

PAC Form 1 will no longer require the addition of the inspection certificate number on it. In addition, PAC Forms 7 and 7(c) will not be required from handlers wishing to be approved handlers of immature papayas. In the absence of mandatory inspection, no handlers will be required to apply for approval to handle immature papayas using PAC Form 7 nor report shipments of immature papayas to the committee using PAC Form 7(c). This rule will decrease the burden by 9.25 hours.

The Department has not identified any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule.

In addition, the committee's meetings were widely publicized throughout the papaya industry and all interested persons were encouraged to attend the meetings and participate in committee deliberations on all issues. Like all committee meetings, the December 28, 2000, and the subsequent January 11, 2001, meetings were public meetings and all entities, both large and small, were encouraged to express views on this issue. The committee itself is comprised of 13 members, consisting of nine producer members and three handlers members. The committee also includes a public member who does not represent an agricultural interest nor have a financial interest in papayas. Finally, interested persons are invited to submit information on the regulatory and informational impacts of this action on small businesses.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at the following web site: <http://www.ams.usda.gov/fv/moab.html>. Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant matters presented, including the information and recommendation submitted by the committee and other available information, it is hereby found that the suspensions and revision made by this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect, and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) This rule needs to be in effect as soon as possible to continue to

provide relief to the Hawaii papaya industry; (2) this action reflects the emergency recommendation of the committee and the Department's assessment of the industry; and (3) this rule provides a 60-day comment period and any comments received will be considered prior to finalization of this rule.

#### List of Subjects in 7 CFR Part 928

Marketing agreements, Papayas, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 928 is amended as follows:

#### **PART 928—PAPAYAS GROWN IN HAWAII**

1. The authority citation for 7 CFR part 928 continues to read as follows:

**Authority:** 7 U.S.C. 601–674.

#### **§§ 928.150, 928.152, 928.313 [Suspended]**

2. Sections 928.150, 928.152, and 928.313 are indefinitely suspended in their entirety.

3. In § 928.160, paragraph (a)(1) is revised to read as follows:

#### **§ 928.160 Utilization reports.**

(a) \* \* \*

(1) Quantity of papayas handled subject to assessments including the date and destination of each shipment;

\* \* \* \* \*

Dated: May 21, 2001.

**Kenneth C. Clayton,**

*Acting Administrator, Agricultural Marketing Service.*

[FR Doc. 01–13472 Filed 5–29–01; 8:45 am]

**BILLING CODE 3410–02–P**

#### **DEPARTMENT OF COMMERCE**

#### **National Institute of Standards and Technology**

#### **15 CFR Part 285**

**[Docket No.: 000831249–1129–02]**

**RIN 0693–ZA39**

#### **National Voluntary Laboratory Accreditation Program; Operating Procedures**

**AGENCY:** National Institute of Standards and Technology, Commerce.

**ACTION:** Final rule.

**SUMMARY:** The Director of the National Institute of Standards and Technology (NIST), United States Department of Commerce, is today issuing a final rule revising regulations found at 15 CFR

part 285 pertaining to the operation of the National Voluntary Laboratory Accreditation Program (NVLAP). The NVLAP procedures are revised to ensure continued consistency with international standards and guidelines currently set forth in the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025:1999, *General requirements for the competence of testing and calibration laboratories*, and ISO/IEC Guide 58:1993, *Calibration and testing laboratory accreditation systems—General requirements for operation and recognition*, thereby facilitating and promoting acceptance of test and calibration results between countries to avoid barriers to trade. Provisions in this regard will facilitate cooperation between laboratories and other bodies, assist in the exchange of information and experience and in the harmonization of standards and procedures, and establish the basis for national and international mutual recognition arrangements.

In addition, NIST is reorganizing and simplifying part 285 for ease of use and understanding. While the existing regulations accurately set forth the NVLAP procedures, the regulations themselves are complex and difficult to understand. In an effort to simplify the format and make the regulations more user friendly, NIST is rewriting in plain English and consolidating sections previously contained in subparts A through C of part 285.

**DATES:** This rule is effective June 29, 2001.

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

**FOR FURTHER INFORMATION CONTACT:** David F. Alderman, Chief, National Voluntary Laboratory Accreditation Program, 301–975–4016.

#### **SUPPLEMENTARY INFORMATION:**

#### **Background**

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

The NVLAP procedures were first published in the **Federal Register** as part 7 of title 15 of the Code of Federal Regulations (CFR) (41 FR 8163, February 25, 1976). On June 2, 1994, the procedures were redesignated as part 285 of title 15 of the CFR, expanded to

include accreditation of calibration laboratories, and updated to be compatible with conformity assurance and assessment concepts, including the provisions contained in ISO/IEC Guide 25:1990, *General requirements for the competence of calibration and testing laboratories* (59 FR 22742, May 3, 1994).

#### Description and Explanation of Proposed Changes

The NVLAP procedures found at 15 CFR Part 285 are revised to ensure continued consistency with international standards and guidelines. At this time, the management and technical requirements of the new standard, ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories*, and the internationally accepted requirements for accrediting bodies, including those found in ISO/IEC Guide 58:1993, *Calibration and testing laboratory accreditation systems—General requirements for operation and recognition*, are applicable; however, the revisions include provisions allowing for updated versions and replacements of these documents. ISO/IEC 17025:1999 supersedes and replaces ISO/IEC Guide 25:1990, upon which the current NVLAP accreditation criteria are based.

In addition, NIST is reorganizing and simplifying part 285 for ease of use and understanding. While the existing regulations accurately set forth the NVLAP procedures, the regulations themselves are complex and difficult to understand. In an effort to simplify the format and make the regulations more user friendly, NIST is rewriting in plain English and consolidating sections previously contained in subparts A through C of part 285. Since the consolidated format does not require subparts, NIST is removing subparts A through C. The removal of these subparts will not alter the operations of NVLAP, but will promote ease of use and facilitate understanding of the program's operations.

To ensure continued consistency with applicable international standards and guidelines, NIST is removing subpart D, Conditions and Criteria for Accreditation, and is applying the conditions and criteria contained in the applicable internationally accepted documents as they are revised from time to time, as set forth in new section 285.14, Criteria for Accreditation.

#### Summary of Comments

On November 7, 2000, the National Institute of Standards and Technology published a notice of proposed rulemaking in the **Federal Register** (65

FR 66659). In response, four letters were received from operators of NVLAP-accredited testing laboratories. The respondents applauded NIST's efforts to revise NVLAP procedures to ensure consistency with ISO/IEC standards and guides and make several specific recommendations, which are addressed below.

*Comment.* The four respondents noted that the proposed rule references the term *NVLAP* as a federally registered certification mark, and stated that this is the first instance they had ever seen the mark of an accreditation body referred to as a certification mark and also one that is federally registered. The respondents recommended that an explanation be given on why this reference is made and what its impact will be on NVLAP-accredited laboratories.

*Response:* The name "National Voluntary Laboratory Accreditation Program" and the acronym "NVLAP" have been in use since the announcement of the formal inception of the program on February 25, 1976. The NVLAP logo was first used in interstate commerce on March 17, 1980, and was first registered with the U.S. Patent and Trademark Office as a certification mark on March 22, 1983. Application for registration of the term *NVLAP* as a certification mark was filed with the U.S. Patent and Trademark Office on November 30, 2000. Registration of the term *NVLAP* is meant to strengthen NIST's rights in the mark. The registration will have no impact on NVLAP-accredited laboratories.

The final rule, section 285.3, Referencing NVLAP accreditation, states: "NIST reserves the right to control the quality of the use of term *NVLAP* and of the logo itself." Control of the term and the logo benefits NVLAP-accredited laboratories by promoting confidence that test and calibration reports endorsed with these certification marks will be accepted by economies throughout the world.

*Comment:* Three respondents wrote that under the proposed new regulations, the termination of a LAP rests with the Chief of NVLAP, and that current regulations require the determination to be made by the Director. Concern was expressed that the proposed rule removes a layer of approval needed to terminate a LAP and leaves the decision solely in the hands of the Chief of NVLAP.

*Response.* There is no change to current regulations, which already state that the Chief of NVLAP may terminate a LAP when the Chief of NVLAP determines that a need no longer exists to accredit laboratories for the services

covered under the scope of the LAP. The final rule that amended the NVLAP procedures by replacing the Director of NIST with the Chief of NVLAP in § 285.19(a) and (c), was published in the **Federal Register** (64 FR 59616) on November 3, 1999, and became effective on that date. The regulations were amended to conform with the delegation of authority at NIST. Subsequently, on November 18, 1999, a NVLAP Policy Guide (PG-3-1999) was published to notify all NVLAP-enrolled laboratories of the change in the regulations, reflecting the delegation of certain designated authorities.

*Comment.* The respondents stated that under the proposed regulation it appears that renewal responsibilities have been shifted entirely to the accredited laboratory. The respondents recommended that the proposed regulations be clarified to indicate who has the responsibility for initiating the renewal of a laboratory's accreditation.

*Response.* NVLAP will continue to notify accredited laboratories when it is time to renew their accreditations; there will be no change in the renewal process. The regulations were simplified and reorganized for the purposes presented in the Summary of this notice and, therefore, no longer describe in detail the steps of the accreditation process. Renewing laboratories will continue to be sent a renewal application package before the expiration date of their accreditations to allow sufficient time to complete the renewal process. (See Section 3.6.1 of NIST Handbook 150, 2001 Edition.)

*Comments.* Three respondents expressed concern about the addition of § 285.12, Monitoring visits, to the regulation, stating that the problem with unannounced monitoring visits by any accreditation body of an unlimited scope is the major disruption of the normal operations of the laboratory. These respondents requested that NVLAP reconsider the type of items that would be appropriate for unannounced monitoring visits and those that would be appropriate for announced monitoring visits and reduce them to a written list.

*Response.* NIST added § 285.12 to the revised rule to be consistent with NVLAP's actual practice and current procedures, which were previously set forth in the 1994 edition of NIST Handbook 150, Sec. 285.22(b)(6), Monitoring visits. This procedure has been added to the regulations to better notify the public of NVLAP's procedures.

Use of the term "monitoring visit" dates back to 1982, when NIST published a notice in the **Federal**

**Register** to update its announcement of the availability of laboratory accreditation programs for certain fields of testing (44 FR 9492, March 5, 1982). Under Supplementary Information, Unannounced Visits, this notice stated:

\* \* \* "In addition to regularly scheduled laboratory visits, unannounced visits \* \* \* may be initiated \* \* \*" (45 FR 5572-5598). Experience has shown that in order to insure the availability of management and staff to demonstrate equipment and perform tests, a call to the laboratory from one day to one week before the visit may be necessary. Therefore, in the future these unannounced visits will be known as "monitoring visits" which may or may not be announced in advance of the visit. Monitoring visits may occur at any time. These visits may be initiated based on random selection or in response to a specific need because, in the opinion of DOC, the laboratory appears to have a testing problem. In general, a complete review of the laboratory is not contemplated for the monitoring visit. In the case of randomly selected visits, key aspects of the laboratory will be checked. In the case of visits due to an apparent problem, aspects relating to the problem, and possibly other selected key aspects as well, will be checked.

Surveillance of laboratories is a requirement of ISO/IEC Guide 58:1993, clause 6.7. NVLAP anticipates that this requirement will be expanded to include "short notice visits" when ISO/IEC Guide 58 is replaced by ISO/IEC 17011, *General requirements for bodies providing assessment and accreditation of conformity assessment bodies* (now in draft status). NVLAP will continue to minimize disruptions to laboratories during on-site visits.

*Comments.* The four respondents stated that the due process protections under § 285.13, Denial, suspension, revocation or termination of accreditation, have been changed substantially from the current regulations, including the elimination of consultation with the laboratory prior to suspension. The respondents also said that it appears there is no recourse for a laboratory if it feels that it has been treated unfairly by the NVLAP auditor.

*Response.* The phrase "after consultation with the laboratory" was removed because consultation is defined as a seeking of opinion or advice and is, therefore, an inappropriate choice of words for this requirement. There are many cases where consultation prior to suspension is inappropriate, such as the failure of an accredited laboratory to pass two rounds of proficiency testing within a set of three consecutive rounds in the Bulk Asbestos Fiber Analysis LAP. In this example, suspension is immediate and automatic because the laboratory failed to meet the program proficiency

testing requirement. (See NIST Handbook 150-3 (1994): NVLAP Bulk Asbestos Analysis).

Under section 285.13(b)(1) of the revised rule, NVLAP will continue to clearly state its requirements, to notify a laboratory of the reasons for and conditions of the suspension, and to specify the action(s) the laboratory must take to have its accreditation reinstated. Except for the deletion of the term "consultation," the procedures contained in § 285.13 of the revised rule remain the same as those contained in section 285.24(c) of the 1994 rule. Some minor changes were made to harmonize the wording of the proposed rule with NVLAP Policy Guide PG-2-1998, *Accreditation Documents for Laboratories Whose Accreditation Has Been Suspended, Revoked, or Otherwise Terminated*, issued to NVLAP-accredited laboratories on May 29, 1998.

If a laboratory feels that it has been treated unfairly by a NVLAP assessor, the laboratory may state its grievance in its response to the assessment report or in a letter of complaint to NVLAP. Complaints from laboratories are addressed in accordance with NVLAP's quality system procedure for complaints, disputes and appeals, which applies to complaints concerning the handling of accreditation matters from laboratories or from users of NVLAP accredited laboratories. Copies of this procedure may be obtained pursuant to § 285.15(a) of the revised regulation.

#### **Paperwork Reduction Act**

The information collection requirements contained in this rule have been approved by the Office of Management and Budget under the Paperwork Reduction Act and have been assigned OMB control number 0693-0003.

#### **Executive Order 12866**

This notice has been determined to be not significant for purposes of Executive Order 12866.

#### **Regulatory Flexibility Act**

The Chief Counsel for Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities for the following reasons: (1) The regulation is procedural and has no impact on any entity unless that entity chooses to participate, in which case, the cost to any participant is the same, small cost (\$500/application, other associated costs cannot be projected

because they are dependent upon the LAP in which an entity is participating, and in some cases LAPs have not yet been established) for any size participant; (2) access to NVLAP's accreditation system is not conditional upon the size of a laboratory or membership of any association or group, nor are there undue financial conditions to restrict participation; and (3) the technical components of NVLAP, that is, the specific technical criteria that individual laboratories are accredited against, are not significantly changed by this rule.

#### **List of Subjects in 15 CFR Part 285**

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

Dated: May 22, 2001.

**Karen H. Brown,**  
Deputy Director.

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

#### **PART 285—NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM**

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

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

2. Part 285 is revised to read as follows:

#### **PART 285—NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM**

- Sec.
- 285.1 Purpose.
  - 285.2 Confidentiality.
  - 285.3 Referencing NVLAP accreditation.
  - 285.4 Establishment of laboratory accreditation programs (LAPs) within NVLAP.
  - 285.5 Termination of a LAP.
  - 285.6 Application for accreditation.
  - 285.7 Assessment.
  - 285.8 Proficiency testing.
  - 285.9 Granting accreditation.
  - 285.10 Renewal of accreditation.
  - 285.11 Changes to scopes of accreditation.
  - 285.12 Monitoring visits.
  - 285.13 Denial, suspension, revocation or termination of accreditation.
  - 285.14 Criteria for accreditation.
  - 285.15 Obtaining documents.

#### **§ 285.1 Purpose.**

The purpose of part 285 is to set out procedures and general requirements under which the National Voluntary Laboratory Accreditation Program (NVLAP) operates as an unbiased third party to accredit both testing and calibration laboratories. Supplementary technical and administrative

requirements are provided in supporting handbooks and documents as needed, depending on the criteria established for specific Laboratory Accreditation Programs (LAPs)

#### § 285.2 Confidentiality.

To the extent permitted by applicable laws, NVLAP will protect the confidentiality of all information obtained relating to the application, on-site assessment, proficiency testing, evaluation, and accreditation of laboratories.

#### § 285.3 Referencing NVLAP accreditation.

The term *NVLAP* (represented by the NVLAP logo) is a federally registered certification mark of the National Institute of Standards and Technology and the federal government, who retain exclusive rights to control the use thereof. Permission to use the term and/or logo is granted to NVLAP-accredited laboratories for the limited purposes of announcing their accredited status, and for use on reports that describe only testing and calibration within the scope of accreditation. NIST reserves the right to control the quality of the use of the term *NVLAP* and of the logo itself.

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

NVLAP establishes LAPs in response to legislative actions or to requests from private sector entities and government agencies. For legislatively mandated LAPs, NVLAP shall establish the LAP. For requests from private sector entities and government agencies, the Chief of NVLAP shall analyze each request, and after consultation with interested parties through public workshops and other means shall establish the requested LAP if the Chief of NVLAP determines there is need for the requested LAP.

#### § 285.5 Termination of a LAP.

(a) The Chief of NVLAP may terminate a LAP when he/she determines that a need no longer exists to accredit laboratories for the services covered under the scope of the LAP. In the event that the Chief of NVLAP proposes to terminate a LAP, a notice will be published in the **Federal Register** setting forth the basis for that determination.

(b) When a LAP is terminated, NVLAP will no longer grant or renew accreditations following the effective date of termination. Accreditations previously granted shall remain effective until their expiration date unless terminated voluntarily by the laboratory or revoked by NVLAP. Technical expertise will be maintained

by NVLAP while any accreditation remains effective.

#### § 285.6 Application for accreditation.

A laboratory may apply for accreditation in any of the established LAPs. The applicant laboratory shall provide a completed application to NVLAP, pay all required fees and agree to certain conditions as set forth in the NVLAP Application for Accreditation, and provide a quality manual to NVLAP (or a designated NVLAP assessor) prior to the assessment process.

#### § 285.7 Assessment.

(a) *Frequency and scheduling.* Before initial accreditation, during the first renewal year, and every two years thereafter, an on-site assessment of each laboratory is conducted to determine compliance with the NVLAP criteria.

(b) *Assessors.* NVLAP shall select qualified assessors to evaluate all information collected from an applicant laboratory pursuant to § 285.6 of this part and to conduct the assessment on its behalf at the laboratory and any other sites where activities to be covered by the accreditation are performed.

(c) *Conduct of assessment.* (1) Assessors use checklists provided by NVLAP so that each laboratory receives an assessment comparable to that received by others.

(2) During the assessment, the assessor meets with management and laboratory personnel, examines the quality system, reviews staff information, examines equipment and facilities, observes demonstrations of testing or calibrations, and examines tests or calibration reports.

(3) The assessor reviews laboratory records including resumes, job descriptions of key personnel, training, and competency evaluations for all staff members who routinely perform, or affect the quality of the testing or calibration for which accreditation is sought. The assessor need not be given information which violates individual privacy, such as salary, medical information, or performance reviews outside the scope of the accreditation program. The staff information may be kept in the laboratory's official personnel folders or separate folders that contain only the information that the NVLAP assessor needs to review.

(4) At the conclusion of the assessment, the assessor conducts an exit briefing to discuss observations and any deficiencies with the authorized representative who signed the NVLAP application and other responsible laboratory staff.

(d) *Assessment report.* At the exit briefing, the assessor submits a written

report on the compliance of the laboratory with the accreditation requirements, together with the completed checklists, where appropriate.

(e) *Deficiency notification and resolution.* (1) Laboratories are informed of deficiencies during the on-site assessment, and deficiencies are documented in the assessment report (see paragraph (d) of this section).

(2) A laboratory shall, within thirty days of the date of the assessment report, provide documentation that the specified deficiencies have either been corrected and/or a plan of corrective actions as described in the NVLAP handbooks.

(3) If substantial deficiencies have been cited, NVLAP may require an additional on-site assessment, at additional cost to the laboratory, prior to granting accreditation. All deficiencies and resolutions will be subject to thorough review and evaluation prior to an accreditation decision.

(4) After the assessor submits their final report, NVLAP reviews the report and the laboratory's response to determine if the laboratory has met all of the on-site assessment requirements.

#### § 285.8 Proficiency testing.

(a) NVLAP proficiency testing is consistent with the provisions contained in ISO/IEC Guide 43 (Parts 1 and 2), Proficiency testing by interlaboratory comparisons, where applicable, including revisions from time to time. Proficiency testing may be organized by NVLAP itself or a NVLAP-approved provider of services. Laboratories must participate in proficiency testing as specified for each LAP in the NVLAP program handbooks.

(b) *Analysis and reporting.* Proficiency testing data are analyzed by NVLAP and reports of the results are made known to the participants. Summary results are available upon request to other interested parties; e.g., professional societies and standards writing bodies. The identity and performance of individual laboratories are kept confidential.

(c) *Proficiency testing deficiencies.* (1) Unsatisfactory participation in any NVLAP proficiency testing program is a technical deficiency which must be resolved in order to obtain initial accreditation or maintain accreditation.

(2) Proficiency testing deficiencies are defined as, but not limited to, one or more of the following:

(i) Failure to meet specified proficiency testing performance requirements prescribed by NVLAP;

(ii) Failure to participate in a regularly scheduled "round" of proficiency

testing for which the laboratory has received instructions and/or materials;

(iii) Failure to submit laboratory control data as required; and

(iv) Failure to produce acceptable test or calibration results when using NIST Standard Reference Materials or special artifacts whose properties are well-characterized and known to NIST/NVLAP.

(3) NVLAP will notify the laboratory of proficiency testing deficiencies and actions to be taken to resolve the deficiencies. Denial or suspension of accreditation will result from failure to resolve deficiencies.

#### **§ 285.9 Granting accreditation.**

(a) The Chief of NVLAP is responsible for all NVLAP accreditation actions, including granting, denying, renewing, suspending, and revoking any NVLAP accreditation.

(b) Initial accreditation is granted when a laboratory has met all NVLAP requirements. One of four accreditation renewal dates (January 1, April 1, July 1, or October 1) is assigned to the laboratory and is usually retained as long as the laboratory remains in the program. Initial accreditation is granted for a period of one year; accreditation expires and is renewable on the assigned date.

(c) Renewal dates may be reassigned to provide benefits to the laboratory and/or NVLAP. If a renewal date is changed, the laboratory will be notified in writing of the change and any related adjustment in fees.

(d) When accreditation is granted, NVLAP shall provide to the laboratory a Certificate of Accreditation and a Scope of Accreditation,

#### **§ 285.10 Renewal of accreditation.**

(a) An accredited laboratory must submit both its application for renewal and fees to NVLAP prior to expiration of the laboratory's current accreditation to avoid a lapse in accreditation.

(b) On-site assessments of currently accredited laboratories are performed in accordance with the procedures in § 285.7. If deficiencies are found during the assessment of an accredited laboratory, the laboratory must follow the procedures set forth in § 285.7(e)(2) or face possible suspension or revocation of accreditation.

#### **§ 285.11 Changes to scope of accreditation.**

A laboratory may request in writing changes to its Scope of Accreditation. If the laboratory requests additions to its Scope, it must meet all NVLAP criteria for the additional tests or calibrations, types of tests or calibrations, or

standards. The need for an additional on-site assessment and/or proficiency testing will be determined on a case-by-case basis.

#### **§ 285.12 Monitoring visits.**

(a) In addition to regularly scheduled assessments, monitoring visits may be conducted by NVLAP at any time during the accreditation period. They may occur for cause or on a random selection basis. While most monitoring visits will be scheduled in advance with the laboratory, NVLAP may conduct unannounced monitoring visits.

(b) The scope of a monitoring visit may range from checking a few designated items to a complete review. The assessors may review deficiency resolutions, verify reported changes in the laboratory's personnel, facilities, or operations, or administer proficiency testing, when appropriate.

#### **§ 285.13 Denial, suspension, revocation, or termination of accreditation.**

(a) A laboratory may at any time voluntarily terminate its participation and responsibilities as an accredited laboratory by advising NVLAP in writing of its desire to do so.

(b) If NVLAP finds that an accredited laboratory does not meet all NVLAP requirements, has violated the terms of its accreditation, or does not continue to comply with the provisions of these procedures, NVLAP may suspend the laboratory's accreditation, or advise of NVLAP's intent to revoke accreditation.

(1) If a laboratory's accreditation is suspended, NVLAP shall notify the laboratory of that action stating the reasons for and conditions of the suspension and specifying the action(s) the laboratory must take to have its accreditation reinstated. Conditions of suspension will include prohibiting the laboratory from using the NVLAP logo on its test or calibration reports, correspondence, or advertising during the suspension period in the area(s) affected by the suspension.

(2) NVLAP will not require a suspended laboratory to return its Certificate and Scope of Accreditation, but the laboratory must refrain from using the NVLAP logo in the area(s) affected until such time as the problem(s) leading to the suspension has been resolved. When accreditation is reinstated, NVLAP will authorize the laboratory to resume testing or calibration activities in the previously suspended area(s) as an accredited laboratory.

(c) If NVLAP proposes to deny or revoke accreditation of a laboratory, NVLAP shall inform the laboratory of the reasons for the proposed denial or

revocation and the procedure for appealing such a decision.

(1) The laboratory will have thirty days from the date of receipt of the proposed denial or revocation letter to appeal the decision to the Director of NIST. If the laboratory appeals the decision to the Director of NIST, the proposed denial or revocation will be stayed pending the outcome of the appeal. The proposed denial or revocation will become final through the issuance of a written decision to the laboratory in the event that the laboratory does not appeal the proposed denial or revocation within the thirty-day period.

(2) If accreditation is revoked, the laboratory may be given the option of voluntarily terminating the accreditation.

(3) A laboratory whose accreditation has been revoked must cease use of the NVLAP logo on any of its reports, correspondence, or advertising related to the area(s) affected by the revocation. If the revocation is total, NVLAP will instruct the laboratory to return its Certificate and Scope of Accreditation and to remove the NVLAP logo from all test or calibration reports, correspondence, or advertising. If the revocation affects only some, but not all of the items listed on a laboratory's Scope of Accreditation, NVLAP will issue a revised Scope that excludes the revoked area(s) in order that the laboratory might continue operations in accredited areas.

(d) A laboratory whose accreditation has been voluntarily terminated, denied or revoked, may reapply and be accredited if the laboratory:

(1) Completes the assessment and evaluation process; and

(2) Meets the NVLAP conditions and criteria for accreditation.

#### **§ 285.14 Criteria for accreditation.**

The requirements for laboratories to be recognized by the National Voluntary Laboratory Accreditation Program as competent to carry out tests and/or calibrations are contained in clauses 4 and 5 of ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*, including revisions from time to time.

#### **§ 285.15 Obtaining documents.**

(a) Application forms, NVLAP handbooks, and other NVLAP documents and information may be obtained by contacting the NVLAP, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 2140, Gaithersburg, Maryland 20899-2140; phone: 301-975-4016; fax: 301-926-2884; e-mail: nvlap@nist.gov.

(b) Copies of all ISO/IEC documents are available from the American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, New York 10036; phone: 212-642-4900; fax: 212-398-0023; web site: www.ansi.org. You may inspect copies of all applicable ISO/IEC documents at the National Voluntary Laboratory Accreditation Program, National Institute of Standards and Technology, 820 West Diamond Avenue, Room 297, Gaithersburg, MD.

[FR Doc. 01-13448 Filed 5-29-01; 8:45 am]

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## SECURITIES AND EXCHANGE COMMISSION

### 17 CFR Parts 270 and 275

[Release Nos. IC-24991 and IA-2945; File No. S7-06-01]

RIN 3235-A105

#### Electronic Recordkeeping by Investment Companies and Investment Advisers

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Final rule.

**SUMMARY:** The Securities and Exchange Commission is adopting amendments to rules under the Investment Company Act of 1940 and the Investment Advisers Act of 1940 that permit registered investment companies and registered investment advisers to preserve required records using electronic storage media such as magnetic disks, tape, and other digital storage media. The amendments expand the ability of advisers and funds to use electronic storage media to maintain and preserve records. This release and these rule amendments respond to the enactment of the Electronic Signatures in Global and National Commerce Act, which encourages federal agencies to accommodate electronic recordkeeping.

**EFFECTIVE DATE:** May 31, 2001.

**FOR FURTHER INFORMATION CONTACT:** William C. Middlebrooks, Jr., Attorney, or Martha B. Peterson, Special Counsel, (202) 942-0690, Office of Regulatory Policy, Division of Investment Management, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549-0506.

**SUPPLEMENTARY INFORMATION:** The Securities and Exchange Commission ("Commission") is adopting amendments to rule 31a-2 (17 CFR 270.31a-2) under the Investment Company Act of 1940 (15 U.S.C. 80a) (the "Investment Company Act"), and

rule 204-2 (17 CFR 275.204-2) under the Investment Advisers Act of 1940 (15 U.S.C. 80b) (the "Advisers Act").<sup>1</sup>

#### Executive Summary

The Commission is adopting amendments to rules regarding electronic recordkeeping by registered investment companies ("funds") and registered investment advisers ("advisers"). The federal securities laws require funds, advisers, and others to make and keep books and records. The recordkeeping requirements are a key part of the Commission's regulatory program for funds and advisers, as they allow us to monitor fund and adviser operations, and to evaluate their compliance with federal securities laws. Last year, Congress passed the Electronic Signatures in Global and National Commerce Act (the "Electronic Signatures Act," "Act," or "ESIGN") to facilitate the use of electronic records and signatures in interstate and foreign commerce.<sup>2</sup> Consistent with the purposes and goals of the Electronic Signatures Act, we are adopting rule amendments that expand the circumstances under which funds and advisers may keep records on electronic storage media, and clarify and update our recordkeeping rules. We are also interpreting rules 31a-2 and 204-2 to be the exclusive means by which funds and advisers can comply with the recordkeeping provisions of the Electronic Signatures Act.

#### I. Discussion

##### A. Amendments to Rules 31a-2 and 204-2

The Commission is amending rules 31a-2 and 204-2 to permit funds and advisers to keep all of their records in an electronic format. Prior to today's amendments, rules 31a-2 and 204-2 provided that funds and advisers could keep records on electronic storage media only if the records were originally created or received in an electronic format.<sup>3</sup> The Commission's staff had issued no-action letters to conditionally permit funds and advisers to convert records into an electronic

<sup>1</sup> Unless otherwise noted, all references to rule 31a-2 or rule 204-2, or to any paragraph of those rules, will be to 17 CFR 270.31a-2 and 17 CFR 275.204-2, as amended by this release.

<sup>2</sup> Electronic Signatures in Global and National Commerce Act, Pub. L. No. 106-229, 114 Stat. 464 (2000) (15 U.S.C. 7001), Preamble.

<sup>3</sup> See Electronic Recordkeeping by Investment Companies and Investment Advisers, Investment Company Act Release No. 24890 (Mar. 13, 2001) [66 FR 15369 (Mar. 19, 2001)] ("Proposing Release") at n.4 and accompanying text.

format and retain them electronically.<sup>4</sup> In March of this year we proposed rule amendments to incorporate these no-action letters into rules 31a-2 and 204-2, while eliminating many of the conditions that apply only to electronic records created from non-electronic originals. We also proposed to clarify the obligation of funds and advisers to provide copies of their records to Commission examiners, and to incorporate terminology used in electronic recordkeeping rules under the Securities Exchange Act of 1934 into rules 31a-2 and 204-2.<sup>5</sup> We received seven comment letters addressing the proposal.<sup>6</sup> Commenters supported most of the proposed amendments, and we are adopting them substantially as proposed, with a few changes in response to concerns expressed by commenters.

Under revised rules 31a-2 and 204-2, funds and advisers are permitted to maintain records electronically if they establish and maintain procedures: (i) To safeguard the records from loss, alteration, or destruction, (ii) to limit access to the records to authorized personnel, the Commission, and (in the case of funds) fund directors, and (iii) to ensure that electronic copies of non-electronic originals are complete, true, and legible.<sup>7</sup> In response to a suggestion of one commenter, we are expanding rules 31a-2 and 204-2 to include *all* records that are required to be

<sup>4</sup> See Oppenheimer Management Corporation, SEC No-Action Letter (Aug. 28, 1995); DST Systems, Inc., SEC No-Action Letter (Feb. 2, 1993).

<sup>5</sup> Proposing Release, *supra* note 3, at nn. 7-12 and accompanying text.

<sup>6</sup> The comment letters are available for public inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, NW., Washington, DC (File No. S7-06-01).

<sup>7</sup> Rules 31a-2(f)(3) and 204-2(g)(3). We requested commenters to address whether rules 31a-2 and 204-2 should require funds and advisers to preserve records in a non-rewriteable, non-erasable (also known as "write once, read many," or "WORM") format. Commenters concurred in our preliminary assessment, at the proposing stage, that the costs of such a requirement would be likely to outweigh the benefits (with respect to advisers and funds). Based on our consideration of costs, benefits, and other factors described in the proposing release we are not adopting such a requirement at this time. We recognize that the standards for electronic recordkeeping we are adopting for funds and advisers are different from the rules that we have adopted for broker-dealers, which require brokerage records to be preserved in a WORM format. We have not experienced any significant problems with funds or advisers altering stored records. Moreover, most advisory and mutual fund arrangements involve multiple parties (*e.g.*, brokers, custodians, transfer agents), each with its own, often parallel, recordkeeping requirement. As a result, our compliance examiners typically have an alternative means to verify the accuracy of adviser and fund records. In light of these factors, the costs of requiring funds and advisers to invest in new electronic recordkeeping technologies may not be justified.