under the carpet LAP for 8 test methods (5 simple test methods and 3 complex test methods for carpet), and if proficiency tests are required for 4 of the 8 test methods at a cost of $100 each per year, the annual fee (F) would be:

$$F = A_3 + B_1(N_1) + B_2(N_2) + P$$

$$F = \$350 + \$50(5) + \$150(3) + \$100(4) = \$1,450$$

Example 4: If a laboratory chooses to be accredited under the insulation and carpet LAPs for 14 test methods (5 simple carpet test methods, 7 intermediate insulation test methods, one complex insulation test method, and one complex carpet test method), and if proficiency tests are required for 6 of the 14 test methods at a cost of $100 each per year, the annual fee (F) would be:

$$F = A_1 + A_3(.20) + B_1(N_1) + B_2(N_2) + B_3(N_3) + P$$

$$F = \$750 + \$350(.20) + \$50(5) + \$100(7) + \$150(2) + \$100(6) = \$2,670$$

Example 5: If a laboratory chooses to be accredited under all three LAPs (insulation, concrete, and carpet) for the following test methods: 4 simple insulation test methods, 5 simple carpet test methods, 7 intermediate insulation test methods, 2 complex insulation test methods, and all concrete test methods in the Field and Laboratory Test Method Group, and if proficiency tests are required for 6 of the 22 test methods at a cost of $100 each per year, the equivalent annual fee (F) would be:

$$F = A_1 + A_3(.20) + A_4(.20) + B_1(N_1) + B_2(N_2) + B_3(N_3) + C + P$$

$$F = \$750 + \$500(.20) + \$350(.20) + \$50(9) + \$100(7) + \$150(2) + \$400 + \$100(6) = \$5,370$$

Inquiries. Any inquiries should be addressed to Dr. Howard I. Forman, Deputy Assistant Secretary for Product Standards, Room 3876, U.S. Department of Commerce, Washington, D.C. 20230, 202–377–3221.

Dated: January 18, 1980.

Jordan J. Baruch,

Assistant Secretary for Science and Technology.

[FR Doc. 80-2101 Filed 1-22-80; 8:45 am]

BILLING CODE 3510-13-M

GUIDE 2

Third edition — 1980-02-15

General terms and their definitions concerning standardization and certification

UDC 006 : 001.4

Ref. No. ISO GUIDE 2-1980 (E)

Descriptors : standardization, certification, standards, standards bodies, reference to standards, vocabulary.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards institutes (ISO member bodies). The work of developing International Standards is carried out through ISO technical committees. Every member body interested in a subject for which a technical committee has been set up has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work.

ISO Guides are intended essentially for internal use in ISO committees or in some cases for the guidance of member bodies when dealing with matters which would not normally be the subject of an International Standard.

ISO Guide 2 was drawn up by ISO/STACO. The first edition, containing a "first series" of terms and definitions (marked with an asterisk in this edition), was circulated to the member bodies for comment in June 1975. The document secured the necessary support of the member bodies, and was subsequently accepted by the ISO Council.

A "second series" of terms and definitions was circulated to the member bodies for comment in January 1977 and, in a revised form, in April 1977. The document secured the necessary support of the member bodies and was subsequently accepted by the ISO Council for publication together with the "first series", in the form of the second edition of ISO Guide 2.

The "third series" was circulated to the member bodies for comment in July 1977 and, in a revised form in May 1978. It was then discussed at the STACO meeting in May 1978 and in CERTICO in July 1978. A revised text was circulated in January 1979 to STACO and CERTICO for approval by correspondence and to all ISO member bodies. It secured general support of the member bodies and was subsequently accepted by the ISO Council for publication together with the first two series, in the form of this third edition of ISO Guide 2.

Printed in Switzerland

GUIDE 2-1980 (E)

General terms and their definitions concerning standardization and certification

0 Introduction

This guide is the third edition of a guide published in 1976. It contains a comprehensive set of general terms concerning standardization and certification. These definitions have been prepared in three steps. As a first step, definitions for some terms were prepared in the United Nations Economic Commission for Europe in close co-operation with ISO, primarily to facilitate the work of the Economic Commission for Europe aimed at the removal of barriers to international trade arising from lack of harmonization of standards or inadequate international application of standards. The terms and definitions from this first series, adopted by ECE and ISO, are marked with an asterisk in the present edition.

The second series of terms and definitions had a general character and was also intended, *inter alia*, to contribute towards mutual understanding between standards bodies and governmental authorities.

As a third step, a series of terms and definitions related to the different types of standards and some aspects of certification were prepared in ISO/STACO and ISO/CERTICO respectively.

The different types of standards defined in this Guide are primarily those for which widely used terms exist and for which definitions are necessary because of evidence of divergent interpretations (for example product standard, performance standard). In some cases, a choice had to be made among several terms which are almost equivalent (see the notes to the definition of the term "basic standard"). In other cases, some concepts were well known, but no generally accepted term was available. It was therefore necessary to find some terms in order to make a distinction, whenever necessary, between such types of standards (for example variety control standard).

The terms commonly in use lay emphasis on elements associated with a variety of approaches, which means that these types do not belong to a single hierarchy of standards. This emphasis is arbitrary in that a standard may often be categorized as being of more than one type. For example, a product standard may simultaneously be a performance standard or a descriptive standard; or it may also be a variety control standard and an interface standard; a basic standard may also be a terminology standard; or a safety standard.

1 Standardization

1.1 General terms

1.1.1 standardization : An activity giving solutions for repetitive application, to problems essentially in the spheres of science, technology and economics, aimed at the achievement of the optimum degree of order in a given context. Generally, the activity consists of the processes of formulating, issuing and implementing standards.

NOTE – An important benefit of standardization is improvement of the suitability of goods and services for their intended purposes.

1.1.2 consensus : General acceptance implying the absence of strong opposition by an important part of the interests concerned to substantial issues.

1.1.3 variety control : The selection of the optimum number of sizes, other characteristics or types of a product, required to meet prevailing needs.

1.1.4 fitness for purpose : The ability of a product, a process or a service to fulfil a defined purpose under specific conditions.

1.1.5 performance characteristic : A characteristic of fitness for purpose in direct relation to the behaviour of the product in use, without [illegible] features related to manufacture.

1.1.6 performance test : A test for assessing a performance characteristic directly or through simulation of the influencing factors occurring in use, sometimes under more severe conditions.

1.1.7 descriptive characteristic : A characteristic of fitness for purpose stating features related to the manufacture of the product (usually describing constructional details with dimensions and material composition).

1.1.8 interchangeability : The suitability of a product (products) to be used in place of another product (products) to fulfil the relevant requirements.

NOTE – The functional aspect of interchangeability is called "functional interchangeability", and the dimensional aspect, "dimensional interchangeability".

1.1.9 compatibility : The suitability of products or systems to be used together under specified conditions to fulfil the relevant requirements without causing unacceptable interactions.

1.1.10 tolerance : The permissible variation of the specified value of a quantity.

NOTES

1 According to needs, "tolerance" may be expressed as :

a) the difference between permissible maximum and minimum values; or

b) the difference between the permissible maximum value and the nominal value, and the difference between the permissible minimum value and the nominal value (plus and minus tolerances).

2 The term "tolerance" also has the meaning of the permissible portion, in a lot, of products not in conformity with the relevant requirements.

1.1.11 code : A symbolic mode agreed upon for representation of objects or concepts. It generally consists of letters, numerals, signs, symbols, colours, or a combination thereof.

NOTE – The term "code" also has the meaning of a compilation of technical or other provisions and in this sense is used in expressions such as "code of practice" or "boiler code".

1.1.12 designation : A name, symbol, code, or a combination thereof identifying products, groups of products or other subjects, concrete or abstract.

1.1.13 marking : Application of indications on a product or on a package primarily for the purpose of identifying the product and/or certain features of the product.

NOTE – Such indications may include : marks of origin, identification marks, marks of conformity, characteristics of the product, etc. Marking may also be applied to equipment employed in transferring a product to the user; for example, dispensers such as petrol pumps.

1.2 Standards and regulations

1.2.1 technical specification* : A document which lays down characteristics of a product or a service such as levels of quality, performance, safety, dimensions. It may include terminology, symbols, testing and test methods, packaging, marking or labelling requirements. A technical specification may also take the form of a code of practice.

1.2.2 standard* : A technical specification or other document available to the public, drawn up with the co-operation and consensus or general approval of all interests affected by it based on the consolidated results of science, technology and experience, aimed at the promotion of optimum community benefits and approved by a body recognized on the national, regional or international level.

NOTES

1 A technical specification which does satisfy all the conditions given in the definition may sometimes be called by other names, for example : "recommendation".

2 In some languages the word "standard" is often used with another meaning than in this definition, and in such cases, it may refer to a technical specification which does not satisfy all the conditions given in the definition, for example : "company standard".

* Terms marked with an asterisk appeared in the first edition.

1.2.2.1 harmonized standards* : Standards of the same scope that have been approved by different standardizing bodies and which are either technically identical or recognized as technically equivalent in practice.

NOTE – Harmonization of standards is generally carried out in order to prevent or eliminate technical barriers to trade in the region of the world in which they are applied.

1.2.2.2 mandatory standard* : A standard of which the application has been made mandatory by a regulation.

1.2.2.3 national standard* : A standard adopted by a national standards body.

1.2.2.4 international standard* : A standard adopted by an international standards organization or in certain cases a technical specification adopted by an international standardizing body.

1.2.2.5 regional standard* : A standard adopted by a regional standards organization or in certain cases a technical specification adopted by a regional standardizing body.

1.2.3 code of practice : A document describing recommended practices for the design, manufacturing, setting up, maintenance or utilization of equipment, installations, structures or products.

NOTE – The term "specification" is currently used in many national standards bodies with the same meaning as the term "technical specification" save that it does not include codes of practice.

1.2.4 regulation* : A binding document which contains legislative, regulatory or administrative rules and which is adopted and published by an authority legally vested with the necessary power.

1.2.5 technical regulation* : A regulation containing or referring to a standard or a technical specification.

NOTE – A technical regulation may be supplemented by technical guidance which outlines some way(s) to fulfil the regulation.

1.2.6 reference to standards* : A method of drafting a regulation in such a way that a detailed statement of technical specifications is replaced in the text by referring to one or more standards.

1.2.6.1 reference to standards by exact identification* : A method of reference to standards by designating one or more specific standards in such a way that later revisions of the standard or standards will not be applied unless the regulation is modified.

NOTE – The standard is usually designated by its title, number and edition or date.

1.2.6.2 reference to standards by undated identification* : A method of reference to standards by designating one or more specific standards in such a way that later revisions of the standard or standards will be applied without the necessity of modifying the regulation.

NOTE – The standard is usually designated only by its title and number.

1.2.6.3 general reference to standards* : A method of reference to standards by referring in a general way to present or future standards.

NOTE – This general way normally means that the relevant regulation includes a general clause so that all the present or future standards in a specific field are regarded as meeting the aim of the regulation.

1.3 Types of standards

1.3.1 basic standard . A standard having a wide ranging coverage or containing general provisions for one particular field.

NOTES

1 A basic standard may function as a standard of direct application, or as a basis for other standards.

2 The term "fundamental standard" is sometimes used to stress the fundamental character of a basic standard.

3 The term "general standard" is sometimes used to stress the general applicability of a basic standard.

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* Terms marked with an asterisk appeared in the first edition.

1.3.2 product standard : A standard specifying some or all of the requirements to be met by a product or a group of products in order to ensure their fitness for purpose.

NOTES

1 A product standard may include, in addition to requirements, directly or by reference, aspects such as terminology, sampling, testing, packaging and labelling, and sometimes processing requirements (process standards as such are covered by the term "code of practice").

2 A product standard can be either complete or not, according to whether it specifies all or only a part of the necessary requirements.

1.3.2.1 performance standard : A product standard specifying requirements for one or more performance characteristics.

1.3.2.2 descriptive standard : A product standard specifying requirements for one or more descriptive characteristics.

1.3.2.3 variety control standard : A standard aimed at variety control, generally containing a series of selected values or attributes of a product.

1.3.3 service standard : A standard specifying some or all requirements to be met by a service in order to ensure its fitness for purpose.

NOTE — Service standards may be established in fields such as dry-cleaning, laundering, hotel trade, car servicing, communication (post, telegraph, telephone), insurance, banking, trading.

1.3.4 safety standard : A standard aimed at the safety of people and goods.

NOTE — A safety standard generally contains requirements based on the optimum assessment of a number of factors, including non-technical factors such as human behaviour, that will lead to the highest practical degree of safety.

1.3.5 interface standard : A standard specifying requirements concerned with the compatibility of products or systems at their points of communication.

1.3.6 standard on supplier's data : A standard containing a list of characteristics for which values or other data are to be stated by the supplier.

1.3.7 terminology standard : A standard concerned exclusively with terms, usually accompanied by their definitions and sometimes by explanatory notes, illustrations, examples, etc.

1.3.8 testing standard : A standard concerned exclusively with test methods, sometimes supplemented with other provisions related to testing, such as sampling, use of statistical methods and sequence of tests.

1.4 Bodies

1.4.1 standardizing body* : A body, governmental or non-governmental, one of whose recognized activities is in the field of standardization.

1.4.1.1 international standardizing body* : A standardizing body whose membership is open to all countries of the world.

1.4.1.2 regional standardizing body* : A standardizing body whose membership is usually limited to certain countries from a given region of the world.

1.4.2 standards body : A standardizing body recognized at national, regional or international level whose principal function, by virtue of its statutes, is the preparation and/or publication of standards and/or approval of standards prepared by other bodies.

1.4.2.1 national standards body* : A nationally recognized body whose principal function at the national level, by virtue of its statutes or the law of the country, is the preparation and/or publication of national standards and/or approval of standards prepared by other bodies. This body is eligible to be the national member of the corresponding international and regional standards organizations.

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* Terms marked with an asterisk appeared in the first edition.

1.4.2.2 international standards organization* : An organization, governmental or non-governmental, whose membership is open to all countries of the world and whose principal function, by virtue of its statutes, is the preparation and/or publication of standards and/or harmonization of the standards of its members.

1.4.2.3 regional standards organization* : An organization, governmental or non-governmental, whose membership is usually limited to certain countries from a given region of the world and whose principal function, by virtue of its statutes, is the preparation and/or publication of standards, and/or the harmonization of the standards of its members.

2 Certification

2.1 Conformity

2.1.1 conformity with standards or technical specifications* : The conformity of a product or a service with all the requirements of specific standards or technical specifications.

2.1.2 administrative procedure for determining conformity* : The administrative measures needed to determine whether or not a product or a service is in conformity with specific standards or technical specifications. It may include administrative arrangements for controlling the frequency and location of testing, for carrying out tests and for supervising the control of quality by producers.

2.1.3 certificate of conformity* : A document attesting that a product or a service is in conformity with specific standards or technical specifications.

2.1.4 mark of conformity* : A mark attesting that a product or a service is in conformity with specific standards or technical specifications.

2.1.5 conformity certification* : The action of certifying by means of a certificate of conformity or mark of conformity that a product or service is in conformity with specific standards or technical specifications.

2.1.6 self-certification* : A form of conformity certification in which one or more manufacturers are responsible for conformity certification of their products with no surveillance from any certification body.

2.2 Systems

2.2.1 certification system* : A system having its own rules of procedure and management, for carrying out conformity certification.

2.2.1.1 national certification system* : Certification system organized and managed by a governmental or non-governmental body on a national level.

2.2.1.2 international certification system* : Certification system organized and managed by a governmental or non-governmental international organization whose membership is open to all countries of the world.

2.2.1.3 regional certification system* : Certification system organized and managed by a governmental or non-governmental regional organization whose membership is usually limited to certain countries from a given region of the world.

2.2.1.4 third party certification system* : A certification system managed by a certification body or under its surveillance.

2.2.1.5 mandatory certification system : A certification system, the application of which has been made mandatory by a regulation.

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* Terms marked with an asterisk appeared in the first edition.

2.2.2 **certification scheme** : Part of a certification system relating to a certain product or group of products to which the same particular rules (such as rules on type testing, assessment of the manufacturer, product surveillance and/or production surveillance) and the same procedure apply.

NOTE – The term "certification program(me)" covers the same concept as "certification scheme".

2.2.3 **certification body*** : An impartial body, governmental or non-governmental, possessing the necessary competence and reliability to operate a certification system, and in which the interests of all parties concerned with the functioning of the system are represented.

2.2.4 **approval** : Declaration by a body vested with the necessary authority that a set of published criteria has been fulfilled.

2.2.5 **type approval** : Approval of a certain product or group of products considered by the approval body as representative for the continuous production.

2.2.6 **access to a certification system** : The opportunity to obtain certification under the rules of the system.

2.2.7 **participation in a certification system** : Status of a certification body which has undertaken the obligations and obtained the rights to certify and accept conformity certification under the rules of the system without taking part in the management of the system.

2.2.8 **membership in a certification system** : Status of a certification body which has undertaken the obligations and obtained the rights to certify and accept conformity certification under the rules of the system and which takes part in the management of the system.

2.2.9 **certification arrangement** : An arrangement which establishes the mutual acceptability of certification systems or related procedures in order to facilitate trade.

* Terms marked with an asterisk appeared in the first edition.

Alphabetical index

ISO/STACO (DRAFT)
May 1980

REPORT FROM THE ISO/STACO AD HOC GROUP ON DEFINITIONS REQUIRED FOR LABORATORY ACCREDITATION PURPOSES

Introduction

The second International Laboratory Accreditation Conference, ILAC/78, held in Washington in October 1978 established a Task Force whose terms of reference included the responsibility of preparing definitions of terms used in laboratory accreditation. In its report to ILAC/79, the Task Force suggested that ISO be invited to participate on a co-operative basis with ILAC in the preparation of these definitions.

ISO Council accepted the proposal and decided that its Standing committee for the study of principles of standardization (ISO/STACO) be requested to assist in the development of definitions required for laboratory accreditation purposes.

Membership

An ad hoc working group of ISO/STACO was established, consisting of

Chairman	Mrs. M. Muller, SII - Israel
Members	Mr. K. Bergholm, Finland
	Mr. A.J. Bryden, Chairman of ILAC 80 - France
	Mr. A. de Chauveron, AFNOR - France
	Mr. R.H. Ford, SABS - South Africa
	Dr. P.G. Forrest, ILAC - U.K.
	Mr. J.A. Gilmour, Chairman ILAC Task Force C, Australi
	Mr. J.P. Leteurtrois, AFNOR - France
	Mr. B. Lindkvist, ILAC - Sweden
	Mr. J.W. Locke, ILAC - USA
	Mr. L. van Rooij, IEC Deputy General Secretary
	Mr. J.E. Ware, BSI - U.K.
	Mr. F. Wilson, ANSI - USA
Observer	Mr. E. Stackelberg, ECF

Report of Meeting

The group met in Geneva on 28-29 May 1980 and agreed on the following proposals:

1. That the terms and their definitions in Annex 1 be adopted by ISO and ILAC and be brought to the attention of the IEC.
2. That they will be published as a part of a new edition of ISO Guide 2 with amendments to the foreword and introduction to Guide 2 set out in Annex 2.
3. That IEC be invited to participate in the preparation of the revised edition of ISO Guide 2 if it so wished.
4. That the United Nations Economic Commission for Europe (ECE) and the General Agreement on Tariffs and Trade (GATT) be informed of this work.

DEFINITIONS OF BASIC TERMS USED IN ACCREDITATION OF TESTING LABORATORIES

(Draft Section 3 of ISO Guide 2)

Explanatory notes.

Note 1. The generic term "accreditation" can cover the recognition of both the technical competence and the impartiality of a testing laboratory or only its technical competence. Accreditation is normally awarded following successful laboratory assessment.

Note 2. An accrediting body may wish to delegate fully or partially the assessment of a testing laboratory to another competent body (assessment agency). Whilst recognizing that this may be a practical solution to extending recognition of testing laboratories, it is essential that such assessment be equivalent to that applied by the accrediting body and that the accrediting body take full responsibility for such extended accreditation. The term "assessment agency" has not been defined because of the wide variety of agreements that may be arranged.

1. testing laboratory: A laboratory which measures, examines, tests, calibrates or otherwise determines the characteristics or performance of materials or products.

2. laboratory accreditation: A formal recognition that a testing laboratory is competent to carry out specific test or specific types of tests.

3. laboratory accreditation system: A system having its own rules of procedure and management, for carrying out laboratory accreditation.

4. accrediting body: A governmental or non governmental body which conducts and administers a laboratory accreditation system and grants accreditation.

5. accredited laboratory: A testing laboratory to which accreditation has been granted.

6. accreditation criteria: A set of requirements used by an accrediting body which a testing laboratory must meet to be accredited.

7. laboratory assessment: Examination of a testing laboratory to evaluate its compliance with specific criteria.

8. laboratory assessor: An individual who carries out some or all functions related to laboratory assessment.

9. test method: A defined technical procedure to determine one or more specified characteristics of a material or product.

10. traceability of the accuracy of measuring instruments: Documented chain of comparison connecting the accuracy of a measuring instrument to other measuring instruments of higher accuracy and ultimately to a primary standard.

11. reference material (RM): A material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus or for the verification of a measurement method. (Definition taken from ISO Guide 6 but without the Note appearing therein).

12. proficiency testing: Methods of checking laboratory testing performance by means of interlaboratory tests.

13. test report: A document which presents the test results and other information relevant to the test.

14. accredited laboratory test report: A test report which includes a statement by the testing laboratory that it is accredited for the test reported and that the test has been performed in accordance with the conditions prescribed by the accrediting body.

15. approved signatory: A person recognized by an accrediting body to sign accredited laboratory test reports.

Annex 2 to
ISO/STACO (DRAFT)

DRAFT ADDITIONS TO ISO GUIDE 2 - 1980 "GENERAL TERMS AND THEIR DEFINITIONS CONCERNING STANDARDIZATION AND CERTIFICATION".

If the terms and definitions in Annex 1 are approved for introduction into ISO Guide 2, the following additions are proposed to the third edition (1980-02-15) of the Guide:

Title. - Amend to read:
"General terms and their definitions concerning standardization, certification and testing laboratory accreditation".

Foreword. - Add the following paragraphs:
A "fourth series" (section 3 of the Guide) includes terms and definitions related to the accreditation of testing laboratories, prepared by a STACO ad hoc Group in co-operation with the International Conference on Laboratory Accreditation (ILAC). [It was circulated to Member bodies for comments in July 1980 and was presented to the ILAC 80 Conference in Paris in October 1980. It was then discussed at the STACO meeting in November 1980, as a result of which ... (to be completed in due course)...]

Introduction.

- Amend the first two sentences of the first paragraph, to read:
"This Guide is the fourth edition of a guide published in 1976. It contains a comprehensive set of general terms concerning standardization, certification and testing laboratory accreditation".

- Add the following two paragraphs:
"The fourth stage was the preparation of terms and definitions related to testing laboratory accreditation by ISO/STACO and ILAC.

Laboratory accreditation is frequently confused with product certification. Laboratory accreditation is simply a formal recognition that a testing laboratory is competent to carry out specific tests or specific types of tests. It is not concerned with product certification".

Addition of Section 3.

Annex 1, including the explanatory notes would be inserted under the heading
"3.Accreditation of testing laboratories"
and the terms numbered 3.1 to 3.15, with corresponding entries in the alphabetical index of the Guide.