2132, 2146, 2154, 2160, 2202b, 2211, 2243, 2252, 2278b, 2278b-6, 2279aa, 2279aa-4, 2279aa-6, 2279aa-7, 2279aa-8, 2279aa-10, 2279aa-12; sec. 301(a) of Pub. L. 100–233, 101 Stat. 1568, 1608.

Subpart E—Investment Management

§ 615.5140 [Corrected]

Section 615.5140(a)(8)(i)(B) and (a)(11)(ii) is corrected by removing the reference "§ 615.5131(i)" and adding in its place, the reference "§ 615.5131(j)".

Dated: April 26, 1994.

Curtis M. Anderson,

Secretary, Farm Credit Administration Board.

[FR Doc. 94–10490 Filed 5–2–94; 8:45 am]

BILLING CODE 6705–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 94–ACE–01]

Establishment of Class E Airspace; Belle Plaine, IA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace at Belle Plaine, Iowa. The development of a new standard instrument approach procedure (SIAP) at the Belle Plaine Municipal Airport, Belle Plaine, Iowa, utilizing the Cedar Rapids, Iowa, Very High Frequency Omnidirectional Range Tactical Air Navigation (VORTAC) and the Belle Plaine non-directional beacon (NDB) on the airport as a navigational aid has made this action necessary. Controlled airspace extending from 700 to 1200 feet above ground level (AGL) is needed for aircraft executing the approach. The area will be depicted on aeronautical charts to provide a reference for pilots operating in the area.

EFFECTIVE DATE: 0901 u.t.c., October 13, 1994.

FOR FURTHER INFORMATION CONTACT: Dale L. Carnine, Airspace Specialist, System Management Branch, ACE–530b, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; telephone number: (816) 426–3408.

SUPPLEMENTARY INFORMATION:

History

On January 21, 1994, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish Class E airspace at the Belle Plaine Municipal Airport, Belle Plaine, Iowa (59 FR 8566).

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. We discovered there was a minor error in the geographic coordinates of the Belle Plaine Municipal Airport. In addition, there was a reference to the Belle Plaine, Iowa, NDB and Cedar Rapids, Iowa, VORTAC in the official description, which is not required. They were corrected in this document. Other than these changes, this amendment is the same as that proposed in the notice. Class E airspace designations for airspace areas extending upward from 700 feet or more above ground level are published in paragraph 6005 of FAA Order 7400.9A, dated June 17, 1993, and effective September 16, 1993, which is incorporated by reference in 14 CFR 71.1 (58 FR 36298; July 6, 1993). The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) establishes Class E airspace at Belle Plaine, Iowa, extending upward from 700 feet above the surface excluding that portion which overlies the Cedar Rapids, Iowa, Class E airspace. The development of new SIAPs at Belle Plaine Municipal Airport has made this rule necessary. The intended effect of this rule is to provide adequate Class E airspace for aircraft executing the NDB or VOR/DME–A SIAPs at Belle Plaine Municipal Airport.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 CFR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9A, Airspace designations and Reporting Points, dated June 17, 1993, and effective September 16, 1993, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ACE IA E5 Belle Plaine, IA [New]

Belle Plaine Municipal Airport, IA
(lat. 41°52'39" N, long. 92°17'08" W)

That airspace extending upward from 700 feet above the surface within a 6.5–mile radius of the Belle Plaine Municipal Airport, Iowa, excluding that portion which overlies the Cedar Rapids, Iowa, Class E airspace.

* * * * *

Issued in Kansas City, Missouri, on April 13, 1994.

Clarence E. Newbern,

Manager, Air Traffic Division, Central Region

[FR Doc. 94–10378 Filed 5–2–94; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 71

[Airspace Docket No. 93–ACE–03]

Revision of Class D Airspace; Kansas City, MO, Richard-Gebaur Airport

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class D airspace at the Kansas City Richards-Gebaur Airport, Missouri. This change is necessary to exclude the Hillside Airport at Stilwell, Kansas, from this Class D airspace.

EFFECTIVE DATE: 0901 u.t.c., June 23, 1994.

FOR FURTHER INFORMATION CONTACT: Dale L. Carnine, Airspace Specialist, System Management Branch, ACE–530b, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; telephone number: (816) 426–3408.

SUPPLEMENTARY INFORMATION:

History

On January 7, 1994, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to amend the Class D airspace at the Kansas City Richards-Gebaur Airport, Missouri (59 FR 4608).

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. This amendment is the same as that proposed in the notice. Class D airspace areas are published in paragraph 5000 of FAA Order 7400.9A, dated June 17, 1993, and effective September 16, 1993, which is incorporated by reference in 14 CFR 71.1 (58 FR 36298; July 6, 1993). The Class D airspace designation listed in this document will be published subsequently in the order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) amends the Class D airspace at the Kansas City Richards-Gebaur Airport. On September 16, 1993, Airspace Reclassification discontinued the use of the term "airport traffic area." Airspace designated from the surface for an airport where there is an operating control tower is now Class D airspace. During the Airspace Reclassification project, the Hillside Airport at Stilwell, Kansas, was to be excluded from the Richards-Gebaur Class D airspace. However, it was inadvertently not addressed in the official description. Hillside is a public use airport which was established in 1956 and serves numerous non-radio aircraft, as well as ultralight vehicles. Under the rules prior to September 16, 1993, an aircraft could land and take off at this airport without contacting the Richards-Gebaur Tower. Under the present rules, an aircraft operating to/from the Hillside Airport must contact this Tower. The intended effect of this rule is to provide access for aircraft utilizing the Hillside Airport without the requirement to establish radio contact with the Richards-Gebaur Tower. The coordinates for this airspace docket are based on North American Datum 83.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9A, Airspace Designations and Reporting Points, dated June 17, 1993, and effective September 16, 1993, is amended as follows:

Paragraph 5000 General

* * * * *

ACE MO D Kansas City, MO [Revised]

Richard-Gebaur Airport, MO
(lat. 38°50'38" N, long. 94°33'37" W)

That airspace extending upward from the surface to and including 3,600 feet MSL within a 4.3-mile radius of Richards-Gebaur Airport; excluding that airspace from the surface to 1,700 feet MSL bounded on the north by lat. 38°50'00" N and on the east by long. 94°36'00" W. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in Kansas City, Missouri, on April 13, 1994.

Clarence E. Newbern,

Manager, Air Traffic Division, Central Region.

[FR Doc. 94–10376 Filed 5–2–94; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 71

[Airspace Docket No. 93–ACE–06]

Establishment of Class E Airspace; Sullivan, MO, Sullivan Regional Airport

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace at the Sullivan Regional Airport, Sullivan, Missouri. The development of a standard instrument approach procedure (SIAP) at the Sullivan Regional Airport, Sullivan, Missouri, utilizing a new nondirectional beacon (NDB) has made this action necessary. Controlled airspace extending from 700 to 1200 feet above ground level (AGL) is needed. For aircraft executing the approach. The area will be depicted on aeronautical charts to provide a reference for pilots operating in the area.

EFFECTIVE DATE: 0901 u.t.c., June 23, 1994.

FOR FURTHER INFORMATION CONTACT: Dale L. Carnine, Airspace Specialist, System Management Branch, ACE–530b, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; telephone number: (816) 426–3408.

SUPPLEMENTARY INFORMATION:

History

On January 7, 1994, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish Class E airspace at the Sullivan Regional Airport, Sullivan, Missouri (59 FR 4611).

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. This amendment is the same as the proposed in the notice. Class E airspace designations for airspace areas extending upward from 700 feet or more above ground level are published in paragraph 6005 of FAA Order 7400.9A, dated June 17, 1993, and effective September 16, 1993, which is incorporated by reference in 14 CFR 71.1 (58 FR 36298; July 6, 1993). The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) establishes Class E airspace at Sullivan, Missouri, extending from 700 feet AGL to 1200 feet AGL. The

development of a SIAP based on a new NDB located on the Sullivan Regional Airport, Sullivan, Missouri, made this proposal necessary. The intended effect of this rule is to provide adequate Class E airspace for aircraft executing the NDB SIAP at Sullivan Regional Airport.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a "significant rule" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulation Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9A, Airspace Designations and Reporting Points, dated June 17, 1993, and effective September 16, 1993, is amended as follows:

Paragraph 6005 Class E airspace areas extending from 700 feet or more above the surface of the earth

* * * * *

ACE MO E5 Sullivan, MO [New]

Sullivan Regional Airport, MO
(lat. 38°14'01" N, long. 91°09'53" W)

That airsapce extending upward from 700 feet above the surface within a 6.4-mile radius of Sullivan Regional Airport and within 2.5 miles each side of the 068-degree bearing from the Sullivan Regional Airport extending from the 6.4-mile radius to 6.7 miles northeast of the airport.

* * * * *

Issued in Kansas City, Missouri, on April 13, 1994.

Clarence E. Newbern,

Manager, Air Traffic Division, Central Region.

[FR Doc. 94–10380 Filed 5–2–94; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 97

[Docket No. 27715; Amdt. No. 1599]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: An effective date for each SIAP is specified in the amendatory provisions.

Incorporation by reference-approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located; or

3. The Flight Inspection Area Office which originated the SIAP.

For Purchase

Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription

Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Paul J. Best, Flight Procedures Standards Branch (AFS–420), Technical Programs Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–8277.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs). The complete regulatory description of each SIAP is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation Regulations (FAR). The applicable FAA Forms are identified as FAA Form 8260–5. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

This amendment to part 97 is effective upon publication of each separate SIAP as contained in the transmittal. The SIAPs contained in this amendment are based on the criteria contained in the United States Standard for Terminal Instrument Approach Procedures (TERPS). In developing these SIAPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports.

The FAA has determined through testing that current non-localizer type, non-precision instrument approaches developed using the TERPS criteria can be flown by aircraft equipped with

Global Positioning System (GPS) equipment. In consideration of the above, the applicable Standard Instrument Approach Procedures (SIAPs) will be altered to include "or GPS" in the title without otherwise reviewing or modifying the procedure. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are unnecessary, impracticable, and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Navigation (Air).

Issued in Washington, DC, on April 22, 1994.

Thomas C. Accardi,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. app. 1348, 1354(a), 1421 and 1510; 49 U.S.C. 106(g); and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.27, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.27 NDB, NDB/DME; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

Effective June 23, 1994

Gambell, AK, Gambell, NDB or GPS RWY 16, Orig.
Gambell, AK, Gambell, NDB/DME or GPS RWY 34, Amdt. 1
Gulkana, AK, Gulkana, VOR or GPS RWY 32, Amdt. 6
Gulkana, AK, Gulkana, VOR or GPS RWY 14, Amdt. 6
Homer, AK, Homer, NDB or GPS RWY 3, Amdt. 2B
Northway, AK, Northway, NDB or GPS RWY 4, Orig.
Northway, AK, Northway, NDB or GPS RWY 22, Orig.
Northway, AK, Northway, VOR/DME or GPS–A, Orig.
Northway, AK, Northway, VOR or GPS–B, Amdt. 3
Hamilton, AL, Marion County, VOR or GPS RWY 18, Amdt. 4A
Muscle Shoals, AL, Muscle Shoals Regional, VOR/DME or GPS RWY 11, Amdt. 5A
Muscle Shoals, AL, Muscle Shoals Regional, VOR or GPS RWY 29, Amdt. 26A
Tuscaloosa, AL, Tuscaloosa Muni, NDB or GPS RWY 4, Amdt. 10
Tuscaloosa, AL, Tuscaloosa Muni, VOR or TACAN or GPS RWY 22, Amdt. 13
Fort Smith, AR, Fort Smith Regional, VOR or TACAN or GPS RWY 25, Amdt. 20A
Fort Smith, AR, Fort Smith Regional, VOR/DME or TACAN or GPS RWY 7, Amdt. 10
Jonesboro, AR, Jonesboro Muni, VOR or GPS RWY 23, Amdt. 9
Magnolia, AR, Magnolia Muni, NDB or GPS RWY 35, Orig.
Mountain Home, AR, Baxter County Regional, VOR or GPS–A, Amdt. 9
Mountain Home, AR, Baxter County Regional, VOR/DME RNAV or GPS RWY 5, Amdt. 1
Douglas Bisbee, AZ, Bisbee Douglas Intl, VOR/DME or GPS RWY 17, Amdt. 5
Phoenix, AZ, Phoenix-Deer Valley Muni, NDB or GPS RWY 25L, Amdt. 3
Daggett, CA Barstow-Daggett, VOR or TACAN or GPS RWY 21, Amdt. 8
Firebaugh, CA, Firebaugh, VOR/DME or GPS–A, Amdt. 2
Fortuna, CA, Rohnerville, VOR or GPS RWY 11, Amdt. 2
Modesto, CA, Modesto City-County Airport-Harry Sham Field, VOR or GPS RWY 28R, Amdt. 10A
Napa, CA, Napa County, VOR or GPS RWY 6, Amdt. 11
Oakland, CA Metropolitan Oakland Intl, VOR or GPS RWY 9R, Amdt. 7
Oakland, CA Metropolitan Oakland Intl, VOR/DME or GPS RWY 27L, Amdt. 10
Palmdale, CA, Palmdale Production Flt/Test Instln AF Plant 42, VOR/DME or TACAN or GPS RWY 25, Amdt. 6
Sacramento, CA, Mather Field, VOR or GPS RWY 4R, Orig.
Sacramento, CA, Mather Field, VOR/DME or GPS RWY 22L, Orig.
Willows, CA, Willows-Glenn County, VOR/DME or GPS RWY 34, Amdt. 4
Grand Junction, CO, Walker Field, VOR or GPS RWY 11, Amdt. 1
Montrose, CO, Montrose Regional VOR/DME or GPS RWY 13, Amdt. 8A
Rifle, CO, Garfield County Regional, VOR/DME or GPS–C, Orig.
New Haven, CT, Tweed-New Haven, VOR or GPS RWY 2, Amdt. 22
New Haven, CT, Tweed-New Haven, VOR or GPS–A, Amdt. 2
Washington, DC, Washington National, VOR/DME or GPS RWY 15, Orig.
Wilmington, DE, New Castle County, VOR or GPS RWY 19, Amdt. 4
Wilmington, DE, New Castle County, VOR or GPS RWY 1, Amdt. 3
Immokalee, FL, Immokalee, VOR or GPS RWY 18, Amdt. 4
Marathon, FL, Marathon, NDB or GPS RWY 7, Amdt. 2A
Miami, FL, Miami Intl, VOR or GPS RWY 12, Amdt. 29
Miami, FL, Miami Intl, RNAV or GPS RWY 9L, Amdt. 9
Miami, FL, Miami Intl, NDB or GPS RWY 27L, Amdt. 18
Miami, FL, Miami Intl, VOR or GPS RWY 30, Amdt. 8
Miami, FL, Miami Intl, RNAV or GPS RWY 27R, Amdt. 5A
Titusville, FL, Space Center Executive, NDB or GPS RWY 18, Amdt. 11
Dalton, GA, Dalton Muni, NDB or GPS RWY 14, Orig.
Hazlehurst, GA, Hazlehurst, NDB or GPS RWY 14, Amdt. 3
Milledgeville, GA, Baldwin County, NDB or GPS RWY 28, Orig.
Moultrie, GA, Moultrie Muni, VOR or GPS RWY 22, Amdt. 11A
Statesboro, GA, Statesboro Muni, NDB or GPS RWY 32, Amdt. 4
Sylvania, GA, Plantation Airpark, NDB or GPS RWY 23, Amdt. 1A
Valdosta, GA, Valdosta Regional, VOR or GPS RWY 35, Orig.
Valdosta, GA, Valdosta Regional, VOR or GPS RWY 17, Orig.
Kailua-Kona, HI, Keahole-Kona International, VOR or TACAN or GPS RWY 35, Amdt. 6
Kailua-Kona, HI, Keahole-Kona International, VOR/DME or TACAN or GPS RWY 17, Amdt. 3
Charles City, IA, Charles City Muni, NDB or GPS RWY 30, Amdt. 2C
Charles City, IA, Charles City Muni, NDB or GPS RWY 12, Orig. B
Cherokee, IA, Cherokee Muni, NDB or GPS RWY 36, Amdt. 4
Creston, IA, Creston Muni, NDB or GPS RWY 34, Orig. A
Independence, IA, Independence Muni, NDB or GPS RWY 17, Amdt. 2
Mason City, IA, Mason City Muni, VOR or GPS RWY 35, Amdt. 5A
Mason City, IA, Mason City Muni, VOR/DME or GPS RWY 17, Amdt. 3A
Mason City, IA, Mason City Muni, RNAV or GPS RWY 30, Amdt. 5
Orange City, IA, Orange City Muni, NDB or GPS RWY 34, Amdt. 3
Sheldon, IA, Sheldon Muni, VOR or GPS RWY 33, Amdt. 1
Boise, ID, Boise Air Terminal (Gowen Field), VOR/DME or GPS RWY 10R, Orig.
Twin Falls, ID, Twin Falls-Sun Valley Regional-Joslin Field, NDB or GPS RWY 25, Amdt. 5
Twin Falls, ID, Twin Falls-Sun Valley Regional-Joslin Field, VOR or GPS RWY 7, Amdt. 3

Kankakee, IL, Greater Kankakee, VOR or GPS RWY 4, Amdt. 5
Kankakee, IL, Greater Kankakee, VOR or GPS RWY 22, Amdt. 6
Morris, IL, Morris Municipal-James R. Washburn Field, VOR or GPS–A, Amdt. 9
Mount Carmel, IL, Mount Carmel Muni, VOR or GPS RWY 22, Amdt. 7
Mount Carmel, IL, Mount Carmel Muni, NDB or GPS RWY 4, Amdt. 3
Mount Sterling, IL, Mount Sterling Muni, VOR/DME or GPS–A, Orig.
Salem, IL, Salem-Leckrone, NDB or GPS RWY 18, Amdt. 8
Angola, IN, Tri-State Steuben County, NDB or GPS RWY 5, Amdt. 6
Elkhart, IN, Elkhart Muni, RNAV or GPS RWY 17, Amdt. 3
Elkhart, IN, Elkhart Muni, VOR or GPS RWY 27, Amdt. 13A
Elkhart, IN, Elkhart Muni, VOR or GPS RWY 9, Amdt. 5
Elkhart, IN, Elkhart Muni, VOR/DME or GPS RWY 35, Amdt. 2
Jeffersonville, IN, Clark County, VOR or GPS RWY 18, Amdt. 2
Richmond, IN, Richmond Muni, VOR or GPS RWY 24, Amdt. 11
Richmond, IN, Richmond Muni, VOR or GPS RWY 6, Amdt. 10
Richmond, IN, Richmond Muni, VOR or GPS RWY 33, Orig.
Washington, IN, Daviess County, NDB or GPS RWY 18, Amdt. 5
Anthony, KS, Anthony Muni, VOR or GPS–A, Orig.
Atwood, KS, Atwood-Rawlins County City-County, NDB or GPS RWY 16, Amdt. 1
Colby, KS, Shaltz Field, NDB or GPS RWY 17, Orig.
Concordia, KS, Blosser Muni, NDB or GPS RWY 17, Amdt. 1A
Dodge City, KS, Dodge City Regional, VOR/DME or GPS RWY 32, Amdt. 3A
El Dorado, KS, Captain Jack Thomas/El Dorado, NDB or GPS RWY 4, Amdt. 2
Elkhart, KS, Elkhart-Morton County, NDB or GPS RWY 35, Orig.
McPherson, KS, McPherson, NDB or GPS RWY 18, Orig.
Ulysses, KS, Ulysses, NDB or GPS RWY 12, Amdt. 2
Louisville, KY, Bowman Field, NDB or GPS RWY 32, Amdt. 14
Louisville, KY, Bowman Field, VOR or GPS RWY 14, Amdt. 90
Louisville, KY, Bowman Field, VOR or GPS RWY 24, Amdt. 6A
Shreveport, LA, Shreveport Downtown, VOR or GPS RWY 14, Amdt. 14
Marksville, LA, Marksville Muni, VOR/DME or GPS–A, Amdt. 3
Marksville, LA, Marksville Muni, NDB or GPS RWY 4, Amdt. 1A
Boston, MA, General Edward Lawrence Logan Intl, VOR/DME or GPS–A, Orig.
Boston, MA, General Edward Lawrence Logan Intl, NDB or GPS RWY 4R, Amdt. 22
Boston, MA, General Edward Lawrence Logan Intl, VOR/DME or GPS RWY 15R, Orig.
Boston, MA, General Edward Lawrence Logan Intl, NDB or GPS RWY 22L, Amdt. 9
Salisbury, MD, Salisbury-Wicomico County Regional, VOR or GPS RWY 5, Amdt. 8A
Salisbury, MD, Salisbury-Wicomico County Regional, VOR or GPS RWY 23, Amdt. 8A
Salisbury, MD, Salisbury-Wicomico County Regional, VOR or GPS RWY 32, Amdt. 8A
Houlton, ME, Houlton Intl, VOR or GPS RWY 5, Amdt. 9
Millinocket, ME, Millinocket Muni, NDB or GPS RWY 29, Amdt. 3
Millinocket, ME, Millinocket Muni, VOR or GPS–A, Amdt. 10
Alma, MI, Gratiot Community, NDB or GPS RWY 9, Amdt. 5
Alma, MI, Gratiot Community, VOR/DME RNAV or GPS RWY 27, Amdt. 6
Gladwin, MI, Charles C. Zettel Memorial, NDB or GPS RWY 27, Amdt. 3A
Greenville, MI, Greenville Muni, VOR/DME or GPS–A, Orig.
Ironwood, MI, Gogebic County, VOR/DME or GPS RWY 27, Amdt. 8
Ironwood, MI, Gogebic County, VOR or GPS RWY 9, Amdt. 12
Marquette, MI, Marquette County, VOR or GPS RWY 8, Amdt. 2A
Marquette, MI, Marquette County, VOR or GPS RWY 26, Amdt. 2A
Marshall, MI, Brooks Field, VOR or GPS RWY 28, Amdt. 13
Saginaw, MI, Tri-City Intl, VOR or GPS RWY 5, Amdt. 14
Saginaw, MI, Tri-City Intl, VOR or GPS RWY 14, Amdt. 13
Saginaw, MI, Tri-City Intl, VOR or GPS RWY 23, Amdt. 14
Saginaw, MI, Tri-City Intl, VOR or GPS RWY 32, Amdt. 9
Bemidji, MN, Bemidji-Beltrami County, VOR or GPS RWY 13, Amdt. 16A
Bemidji, MN, Bemidji-Beltrami County, VOR/DME or TACAN or GPS RWY 31, Amdt. 12A
Benson, MN, Benson Muni, NDB or GPS RWY 14, Amdt. 5
Grand Rapids, MN, Grand Rapids/Itasca County-Gordon Newstrom Field, VOR/DME or GPS RWY 16, Orig.
Grand Rapids, MN, Grand Rapids/Itasca County-Gordon Newstrom Field, VOR or GPS RWY 34, Amdt. 9
Pipestone, MN, Pipestone Muni, NDB or GPS RWY 36, Amdt. 5A
Willmar, MN, Willmar Muni-John L. Rice Field, VOR or GPS RWY 10, Amdt. 1A
Willmar, MN, Willmar Muni-John L. Rice Field, VOR or GPS RWY 28, Amdt. 1A
Grain Valley, MO, East Kansas City, VOR/DME RNAV or GPS RWY 27, Amdt. 1
Grain Valley, MO, East Kansas City, VOR or GPS RWY 23, Amdt. 2
Lebanon, MO, Floyd W. Jones Lebanon, NDB or GPS RWY 36, Amdt. 5
Malden, MO, Malden Muni, VOR or GPS RWY 31, Amdt. 7A
Malden, MO, Malden Muni, RNAV or GPS RWY 13, Orig.
Mountain View, MO, Mountain View, NDB or GPS RWY 28, Amdt. 3
Poplar Bluff, MO, Poplar Bluff Muni, NDB or GPS RWY 36, Amdt. 1A
Clarksdale, MS, Fletcher Field, NDB or GPS–A, Orig.
Clarksdale, MS, Fletcher Field, NDB or GPS RWY 36, Amdt. 7
Greenwood, MS, Greenwood-Leflore, RNAV or GPS RWY 36, Amdt. 3
Greenwood, MS, Greenwood-Leflore, VOR or GPS RWY 5, Amdt. 9
Greenwood, MS, Greenwood-Leflore, NDB or GPS RWY 18, Amdt. 1
Miles City, MT, Frank Wiley Field, VOR or GPS RWY 4, Amdt. 11
Miles City, MT, Frank Wiley Field, VOR/DME or GPS RWY 22, Amdt. 8
Shelby, MT, Shelby, NDB or GPS RWY 23, Amdt. 6
Elkin, NC, Elkin Muni, NDB or GPS RWY 25, Amdt. 1
Kenansville, NC, Duplin County, NDB or GPS RWY 22, Amdt. 5
Morganton, NC, Morganton-Lenoir, NDB or GPS RWY 3, Amdt. 4
New Bern, NC, Craven County Regional, VOR or GPS RWY 4, Amdt. 3A
New Bern, NC, Craven County Regional, VOR or GPS RWY 22, Amdt. 1B
Oxford, NC, Henderson-Oxford, NDB or GPS RWY 6, Amdt. 1B
Salisbury, NC, Rowan County, VOR or GPS–A, Amdt. 7
Salisbury, NC, Rowan County, VOR or GPS RWY 2, Amdt. 5
Salisbury, NC, Rowan County, VOR or GPS RWY 20, Amdt. 1
Salisbury, NC, Rowan County, NDB or GPS–B, Amdt. 10
Jamestown, ND, Jamestown Muni, VOR or GPS RWY 13, Amdt. 7
Jamestown, ND, Jamestown Muni, VOR or GPS RWY 31, Amdt. 8
Alliance, NE, Alliance Muni, VOR or GPS RWY 12, Amdt. 2
O'Neill, NE, The O'Neill Muni-John L. Baker Field, VOR or GPS RWY 13, Amdt. 5
O'Neill, NE, The O'Neill Muni-John L. Baker Field, VOR or GPS RWY 31, Amdt. 1
Scottsbluff, NE, William B. Heilig Field, NDB or GPS RWY 12, Amdt. 7
Scottsbluff, NE, William B. Heilig Field, VOR or TACAN or GPS RWY 23, Amdt. 10
Scottsbluff, NE, William B. Heilig Field, VOR/DME or GPS RWY 5, Amdt. 3
York, NE, York Muni, NDB or GPS RWY 35, Amdt. 2
Claremont, NH, Claremont Muni, NDB or GPS–A, Orig.
Lebanon, NH, Lebanon Muni, NDB or GPS–B, Amdt. 3
Teterboro, NJ, Teterboro, VOR/DME RNAV or GPS RWY 24, Orig. A
Teterboro, NJ, Teterboro, VOR/DME or GPS–B, Amdt. 2
Teterboro, NJ, Teterboro, VOR/DME or GPS–A, Amdt. 2
Teterboro, NJ, Teterboro, NDB or GPS RWY 6, Amdt. 17A
Vineland, NJ, Kroelinger, VOR or GPS–B, Orig.
Artesia, NM, Artesia Muni, NDB or GPS RWY 12, Amdt. 2
Artesia, NM, Artesia Muni, NDB or GPS RWY 30, Amdt. 2
Zuni Pueblo, NM, Black Rock, VOR/DME or GPS RWY 7, Orig.
Reno, NV, Reno Cannon Intl, VOR or GPS–D, Amdt. 6
Reno, NV, Reno Cannon Intl, NDB or GPS RWY 16R, Amdt. 5
Newburgh, NY, Stewart Intl, RNAV or GPS RWY 16, Amdt. 2A
Newburgh, NY, Stewart Intl, NDB or GPS RWY 9, Amdt. 7
Newburgh, NY, Stewart Intl, RNAV or GPS RWY 27, Amdt. 1A

Poughkeepsie, NY, Dutchess County, VOR or GPS–A, Amdt. 10
Poughkeepsie, NY, Dutchess County, VOR/DME or TACAN or GPS RWY 24, Amdt. 3
Poughkeepsie, NY, Dutchess County, RNAV or GPS RWY 6, Amdt. 5
Schenectady, NY, Schenectady County, NDB or GPS RWY 22, Amdt. 14
Schenectady, NY, Schenectady County, NDB or GPS RWY 28, Amdt. 9
Ashland, OH, Ashland County, NDB or GPS RWY 18, Amdt. 8
Ashland, OH, Ashland County, VOR or GPS–A, Amdt. 6
Cleveland, OH, Burke Lakefront, NDB or GPS RWY 24R, Orig. B
Ottawa, OH, Putman County, VOR or GPS RWY 27, Amdt. 1
Toledo, OH, Toledo Express, VOR/DME RNAV or GPS RWY 16, Amdt. 5
Toledo, OH, Toledo Express, VOR/DME or GPS RWY 34, Amdt. 5
Toledo, OH, Toledo Express, NDB or GPS RWY 7, Amdt. 23
Van Wert, OH, Van Wert County, NDB or GPS RWY 9, Amdt. 1
Versailles, OH, Darke County, NDB or GPS RWY 9, Amdt. 7
Wilmington, OH, Airborne Airpark, VOR or GPS RWY 4, Amdt. 4
Wilmington, OH, Airborne Airpark, VOR/DME or GPS RWY 22, Amdt. 3
Blackwell, OK, Blackwell-Tonkawa Muni, VOR/DME RNAV or GPS RWY 17, Amdt. 2
Blackwell, OK, Blackwell-Tonkawa Muni, VOR or GPS–A, Amdt. 3
Cushing, OK, Cushing Muni, NDB or GPS RWY 35, Amdt. 3B
Durant, OK, Eaker Field, NDB or GPS RWY 35, Amdt. 5
Guthrie, OK, Guthrie Muni, NDB or GPS RWY 16, Amdt. 3
Guymon, OK, Guymon Muni, NDB or GPS RWY 18, Amdt. 5
Tulsa, OK, Tulsa Intl, VOR or TACAN or GPS RWY 26, Amdt. 22
Tulsa, OK, Tulsa Intl, NDB or GPS RWY 36R, Amdt. 19
Tulsa, OK, Tulsa Intl, VOR/DME or TACAN or GPS RWY 8, Amdt. 3A
Tulsa, OK, Tulsa Intl, NDB or GPS RWY 18L, Amdt. 10
Klamath Falls, OR, Klamath Falls Intl, VOR/DME or TACAN or GPS RWY 14, Amdt. 3
Klamath Falls, OR, Klamath Falls Intl, VOR or GPS–B, Amdt. 3
Klamath Falls, OR, Klamath Falls Intl, NDB or GPS RWY 32, Amdt. 1
Pendleton, OR, Eastern Oregon Regional At Pendleton, NDB or GPS–A, Amdt. 7
Pendleton, OR, Eastern Oregon Regional At Pendleton, VOR or GPS RWY 7, Amdt. 14
Philadelphia, PA, Philadelphia Intl, RNAV or GPS RWY 17, Amdt. 4
Philadelphia, PA, Philadelphia Intl, VOR/DME or GPS–A, Amdt. 1
Philadelphia, PA, Philadelphia Intl, NDB or GPS RWY 27L, Amdt. 5
Philadelphia, PA, Philadelphia Intl, RNAV or GPS RWY 35, Amdt. 3A
Pittsburgh, PA, Allegheny County, VOR/DME RNAV or GPS RWY 10, Amdt. 6
Pittsburgh, PA, Allegheny County, VOR or GPS RWY 5, Amdt. 9A
Pittsburgh, PA, Allegheny County, NDB or GPS RWY 28, Amdt. 22A
Washington, PA, Washington County, NDB or GPS RWY 27, Orig. A
Washington, PA, Washington County, VOR or GPS–B, Amdt. 6A
Aguadilla, PR, Rafael Hernandez, VOR/DME or TACAN or GPS RWY 8, Amdt. 1
Providence, RI, Theodore Francis Green State, VOR or GPS RWY 34, Amdt. 4
Aiken, SC, Aiken Muni, NDB or GPS RWY 24, Amdt. 9
Aiken, SC, Aiken Muni, VOR/DME or GPS–A, Orig.
Greenville, SC, Donaldson Center, NDB or GPS RWY 4, Amdt. 4
Kingstree, SC, Williamsburg County, NDB or GPS RWY 14, Amdt. 3
North Myrtle Beach, SC, Grand Strand, VOR or GPS RWY 5, Amdt. 19
North Myrtle Beach, SC, Grand Strand, VOR or GPS RWY 23, Amdt. 18
Brookings, SD, Brookings Muni, VOR or GPS RWY 12, Amdt. 10
Brookings, SD, Brookings Muni, VOR or GPS RWY 30, Amdt. 9
Centerville, TN, Centerville Muni, VOR/DME or GPS RWY 2, Amdt. 2
Greeneville, TN, Greeneville Muni, NDB or GPS RWY 5, Amdt. 4
Lexington, TN, Franklin Wilkins, VOR or GPS RWY 33, Amdt. 9
Morristown, TN, Moore-Murrell, NDB or GPS RWY 5, Amdt. 4
Pulaski, TN, Abernathy Field, VOR/DME or GPS RWY 33, Orig. A
Pulaski, TN, Abernathy Field, NDB or GPS RWY 15, Amdt. 4
Savannah, TN, Savannah-Hardin County, NDB or GPS RWY 18, Amdt. 3A
Brady, TX, Curtis Field, NDB or GPS RWY 17, Amdt. 2
Carrizo Springs, TX, Dimmit County, NDB or GPS RWY 31, Amdt. 2
Carthage, TX, Panola County-Sharpe Field, NDB or GPS RWY 35, Orig.
Houston, TX, Andrau Airpark, NDB or GPS RWY 16, Amdt. 16
Houston, TX, David Wayne Hooks Memorial, RNAV or GPS RWY 35L, Amdt. 3
Houston, TX, David Wayne Hooks Memorial, RNAV or GPS RWY 17R, Amdt. 3
Houston, TX, William P. Hobby, VOR/DME or GPS RWY 35, Amdt. 2
Houston, TX, William P. Hobby, VOR/DME or GPS RWY 30L, Amdt. 16
Houston, TX, William P. Hobby, VOR/DME or GPS RWY 4, Amdt. 17
Houston, TX, William P. Hobby, VOR or GPS RWY 12R, Amdt. 18
Houston, TX, William P. Hobby, VOR/DME or GPS RWY 22, Amdt. 23A
Jacksonville, TX, Cherokee County, VOR/DME or GPS RWY 13, Amdt. 2
McKinney, TX, McKinney Muni, VOR/DME or GPS–A, Amdt. 3
Mineral Wells, TX, Mineral Wells, VOR or GPS RWY 31, Amdt. 9A
Olney, TX, Olney Muni, NDB or GPS RWY 17, Amdt. 3
Paris, TX, Cox Field, VOR/DME or GPS RWY 35, Amdt. 10
Plainview, TX, Hale County, VOR or GPS RWY 4, Amdt. 8
Snyder, TX, Winston Field, NDB or GPS RWY 35, Amdt. 1
Sonora, TX, Sonora Muni, NDB or GPS RWY 18, Amdt. 3
Van Horn, TX, Culberson County, NDB or GPS RWY 21, Amdt. 1
Waco, TX, Waco Regional VOR/DME or GPS RWY 32, Amdt. 13
Waco, TX, Waco Regional VOR or GPS RWY 14, Amdt. 20
Waco, TX, Waco Regional NDB or GPS RWY 19, Amdt. 17
Salt Lake City UT, Salt Lake City Intl, VOR/DME or TACAN or GPS RWY 34, Amdt. 6
Salt Lake City UT, Salt Lake City Intl, VOR or TACAN or GPS RWY 16, Amdt. 22
Salt Lake City UT, Salt Lake City Intl, VOR or TACAN or GPS RWY 17, Amdt. 10
Culpeper, VA, Culpeper County, NDB or GPS–B, Orig.
Culpeper, VA, Culpeper County, VOR or GPS–A, Amdt. 4
Culpeper, VA, Culpeper County, VOR/DME RNAV or GPS RWY 22, Amdt. 1
South Boston, VA, William M. Tuck, VOR or GPS–A, Amdt. 6
Wakefield, VA, Wakefield Muni, NDB or GPS RWY 20, Amdt. 4
Wise, VA, Lonesome Pine, RNAV or GPS RWY 24, Amdt. 2
Burlington/Mount Vernon, WA, Skagit Regional/Bay View, NDB or GPS RWY 10, Amdt. 2
Renton, VA, Renton Muni, NDB or GPS RWY 15, Amdt. 2
Seattle, WA, Seattle-Tacoma Intl, VOR or GPS RWY 34L/R, Amdt. 8
Seattle, WA, Seattle-Tacoma Intl, VOR or GPS RWY 16L/R, Amdt. 12
Clintonville, WI, Clintonville Muni, NDB or GPS RWY 32, Amdt. 6
Fort Atkinson, WI, Fort Atkinson Muni, VOR or GPS–A, Orig.
Manitowish Waters, WI, Manitowish Waters, NDB or GPS RWY 32, Orig.
Manitowoc, WI, Manitowoc County, VOR or GPS RWY 35, Amdt. 12
Manitowoc, WI, Manitowoc County, VOR or GPS RWY 17, Amdt. 13
Platteville, WI, Grant County, VOR/DME RNAV or GPS RWY 25, Amdt. 6
Sturgeon Bay, WI, Door County Cherryland, NDB or GPS RWY 1, Amdt. 9
West Bend, WI, West Bend Muni, VOR or GPS RWY 24, Amdt. 2
West Bend, WI, West Bend Muni, RNAV or GPS RWY 13, Amdt. 5
West Bend, WI, West Bend Muni, NDB or GPS RWY 31, Amdt. 10
Morgantown, WV, Morgantown Muni-Walter L. Bill Hart Field, VOR or GPS–A, Amdt. 11
Morgantown, WV, Morgantown Muni-Walter L. Bill Hart Field, NDB or GPS–18, Amdt. 15
Parkersburg, WV, Wood County Airport Gill Robb Wilson Field, VOR or GPS RWY 21, Amdt. 14
Big Piney, WV, Big Piney-Marbleton, VOR or GPS RWY 31, Amdt. 3
Riverton, WY, Riverton Regional, VOR or GPS RWY 28, Amdt. 8
Riverton, WY, Riverton Regional, VOR or GPS RWY 10, Amdt. 8

The following are corrected procedure titles adding "or GPS" published in Transmittal Letter 94–09.

Hot Springs, AR, Memorial Field, VOR or GPS–2 RWY 5, Amdt. 3

Bedford, IN, Virgil I. Grissom Muni, VOR/DME or GPS RWY 13, Amdt. 9
Manistee, MI, Manistee County-Blacker, VOR or GPS RWY 9, Amdt. 11
Manistee, MI, Manistee County-Blacker, VOR or GPS RWY 27, Amdt. 11
Alexandria, MN, Chandler Field, VOR or GPS RWY 22, Amdt. 14
Laconia, NH, Laconia Muni, NDB or GPS RWY 8, Amdt. 8
Las Vegas, NV, McCarran Intl, VOR/DME or GPS RWY 1R, Orig.
Aberdeen, SD, Aberdeen Regional, VOR/DME or GPS RWY 13, Amdt. 11

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DEPARTMENT OF COMMERCE

Office of the Secretary

15 CFR Part 7

National Institute of Standards and Technology

15 CFR Part 285

[Docket No. 930103-4017]

RIN 0693-AB15

National Voluntary Laboratory Accreditation Program

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Final rule.

SUMMARY: The Director of the National Institute of Standards and Technology, United States Department of Commerce, is today issuing a final rule making changes to regulations previously found at 15 CFR part 7 pertaining to the operation of the National Voluntary Laboratory Accreditation Program (NVLAP). The NVLAP procedures are redesignated as part 285 of title 15 of the Code of Federal Regulations, and are revised to expand the procedures to include accreditation of calibration laboratories; update the procedures for compatibility with conformity assurance and assessment concepts; assure consistency with relevant International Organization for Standardization (ISO) documents (e.g., ISO Guides 25, 38, 43, 58, and 9000); and facilitate and promote acceptance of calibration and test results between countries to avoid barriers to trade. Provisions in this regard will facilitate cooperation between laboratories and other bodies to assist in the exchange of information and experience, harmonize standards and procedures, and establish the basis for bi-lateral and multi-lateral agreements.

EFFECTIVE DATE: This rule is effective June 2, 1994.

ADDRESSES: Albert D. Tholen, Chief, National Voluntary Laboratory Accreditation Program, National Institute of Standards and Technology, Building 411, room A162, Gaithersburg, MD 20899, telephone number (301) 975-4016.

FOR FURTHER INFORMATION CONTACT: Albert D. Tholen, Chief, National Voluntary Laboratory Accreditation Program, (301) 975-4016.

SUPPLEMENTARY INFORMATION: The Director of the National Institute of Standards and Technology, (NIST) is today issuing a final rule making changes to regulations previously found at 15 CFR Part 7 pertaining to the operation of the National Voluntary Laboratory Accreditation Program (NVLAP). NVLAP provides an unbiased third party evaluation and recognition of laboratory performance, as well as expert technical assistance to upgrade that performance, by accrediting calibration laboratories and testing laboratories found competent to perform specific tests or calibrations.

Competence is defined as the ability of a laboratory to meet the NVLAP conditions set out in the NVLAP regulations and to conform to the criteria in NVLAP publications for particular calibration and test methods. Specifically, NVLAP accreditation indicates that a laboratory's quality system, staff, facilities and equipment, calibration protocols, methods and procedures, records and reports have been evaluated and found to meet NVLAP criteria.

Accreditation is granted following successful completion of a process which includes submission of an application and payment of fees by the laboratory, an on-site assessment, resolution of any deficiencies identified during the on-site assessment, participation in proficiency testing, technical evaluation, and administrative review. The accreditation is formalized through issuance of a Certificate of Accreditation and Scope of Accreditation and is publicized by announcement in various government and private media. NVLAP accreditation does not imply any guarantee or certification of laboratory performance or test/calibration data; it is solely a finding of laboratory competence.

NVLAP accreditation is available to commercial laboratories, manufacturers' in-house laboratories, university laboratories, and federal, state and local government laboratories. Foreign-based laboratories may also be accredited if they meet the same requirements as domestic laboratories and pay any additional fees required for travel expenses.

NVLAP is comprised of a series of laboratory accreditation programs (LAPs) which are established on the basis of requests and demonstrated need. Each LAP includes specific calibration and/or test standards and related methods and protocols assembled to satisfy the unique needs for accreditation in a field of testing, field of calibration, product or service.

Description of the Changes

The NVLAP procedures are redesignated as part 285 of title 15 of the Code of Federal Regulations; expanded to include accreditation of calibration laboratories; updated for compatibility with conformity assurance and assessment concepts; made consistent with relevant International Organization for Standardization (ISO) documents (e.g., ISO Guides 25, 38, 43, 58, and 9000); revised to facilitate and promote acceptance of calibration and test results between countries to avoid barriers to trade; and to eliminate references to the NVLAP advisory committee. Section D has been replaced with language essentially identical to ISO Guide 25. Provisions in this regard will facilitate cooperation between laboratories and other bodies to assist in the exchange of information and experience, harmonize standards and procedures, and establish the basis for bi-lateral and multi-lateral agreements.

Summary of Comments

On July 27, 1993, the National Institute of Standards and Technology published a notice of proposed rulemaking in the Federal Register (58 FR 40087). A total of 11 letters were received: Four trade associations, three manufacturers, one government agency, one laboratory accrediting organization, one testing laboratory, and one consultant commented. All eleven supported the proposal, especially the changes in procedures that will result in achieving compatibility with international standards and guides and broadening the scope of NVLAP to include accreditation of calibration laboratories.

Other than recommendations to strengthen the national and international recognition of NVLAP accredited laboratory data, the comments covered a wide range of suggestions made by only one or two of the respondents. Recommendations are addressed below with a summary "Recommendation" and a "Response" for each.

Comment. One accreditation organization and one consultant

suggested that NVLAP clarify § 285.24 Denying, Suspending, and revoking accreditation, to specify the conditions for making a suspension decision vis-a-vis a revocation decision.

Response. Section 285.24 (e) clearly states that invoking suspension or revocation "will depend on the nature of the violation(s)". It is very difficult to be prescriptive because of the vast possible combinations of laboratory operations and deficiencies. Selecting suspension action implies the expectation that deficiencies can be resolved before actual suspension is invoked; additionally, if suspension is invoked, the expectation is that it will be rather short lived. Revocation, in contrast, is clearly used in cases of more serious deficiencies that are not likely to be resolved. The return of the Certificate and Scope of Accreditation are required under revocation; it is expected that suspension will be short lived, therefore return of the Certificate and Scope are not required.

Comment. One manufacturer and one laboratory suggested that NVLAP procedures should provide for an "office of government liaison" to work toward reduction of redundant accreditation programs in the United States to save laboratories the expense of paying for multiple programs.

Response. Although redundant programs and multiple audits cause confusion and added expense to accredited laboratories, NVLAP has no authority to add a provision regarding redundant programs and/or multiple audits. The NVLAP process is designed so that NVLAP itself does not offer a LAP that duplicates one that exists or could be offered by a public sector accreditor.

Comment. One consultant suggested that although a definition is provided for the term "Certificate of Accreditation", a definition is needed for the term "Certificate" as used in the definition of "Reference material".

Response. See NIST Special Publication 260, "Standard Reference Materials Catalog", for definition and discussion of the term "certificate" as it applies to Standard Reference Materials. Defining the term in the NVLAP procedures would be confusing and out of context with its use.

Comment. One manufacturer suggested that part 285 should be referenced in § 285.6 NVLAP documentation.

Response. Section 285.6 (a) will be changed to include such a reference.

Comment. One trade association suggested that NVLAP modify the definition for Authorized Representative in § 285.5 Definitions to provide an organization with more flexibility in naming an Authorized Representative.

Response. This section will be reworded to provide additional flexibility by stating that the Authorized Representative of an accredited laboratory may be an individual who is authorized by the laboratory or the parent organization.

Comment. One manufacturer suggested adding a definition for Competent to § 285.5 Definitions.

Response. The definition of Competence will be added as "the ability of a laboratory to meet the NVLAP conditions and to conform to the criteria in NVLAP publications for specific calibration and test methods".

Comment. One manufacturer suggested modifying the definition of NVLAP in § 285.5 Definitions to include its relationship to NIST.

Response. Agree. The definition for NVLAP will be changed to state that NVLAP "is an Office within the National Institute of Standards and Technology".

Comment. One trade association suggested changing the definition of Traceability of the accuracy—in § 285.5 Definitions by changing "primary" standard to "reference" standard.

Response. The definition is correct as written. Traceability follows a path which may include the "reference standard" in the laboratory but, as the definition states, must be traceable "ultimately to a primary standard".

Comment. One trade association suggested that § 285.33 (k) Certificates and reports identify the type of laboratory issuing the certificate and report (e.g., independent, manufacturer's, etc.). It is the belief of the writer of this comment that "in-house" laboratories can not necessary produce "unbiased" results.

Response. No change is needed. Information describing the type of laboratory accredited is provided by the laboratory in its application and included in the NVLAP data base. However, the type of laboratory has no bearing on the accreditation decision; rather, the accreditation decision is based on the judgment (using results from on-site assessments, proficiency testing, and monitoring visits) that the laboratory meets all of the criteria established for a particular Laboratory Accreditation Program (LAP), independent of the "organizational" association of the laboratory.

Comment: One consultant suggested revision of § 285.23(a) Granting and renewing accreditation to remove decisions based on variations of compliance.

Response: Full compliance results in accreditation action. Less than full compliance can result in accreditation or other actions depending on variation from full compliance in terms of deficiencies and the expectations of corrective action.

Comment: One consultant suggested that § 285.23(b)(3) Granting and renewing accreditation should contain a stronger statement than "reminding" laboratories of their legal obligations.

Response: NVLAP has no responsibility or authority to do more than remind laboratories of this fact.

Comment: One trade association and one laboratory suggested that §§ 285.32(a)(10) and 285.33(b)(2)(ii) and (iii) be either deleted or limited to ensure that the requirement for laboratories to avoid undue or coercive commercial or financial pressures on staff are not applied to the normal course of employer-employee and independent contractor relationships of a manufacturer's in-house laboratory.

Response: These Sections clearly avoid undue interference by limiting the requirement to "pressures which might adversely affect the quality of the work." Accreditation of a laboratory depends on NVLAP's confidence that the laboratory will provide accurate test and calibration services. These services must no be degraded by pressures of any kind. NVLAP cannot deal with degrees or types of pressure, only with the accuracy of data provided to customers.

Comment: One trade association suggested that NVLAP needs to clarify its policy for addressing the recognition of foreign-based laboratories based on accreditation by a foreign government or accrediting organization.

Response: The policy will be clarified by adding to § 285.11 Requesting a LAP a new paragraph (f) which states that "consistent with applicable laws and regulations, the Director may negotiate and conclude agreements with the governments of other countries for NVLAP recognition of foreign laboratories. At a minimum, any agreement must provide that accredited foreign laboratories meet conditions for accreditation comparable to and consistent with those set out in these requirements".

Comment: One manufacturer suggested deleting the requirement in § 285.26 Change in status of laboratory for laboratories to advise NVLAP of any change in location and/or configuration of its facilities.

Response: NVLAP must get this information prior to the laboratory making any changes. The fact of moving or reconfiguration of a laboratory could

significantly affect the quality of its testing or calibration activities.

Comment: One trade association suggested revising § 285.32(a)(6) Conditions for accreditation, to limit the services that a laboratory offers to customers to NVLAP accredited areas.

Response: NVLAP accreditation does not limit the freedom of laboratories to offer services outside the scope of accreditation. NVLAP only limits laboratories from claiming accreditation for services not included on their Scopes of Accreditation issued to the laboratories.

Comment: One trade association asked that the regulation be made more specific in defining the meaning of "staffing" in § 285.26., stating that it is too broad.

Response: NVLAP believes that there are so many possibilities regarding staffing changes that the reference needs to be general so that an objective opinion can be made on the specific change proposed or made. NVLAP focuses on staffing changes that could affect the quality of the testing or calibration work.

Comment: One trade association suggested changing § 285.33 (1) Subcontracting of calibration or testing to limit subcontracting to accredited laboratories only.

Response: This section is in full conformity with international requirements which do not impose such a restriction. This is partly based on the fact that no other accredited laboratory may be geographically available or willing to provide the services needed. NVLAP believes that its procedures for subcontracting will ensure that the data provided by the subcontractor will meet the established quality standards.

Comment. Two trade associations and one Government agency stated that NVLAP procedures need to be more explicit regarding coordination with the private and public sectors in defining the contents of a LAP, especially when the LAP will be addressing regulatory responsibilities of other agencies.

Response. NVLAP invites the participation of all interested parties in the determination of need and in the design of a new accreditation program (§§ 285.15 and 285.16). The Federal Register, public workshops, news releases, direct mailings to organizations and associations, and participation in industry and professional meetings are all mechanisms used in order to encourage such participation.

Comment. A trade association, a Government agency and an accreditation organization commented that § 285.12(b)(3) LAP development decision does not adequately prevent a conflict of interest for NIST in making LAP development decisions that could be in competition with private sector accreditation programs.

Response. The conditions under which NVLAP establishes and operates accreditation programs is explicit and addresses the conflict of interest question. NVLAP believes that the requirements followed in making a development decision are adequate and that NVLAP has guarded against establishment of programs already existing or that could be offered by private sector accreditors.

Comment. A trade association, a Government agency and an accreditation organization commented that § 285.18 Adding to or modifying an established LAP should be strengthened to require NVLAP to follow the same requirements for modifying a LAP as for establishing a new LAP. NVLAP should not add test methods without going through a full "need" analysis.

Response. Every LAP is established after an exhaustive process that includes the determination of need. Changes needed by a LAP sponsor, caused by standards updated by standards bodies, or due to revisions in regulatory requirements, must be made expeditiously so that the accreditation program continues to meet the needs of its sponsor.

Comment. One manufacturer and one government agency suggested that § 285.13 Request from a government agency be revised to contain all of the information required from a private sector organization requesting a LAP (§ 285.14).

Response. The procedures to be followed by private sector organizations and government agencies are, of necessity, different. Regulatory and public service program authorities are specified in laws and administrative procedures. Accreditation requirements established by government agencies may contain the conditions noted in § 285.14 and are automatically referenced in the specific authority establishing a laboratory accreditation program.

NVLAP, however, agrees that the procedures do need to explicitly address establishing or modifying NVLAP LAPs to meet the requirements mandated by the Federal Government including legislative action and/or intergovernmental understandings or agreements. Accordingly, section 285.1 is revised to state that NVLAP will operate to accredit both calibration laboratories and testing laboratories "in response to (a) Mandates by the Federal government through legislative or administrative action; (b) Requests from a government agency (§ 285.13); and (c) Requests from a private section organization (§ 285.14)".

In addition, § 285.11, Requesting a LAP, is revised to provide that following receipt of the identification of a mandate for a LAP based on legislative or administrative action, the Director must publish a Federal Register notice (1) stating the purpose of the LAP including the national or international need; (2) describing the general scope of the LAP; (3) identifying government agencies having oversight; and (4) providing information to any interested party wishing to be on the NVLAP mailing list to receive routine information on the development of the LAP. In addition, § 285.12 is revised to provide that the Director of NIST shall establish all LAPs on the basis of need; and that a mandate to develop a LAP by NVLAP will be interpreted as a defacto decision to develop the specified LAP, and a LAP will be developed (or existing LAPs modified, if practical) following these procedures.

Comment. In the context of the establishment of LAPs at the request of Government agencies, one manufacturer stated that the proposed change to the NVLAP procedures does not cover: (1) Requirements for factory inspections as a part of certification; (2) certification organizations; and (3) the need for a public review of the findings. Further, the changes would allow the use of subcontractors who are not independent of manufacturers, employers, and distributors.

Response. No changes are made. The comments reflect some of the conditions of accreditation required by a government agency. These kinds of conditions are normally addressed in gathering information leading to a decision whether or not to develop a new LAP. The NVLAP procedures can not be complete in anticipation of any and all possible conditions required by a sponsor.

Comment. Three trade associations, two manufacturers, a Government agency, an accreditation organization and a consultant each commented on the need for more specifics regarding international trade, international recognition of testing and calibration data, and memoranda of understanding (MOUs) and mutual recognition agreements. Most letters contained some reference to these issues, either pointing out the need for explicit language recognizing international trade interests such as "reduction of non-tariff barriers"; working to "make the program more acceptable nationally and internationally"; stating that "it is of great interest to U.S. manufacturers to have U.S./EC recognized accreditation

for testing to European specifications"; and identifying the need to "promote the acceptance of calibration and testing results between countries to encourage international trade".

The comment was also made that the NVLAP revision should state that inquiries from other countries regarding memoranda of understandings (MOUs) and mutual recognition agreements (MRAs) will be referred to the appropriate U.S. agency to participate in any detailed negotiations.

Response. Other than a general statement, the proposed regulation did not specifically deal with these concerns.

Comment. One consultant suggested changing § 285.22 Assessing and evaluating a laboratory to eliminate the suggestion that NVLAP provides consulting or legal services.

Response. Regarding consulting services, communications with laboratories are in the context of these procedures, none of which provide for consulting services. NVLAP identifies the deficiencies noted; it is the responsibility of the laboratory, not NVLAP, to determine how deficiencies will be rectified. Regarding legal services, NVLAP provides guidance to the accredited laboratories on the conditions for referencing accredited status; this is procedural, not legal advice.

Comment. One consultant suggested that NVLAP expand and elaborate § 285.3 Description and goal of NVLAP to include additional information explaining methods for achieving the various objectives and goals in the section.

Response. The language in this section clearly defines the goals and objectives of NVLAP. Methods for achieving these goals and objectives are already contained in many other publications, including NIST administrative procedures and various NVLAP programmatic documents.

Comments. One trade association and one consultant suggested that NVLAP reword § 285.8 Referencing NVLAP accreditation, to remove the implication that laboratories must advertise accredited status, etc.

Response. Section 285.8(a) has been revised to make clear that advertising is voluntary.

Comment. One accreditation organization suggested that NVLAP should not make any changes to § 285.33 Criteria for accreditation in response to comments received as a result of the **Federal Register** notice because it is important that the NVLAP regulation remain compatible with the ISO Guide 25. It was recommended that such changes should be compiled for use in discussions at upcoming ISO meetings related to changing ISO Guide 25.

Response. NVLAP agrees, and is doing this.

Comment. One accreditation organization suggested that ASTM Standard E 1301 should be referenced instead of ISO Guide 38, which is "no longer a viable standard"; ISO Guide 43 should not be referenced because it is very general and being revised.

Response. Guides 38 and 43 served as reference to ensure that the NVLAP procedures meet all current international requirements. In fact, the NVLAP procedures are more robust than the procedures contained in either Guide 38 or Guide 43. NVLAP is committed to meeting international requirements for laboratory accreditation, therefore we reference the ISO guides and standards. We also know that ISO "equivalents" are published by other standards bodies. However, we do not plan to invest time in evaluating the equivalence of these standards in order to reference them in our procedures.

Comment. One accreditation organization suggested that the reference to ISO Series 9000 documents in § 285.4 References might imply that NVLAP accreditation also conveys ISO 9000 registration.

Response. Reference to the ISO Series 9000 does not imply that NVLAP is an ISO 9000 registrar. However, NVLAP accepts the statement in ISO Guide 25 that "laboratories meeting the requirements of the Guide comply with the relevant requirements of the ISO 9000 series of standards including those of the model described in ISO 9002".

Comment. One consultant suggested deleting reference to ISO 9004 because it is intended only as a guideline document for use by operators of quality management systems and not for regulatory adoption or referencing as being compatible.

Response. The entire ISO Series is referenced because of the strong relationship of this series with the quality systems criteria of ISO Guide 25.

Additional Information

Executive Order 12866

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

Executive Order 12612

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

Regulatory Flexibility Act

The General Counsel 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 because (1) participation in NVLAP is entirely voluntary, and (2) the changes are primarily administrative, affecting the management of the program rather than laboratories seeking or holding accreditation. Further, the technical components of NVLAP, that is, the specific technical criteria that individual laboratories are accredited against, are not changed in any significant way by this proposal.

Paperwork Reduction Act

The information collection requirements contained in this proposed 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.

National Environmental Policy Act

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

List of Subjects in 15 CFR Part 285

Business and industry, Commerce, Laboratories, Measurement standards.

Dated: April 25, 1994.

Mary Good,

Under Secretary for Technology, Department of Commerce.

Dated: April 19, 1994.

Samuel Kramer,

Associate Director, NIST.

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

PART 7—[REDESIGNATED AS PART 285]

1. Part 7 is redesignated as part 285.

1a. The authority citation for part 285 is revised to read as follows:

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

PART 285—[AMENDED]

2. The Table of Contents for Part 285 is revised to read as follows:

Subpart A—General Information

Sec.

285.1 Purpose.

285.2 Organization of procedures.

3. Section 285.1 is revised to read as follows:

§ 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 to accredit both calibration laboratories and testing laboratories in response to:

(a) Mandates by the Federal government through legislative or administrative action;

(b) Requests from a government agency (§ 285.13); and

(c) Requests from a private sector organization (§ 285.14).

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).

4. Section 285.2 is revised to read as follows:

§ 285.2 Organization of procedures.

Subpart A describes considerations which relate in general to all aspects of NVLAP. Subpart B describes how new LAPs are requested, developed, and announced, and how LAPs are terminated. Subpart C describes procedures for accrediting laboratories. Subpart D sets out the conditions and criteria for NVLAP accreditation.

5. Section 285.3 is revised to read as follows:

§ 285.3 Description and goal of NVLAP.

(a) NVLAP is a system for accrediting calibration laboratories and testing laboratories found competent to perform specific tests or calibrations. Competence is defined as the ability of a laboratory to meet the NVLAP conditions (§ 285.32) and to conform to the criteria (§ 285.33) in NVLAP publications for specific calibration and test methods.

(b) NVLAP is a process which:

(1) Provides the technical and administrative mechanisms for national and international recognition for competent laboratories based on a comprehensive procedure for promoting confidence in calibration and testing laboratories that show that they operate in accordance with NVLAPs requirements;

(2) Provides laboratory management with documentation for use in the development and implementation of their quality systems;

(3) Identifies competent laboratories for use by regulatory agencies, purchasing authorities, and product certification systems;

(4) Provides laboratories with guidance from technical experts to aid them in reaching a higher level of performance resulting in the generation of improved engineering and product information; and

(5) Promotes the acceptance of calibration and test results between countries, and facilitates cooperation between laboratories and other bodies to assist in the exchange of information and experience, facilitating removal of non-tariff barriers to trade and promoting the harmonization of standards and procedures.

(c) NVLAP is comprised of a series of laboratory accreditation programs (LAPs) which are established on the basis of requests and demonstrated need. The specific calibration and test methods, types of calibration and test methods, products, services, or standards to be included in a LAP are determined by an open process during the establishment of the LAP (see § 285.11). The Director of the National Institute of Standards and Technology (NIST) does not unilaterally propose or decide the scope of a LAP. Communication with other laboratory accreditation systems is fostered to encourage development of common criteria and approaches to accreditation and to promote the domestic, foreign, and international acceptance of test data produced by the accredited laboratories.

6. Section 285.4 is revised to read as follows:

§ 285.4 References.

NVLAP is designed to be compatible with domestic and foreign laboratory accreditation programs to ensure the universal acceptance of test data produced by NVLAP-accredited laboratories. In this regard, these Procedures are compatible with:

(a) The most recent official publications of ISO Guides 2, 25, 30, 38, 43, 45, 49, 58, and Standards 8402, 9001, 9002, 9003, and 9004.

(b) International vocabulary of basic and general terms in metrology (VIM) and Guide to the expression of uncertainty in measurement, issued by International Bureau of Weights and Measures (BIPM), International Electrotechnical Commission (IEC), International Federation of Clinical Chemistry (IFCC), International Organization for Standardization (ISO), International Union of Pure and Applied Chemistry (IUPAC), International Union of Pure and Applied Physics (IUPAP), and International Organization of Legal Metrology (OIML).

7. Section 285.5 is revised to read as follows:

§ 285.5 Definitions.

Accreditation (of a laboratory): A formal recognition that a laboratory is competent to carry out specific tests or calibrations or types of test or calibrations.

Accreditation criteria: A set of requirements used by an accrediting body which a laboratory must meet in order to be accredited.

Approved Signatory (of an accredited laboratory): An individual who is recognized by NVLAP as competent to sign accredited laboratory calibration or test reports.

Assessment (of a laboratory): The on-site examination of a testing or calibration laboratory to evaluate its compliance with the conditions and criteria for accreditation.

Authorized Representative (of an accredited laboratory): An individual who is authorized by the laboratory or the parent organization to sign the NVLAP application form and commit the laboratory to fulfill the NVLAP requirements (The Authorized Representative may also be recommended by the laboratory as an Approved Signatory).

Calibration: A set of operations which establish, under specified conditions,

the relationship between values indicated by a measuring instrument or system, or values represented by a material measure, and the corresponding known values of a measurand.

Calibration method: A defined technical procedure for performing a calibration.

Certificate of Accreditation: A document issued by NVLAP to a laboratory that has met the criteria and conditions for accreditation. The Certificate of Accreditation may be used as proof of accredited status. A Certificate of Accreditation is always accompanied with a Scope of Accreditation.

Competence: The ability of a laboratory to meet the NVLAP conditions and to conform to the criteria in NVLAP publications for specific calibration and test methods.

Deficiency: The non-fulfillment of NVLAP conditions and/or criteria for accreditation.

Director of NIST: The Director of the National Institute of Standards and Technology or designate.

Laboratory: An organization that performs calibrations and/or tests. When a laboratory is part of an organization that carries out activities additional to calibration and testing, the term "laboratory" refers only to those parts of that organization that are involved in the calibration and testing process. The laboratory activities may be carried out at or from a permanent location, at or from a temporary facility, or in or from a mobile facility.

LAP: A laboratory accreditation program established and administered under NVLAP, consisting of test methods or calibrations relating to specific products or fields of testing or calibration.

NIST: The National Institute of Standards and Technology.

NVLAP: The National Voluntary Laboratory Accreditation Program. NVLAP is an Office within the National Institute of Standards and Technology.

Person: Associations, companies, corporations, educational institutions, firms, government agencies at the federal, state and local level, partnerships, and societies—as well as divisions thereof—and individuals.

Product: A type or a category of manufactured goods, constructions, installations, and natural and processed materials, or those associated services whose characterization, classification, or functional performance is specified by standards or test methods.

Proficiency testing: The determination of laboratory performance by means of comparing and evaluating calibrations or tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions.

Quality manual: A document stating the quality policy, quality system, and quality practices of an organization. The quality manual may reference other laboratory documentation.

Quality system: The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Reference material: A material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. A "certified reference material" means that one or more of the property values of the reference material are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.

Reference standard: A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.

Scope of accreditation: A document issued by NVLAP which lists the test methods or services, or calibration services for which the laboratory is accredited.

Sub-facility: A laboratory operating under the technical direction and quality system of a main facility that is accredited.

Test: A technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

Test method: A defined technical procedure for performing a test.

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

Traceability of the accuracy of measuring instruments: A documented chain of comparison connecting the accuracy of a measuring instrument to other measuring instruments of higher accuracy and ultimately to a primary standard.

8. Section 285.6 is revised to read as follows:

§ 285.6 NVLAP documentation.

NVLAP publications are available for information and use by staff of accredited laboratories, those seeking accreditation, other laboratory accreditation systems, and others needing information on the requirements for accreditation under the NVLAP program. Accredited laboratories will be sent revised publications routinely. Publications include:

(a) The Procedures and General Requirements, (15 CFR part 285);

(b) Handbooks containing the administrative and operational procedures and technical requirements of specific LAPs;

(c) A directory of accredited laboratories published annually and updated periodically; and

(d) Policy Guides that provide changes to the Procedures and General Requirements and Handbooks between formal revisions of those publications.

9. Section 285.7 is revised to read as follows:

§ 285.7 Confidentiality.

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

10. Section 285.8 is added to read as follows:

§ 285.8 Referencing NVLAP accreditation.

To become accredited and maintain accreditation, a laboratory shall agree in writing to:

(a) Follow NVLAP guidance when advertising its accredited status (including the use of the NVLAP logo) on letterheads, brochures, test reports, and professional, technical, trade, or other laboratory services publications.

(b) Inform its clients that the laboratory's accreditation or any of its calibration or test reports in no way constitutes or implies product certification, approval, or endorsement by NIST.

11. Section 285.11 is amended by revising paragraphs (a), (b)(1), (b)(3)(ii) and (c) and adding paragraphs (e) and (f) to read as follows:

§ 285.11 Requesting a LAP.

(a) A request to establish a LAP must be made to the Director of NIST.

(b) * * *

(1) The scope of the LAP in terms of products, calibration services, or testing services proposed for inclusion;

* * * * *

(3) * * *

(ii) Evidence of a national need to accredit calibration or testing laboratories for the specific scope beyond that served by an existing

laboratory accreditation program in the public or private sector;

* * * * *

(c) NVLAP may request clarification of the information submitted according to paragraph (b) of this section.

* * * * *

(e) Following receipt of the identification of a mandate for a LAP based on legislative or administrative action, the Director shall publish a **Federal Register** notice:

(1) Stating the purpose of the LAP including the national or international need;

(2) Describing the general scope of the LAP;

(3) Identifying government agencies having oversight; and

(4) Providing information to any interested party wishing to be on the NVLAP mailing list to receive routine information on the development of the LAP.

(f) Consistent with applicable laws and regulations, the Director may negotiate and conclude agreements with the governments of other countries for NVLAP recognition of foreign laboratories. At a minimum, any agreement must provide that accredited foreign laboratories meet conditions for accreditation comparable to and consistent with those set out in these requirements.

12. Section 285.12 is amended by revising paragraphs (a) and (b)(6) to read as follows:

§ 285.12 LAP development decision.

(a) The Director of NIST shall establish all LAPs on the basis of need.

(1) A mandate to develop a LAP by NVLAP will be interpreted as a de facto decision to develop the specified LAP, and a LAP will be developed (or existing LAPs modified, if practical) following these procedures.

(2) Government agencies may document the need by using § 285.13, and private sector organizations by using § 285.14.

(b) * * *

(6) The economic and technical feasibility of accrediting laboratories for the calibration or test methods, types of calibration or test methods, products, services, or standards requested; and

* * * * *

13. Section 285.13 is amended by revising paragraphs (a) and (c) to read as follows:

§ 285.13 Request from a government agency.

(a) Any Federal, state or local agency responsible for regulatory or public service programs established under statute or code, which has determined a need to accredit laboratories within the context of its programs, may request the Director of NIST to establish a LAP.

* * * * *

(c) NVLAP may request clarification of the information required by § 285.11(b).

* * * * *

14. Section 285.14 is amended by revising paragraphs (a) introductory text and (c) to read as follows:

§ 285.14 Request from a private sector organization.

(a) Any private sector organization which has determined a need to accredit laboratories for specific products, calibrations, or testing services, may request the Director of NIST to establish a LAP if it uses procedures meeting the following conditions:

* * * * *

(c) NVLAP may request clarification of the information required by § 285.11(b).

* * * * *

15. Section 285.15 is amended by revising paragraphs (a) and (c) to read as follows:

§ 285.15 Development of technical requirements.

(a) Technical requirements for accreditation are specific for each LAP. The requirements tailor the criteria referenced in § 285.33 to the calibration or test methods, types of calibration or test methods, products, services, or standards covered by the LAP.

* * * * *

(c) NVLAP shall make every reasonable effort to ensure that the affected calibration or testing community within the scope of the LAP is informed of any planned workshop. Summary minutes of each workshop will be prepared. A copy of the minutes will be made available for inspection and copying at the NIST Records Inspection Facility.

16. Section 285.17(c) is revised to read as follows:

§ 285.17 Announcing the establishment of a LAP.

* * * * *

(c) NVLAP shall establish fees in amounts that will enable it to recover its full costs, and shall, from time to time as necessary, revise the fees for this purpose.

17. Section 285.18 is revised to read as follows:

§ 285.18 Adding to or modifying an established LAP.

(a) Established or developing LAPs may be added to, modified, or realigned based on either a written request from any person wishing to add or delete specific standards, calibration or test methods, or types of calibration or test methods or a need identified by NIST.

(b) NVLAP may choose to make the additions or modifications available for accreditation under a LAP when:

(1) The additional standards, calibration or test methods, or types of calibration or test methods requested are directly relevant to the LAP;

(2) It is feasible and practical to accredit calibration or testing laboratories for the additional standards, calibration or test methods, or types of calibration or test methods; and

(3) It is likely that laboratories will seek accreditation for the additional standards, calibration or test methods, or types of calibration or test methods.

18. Section 285.19(a) is revised to read as follows:

§ 285.19 Termination of a LAP.

(a) The Director of NIST may terminate a LAP when the Director of NIST 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 Director of NIST proposes to terminate a LAP, a notice will be published in the **Federal Register** setting forth the basis for that determination.

* * * * *

19. Section 285.21 is amended by revising paragraphs (a) and (c) to read as follows:

§ 285.21 Applying for accreditation.

(a) A laboratory may complete and remit an application for accreditation in any of the established LAPs.

* * * * *

(c) Accreditation of laboratories outside of the United States may require:

(1) Translation of laboratory documentation into English; and

(2) Payment of additional traveling expenses for on-site assessments and proficiency testing.

20. Section 285.22 is revised to read as follows:

§ 285.22 Assessing and evaluating a laboratory.

(a) Information use to evaluate a laboratory's compliance with the conditions for accreditation set out in § 285.32, the criteria for accreditation set out in § 285.33, and the technical requirements established for each LAP will include (not necessarily in this order):

(1) Application and other material submitted by the laboratory (§ 285.32(b));

(2) On-site assessment reports;
(3) Laboratory performance on proficiency tests;
(4) Laboratory responses to identified deficiencies; and
(5) Technical evaluation.
(b) NVLAP shall arrange the assessment and evaluation of applicant laboratories in such a way as to minimize potential conflicts of interest.
(c) NVLAP shall inform each applicant laboratory of any additional action(s) that the laboratory must take to qualify for accreditation.

21. Section 285.23 is amended by removing paragraph (d), and by revising paragraphs (a) and (b) to read as follows:

§ 285.23 Granting and renewing accreditation.

(a) NVLAP will take action to: (1) Grant initial accreditation, or (2) renew, suspend, or propose to deny or revoke accreditation of an applicant laboratory, based on the degree to which the laboratory complies with the specific NVLAP requirements.
(b) If accreditation is granted or renewed, NVLAP shall:
(1) Provide a Certificate of Accreditation and a Scope of Accreditation to the laboratory;
(2) Provide guidance on referencing the laboratory's accredited status, and the use of the NVLAP logo by the laboratory and its clients, as needed; and
(3) Remind the laboratory that accreditation does not relieve it from complying with applicable federal, state, and local laws and regulations.

* * * * *

22. Section 285.24 is revised to read as follows:

§ 285.24 Denying, suspending, and revoking accreditation.

(a) 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.
(b) The laboratory will have 30 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 that 30-day period.
(c) If NVLAP finds that an accredited laboratory has violated the terms of its accreditation or the provisions of these procedures, NVLAP may, after consultation with the laboratory, suspend the laboratory's accreditation, or advise of NVLAP's intent to revoke accreditation. If 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.
(d) A laboratory whose accreditation has been denied, revoked, terminated, or expired, or which has withdrawn its application before being accredited, may reapply and be accredited if the laboratory:
(1) Completes the assessment and evaluation process; and
(2) Meets the conditions and criteria for accreditation that are set out in §§ 285.32 and 285.33.
(e) Conditions of suspension will include prohibiting the laboratory from using the NVLAP logo on its test or calibration reports during the suspension period. The determination of NVLAP whether to suspend or to propose revocation of a laboratory's accreditation will depend on the nature of the violation(s) of the terms of its accreditation.

23. Section 285.26 is added to read as follows:

§ 285.26 Change in status of laboratory.

Accreditation of a laboratory is based on specific conditions and criteria including the laboratory ownership, location, staffing, facilities, and configuration. Changes in any of these conditions or criteria could result in loss of accreditation. NVLAP must be informed if any of the conditions or criteria for accreditation are changed so that a determination can be made concerning the status of the accreditation.

24. Section 285.31 is revised to read as follows:

§ 285.32 Application of accreditation conditions and criteria.

To become accredited and maintain accreditation, a laboratory must meet the conditions for accreditation set out in § 285.32, the criteria set out in § 285.33, and the guidance provided in the Handbooks for specific LAPs.

25. Section 285.32 is revised to read as follows:

§ 285.32 Conditions for accreditation

(a) To become accredited and maintain accreditation, a laboratory shall agree in writing to:
(1) Be assessed and evaluated initially and on a periodic basis;
(2) Demonstrate, on request, that it is able to perform the calibrations or tests representative of those for which it is seeking accreditation;
(3) Pay all fees;
(4) Participate in proficiency testing as required;
(5) Be capable of performing the calibrations or tests for which it is accredited according to the latest version of the calibration or test method within one year after its publication or within another time limit specified by NVLAP;
(6) Limit the representation of the scope of its accreditation to only those calibrations, tests or services for which accreditation is granted;
(7) Resolve all deficiencies;
(8) Limit all its work or services of clients to those areas where competence and capacity are available;
(9) Maintain records of all actions taken in response to complaints for a minimum of one year;
(10) Maintain an independent decisional relationship between itself and its clients, affiliates, or other organizations so that the laboratory's capacity to render calibration or test reports objectively and without bias is not adversely affected;
(11) Report to NVLAP within 30 days any major changes involving the location, ownership, management structure, authorized representative, approved signatories, or facilities of the laboratory; and
(12) Return to NVLAP the Certificate of Accreditation and the Scope of Accreditation for revision or other action should it:
(i) Be requested to do so by NVLAP;
(ii) Voluntarily terminate its accredited status; or
(iii) Become unable to conform to any of these conditions, the applicable criteria of § 285.33, and related technical requirements.
(b) To become accredited and maintain accreditation, a laboratory shall supply, upon request, the following information:
(1) Legal name and full address;
(2) Ownership of the laboratory;
(3) Organization chart defining relationships that are relevant to performing testing and calibrations covered in the accreditation request;
(4) General description of the laboratory, including its facilities and scope of operation;
(5) Name, address, and telephone and FAX number of the authorized representative of the laboratory;
(6) Names or titles and qualifications of laboratory staff nominated to serve as approved signatories of calibration or test reports that reference NVLAP accreditation;

(7) The laboratory Quality Manual; and

(8) Other information as may be needed for the specific LAP(s) in which accreditation is sought.

26. Section 285.33 is revised to read as follows:

§ 285.33 Criteria for accreditation.

(a) *Scope.* (1) This section sets out the general requirements in accordance with which a laboratory has to demonstrate that it operates, if it is to be recognized as competent to carry out specific calibrations or tests.

(2) Additional requirements and information which have to be disclosed for assessing competence or for determining compliance with other criteria may be specified by NVLAP, depending upon the specific character of the task of the laboratory.

(3) This section is for use by calibration and testing laboratories in the development and implementation of their quality systems. It may also be used by accreditation bodies, certification bodies and others concerned with the competence of laboratories.

(b) *Organization and management.* (1) The laboratory shall be legally identifiable. It shall be organized and shall operate in such a way that its permanent, temporary and mobile facilities meet these requirements.

(2) The laboratory shall:

(i) Have managerial staff with the authority and resources needed to discharge their duties;

(ii) Have policies to ensure that its personnel are free from any commercial, financial and other pressures which might adversely affect the quality of their work;

(iii) Be organized in such a way that confidence in its independence of judgement and integrity is maintained at all times;

(iv) Specify and document the responsibility, authority and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations and tests;

(v) Provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test and the assessment of the results. The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision;

(vi) Have a technical manager (however named) who has overall responsibility for the technical operations;

(vii) Have a quality manager (however named) who has responsibility for the quality system and its implementation. The quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical manager. In some laboratories, the quality manager may also be the technical manager or deputy technical manager;

(viii) Nominate deputies in case of absence of the technical or quality manager;

(ix) Have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights;

(x) Where appropriate, participate in interlaboratory comparisons and proficiency testing programs.

(c) *Quality system, audit and review.* (1) The laboratory shall establish and maintain a quality system appropriate to the type, range and volume of calibration and testing activities it undertakes. The elements of this system shall be documented. The quality documentation shall be available for use by the laboratory personnel. The laboratory shall define and document its policies and objectives for, and its commitment to, good laboratory practice and quality of calibration or testing services. The laboratory management shall ensure that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned. The quality manual shall be maintained current under the responsibility of the quality manager.

(2) The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the requirements of procedures. The quality manual and related quality documentation shall also contain:

(i) A quality policy statement, including objectives and commitments, by top management;

(ii) The organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;

(iii) The relations between management, technical operations, support services and the quality system;

(iv) Procedures for control and maintenance of documentation;

(v) Job descriptions of key staff and reference to the job descriptions of other staff;

(vi) Identification of the laboratory's approved signatories;

(vii) The laboratory's procedures for achieving traceability of measurements;

(viii) The laboratory's scope of calibrations and/or tests;

(ix) Arrangements for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

(x) Reference to the calibration, verification and/or test procedures used;

(xi) Procedures for handling calibration and test items;

(xii) Reference to the major equipment and reference measurement standards used;

(xiii) Reference to procedures for calibration, verification and maintenance of equipment;

(xiv) Reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes;

(xv) Procedures to be followed for feedback and corrective action whenever discrepancies are detected, or departures from documented policies and procedures occur;

(xvi) The laboratory management policies for departures from documented policies and procedures or from standard specifications;

(xvii) Procedures for dealing with complaints;

(xviii) Procedures for protecting confidentiality and proprietary rights;

(xix) Procedures for audit and review.

(3) The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibration or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

(4) The quality system adopted to satisfy the requirements of this section shall be reviewed at least once each year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.

(5) All audit and review findings and any corrective actions that arise from them shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed timescale.

(6) In addition to periodic audits the laboratory shall ensure the quality of results provided to clients by implementing checks. These checks shall be reviewed and shall include, as appropriate but not be limited to:

(i) Internal quality control schemes using whenever possible statistical techniques;

(ii) Participation in proficiency testing or other interlaboratory comparisons;

(iii) Regular use of certified reference materials and/or in—house quality control using secondary reference materials;

(iv) Replicate testings using the same or different methods;

(v) Re-testing of retained items;

(vi) Correlation of results for different characteristics of an item.

(d) *Personnel.* (1) The testing laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.

(2) The testing laboratory shall ensure that the training of its personnel is kept up-to-date.

(3) Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory.

(e) *Accommodation and environment.* (1) Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of calibrations or tests.

(2) The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

(3) The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, voltage, temperature, and sound and vibration levels, as appropriate to the calibrations or tests concerned.

(4) There shall be effective separation between neighboring areas when the activities therein are incompatible.

(5) Access to and use of all areas affecting the quality of these activities shall be defined and controlled.

(6) Adequate measures shall be taken to ensure good housekeeping in the laboratory.

(f) *Equipment and reference materials.* (1) The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of calibrations and tests. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of this section are met.

(2) All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

(3) Each item of equipment including reference materials shall, when appropriate, be labelled, marked or otherwise identified to indicate its calibration status.

(4) Records shall be maintained of each item of equipment and all reference materials significant to the calibrations or tests performed. The records shall include:

(i) The name of the item of equipment;

(ii) The manufacturer's name, type identification, and serial number or other unique identification;

(iii) Date received and date placed in service;

(iv) Current location, where appropriate;

(v) Condition when received (e.g. new, used, reconditioned);

(vi) Copy of the manufacturer's instructions, where available;

(vii) Dates and results of calibrations and/or verifications and date of next calibration and/or verification;

(viii) Details of maintenance carried out to date and planned for the future;

(ix) History of any damage, malfunction, modification or repair.

(g) *Measurement traceability and calibration.* (1) All measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests shall be calibrated and/or verified before being put into service. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment.

(2) The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards of measurement where available. Calibration certificates shall wherever applicable indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification.

(3) Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons or proficiency testing.

(4) Reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards has not been invalidated.

(5) Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement. There shall be a program of calibration and verification for reference standards.

(6) Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications.

(7) Reference materials shall, where possible, be traceable to national or international standards of measurement, or to national or international standard reference materials.

(h) *Calibration and test methods.* (1) The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

(2) The laboratory shall use appropriate methods and procedures for all calibrations and tests and related activities within its responsibility (including sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement and analysis of calibration and/or test data). They shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

(3) Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published in international or national standards, those published by reputable technical organizations or in relevant scientific texts or journals.

(4) Where it is necessary to employ methods that have not been established as standard, these shall be subject to

agreement with the client, be fully documented and validated, and be available to the client and other recipients of the relevant reports.

(5) Where sampling is carried out as part of the test method, the laboratory shall used documented procedures and appropriate statistical techniques to select samples.

(6) Calculations and data transfers shall be subject to appropriate checks.

(7) Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration or test data, the laboratory shall ensure that:

(i) The requirements of these procedures are complied with;

(ii) Computer software is documented and adequate for use;

(iii) Procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;

(iv) Computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data;

(v) It establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

(8) Documented procedure shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory.

(i) *Handling of calibration and test items.* (1) The laboratory shall have a documented system for uniquely identifying the items to be calibrated or tested, to ensure that there can be no confusion regarding the identity of such items at any time.

(2) Upon receipt, the condition of the calibration or test item, including any abnormalities or departures from standard condition as prescribed in the relevant calibration or test method, shall be recorded. Were there is any doubt as to the item's suitability for calibration or test, where the item does not conform to the description provided, or where the calibration or test required is not fully specified, the laboratory shall consult the client for further instruction before proceeding. The laboratory shall establish whether the item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.

(3) The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the calibration or test item, during storage, handling, preparation, and calibration or test; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a calibration or test item or portion of an item is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.

(4) The laboratory shall have documented procedures for the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity of the laboratory.

(j) *Records.* (1) The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. It shall retain on record all original observations, calculations and derived data, calibration records and a copy of the calibration certificate, test certificate or test report for an appropriate period. The records for each calibration and test shall contain sufficient information to permit their repetition. The records shall include the identity of personnel involved in sampling, preparation, calibration or testing.

(2) All records (including those listed in § 285.33(f)(4) pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client.

(k) *Certificates and reports.* (1) The results of each calibration, test, or series of calibrations or tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, in accordance with any instructions in the calibration or test methods. The results should normally be reported in a calibration certificate, test report or test certificate and should include all the information necessary for the interpretation of the calibration or test results and all information required by the method used.

(2) Each certificate or report shall include at least the following information:

(i) A title, e.g., "Calibration Certificate", "Test Report" or "Test Certificate";

(ii) Name and address of laboratory, and location where the calibration or test was carried out if different from the address of the laboratory;

(iii) Unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;

(iv) Name and address of client, where appropriate;

(v) Description and unambiguous identification of the item calibrated or tested;

(vi) Characterization and condition of the calibration or test item;

(vii) Date of receipt of calibration or test item and date(s) of performance of calibration or test, where appropriate;

(viii) Identification of the calibration or test method used, or unambiguous description of any non-standard method used;

(ix) Reference to sampling procedure, where relevant;

(x) Any deviations from, additions to or exclusions from the calibration or test method, and any other information relevant to a specific calibration or test, such as environmental conditions;

(xi) Measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified;

(xii) A statement of the estimated uncertainty of the calibration or test result (where relevant);

(xiii) A signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue;

(xiv) Where relevant, a statement to the effect that the results relate only to the items calibrated or tested;

(xv) A statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory.

(3) Where the certificate or report contains results of calibrations or tests performed by sub-contractors, these results shall be clearly identified.

(4) Particular care and attention shall be paid to the arrangement of the certificate or report, especially with regard to presentation of the calibration or test data and ease of assimilation by the reader. The format shall be carefully and specifically designed for each type of calibration or test carried out, but the headings shall be standardized as far as possible.

(5) Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Calibration Certificate for Test Report or Test Certificate), serial

number * * * for as otherwise identified]", or equivalent form of wording. Such amendments shall meet all the relevant requirements of § 285.33(j).

(6) The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report or test certificate of amendment to a report or certificate.

(7) The laboratory shall ensure that, where clients require transmission of calibration or test results by telephone, telex, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the requirements of these procedures are met and that confidentiality is preserved.

(l) *Subcontracting of calibration or testing.* (1) Where a laboratory subcontracts any part of the calibration or testing, this work shall be placed with a laboratory complying with these requirements. The laboratory shall ensure and be able to demonstrate that its subcontractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory in respect of the work being subcontracted. The laboratory shall advise the client in writing of its intention to subcontract any portion of the calibration or testing to another party.

(2) The laboratory shall record and retain details of its investigation of the competence and compliance of its subcontractors and maintain a register of all subcontracting.

(m) *Outside support services and supplies.* (1) Where the laboratory procures outside services and supplies, other than those referred to in these procedures, in support of calibrations or tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations or tests.

(2) Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned.

(3) The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for calibrations or tests.

(n) *Complaints.* (1) The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.

(2) Where a complaint, or any other circumstances, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this section or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with this section.

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 284

[Docket No. RM93–4–000]

Standards for Electronic Bulletin Boards Required Under Part 284 of the Commission's Regulations

April 26, 1994.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Correction to notice of consolidation of electronic bulletin board working groups.

SUMMARY: The Federal Energy Regulatory Commission is correcting its notice issued on April 19, 1994 (59 FR 19637, April 25, 1994) regarding the consolidation of the Electronic Bulletin Board Working Groups. The correction is to the name of the person representing the producer sector on the interim steering committee.

ADDRESSES: Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426.

FOR FURTHER INFORMATION CONTACT:

Michael Goldenberg, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, (202) 208–2294

Marvin Rosenberg, Office of Economic Policy, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, (202) 208–1283

Brooks Carter, Office of Pipeline and Producer Regulation, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, (202) 208–0666.

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the **Federal Register**, the Commission also provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours in room 3104, 941 North Capitol Street NE., Washington, DC 20426.

The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the texts of formal documents issued by the Commission. CIPS is available at no charge to the user and may be accessed using a personal computer with a modem by dialing (202) 208–1397. To access CIPS, set your communications software to use 300, 1200, or 2400 bps, full duplex, no parity, 8 data bits, and 1 stop bit. CIPS can also be accessed at 9600 bps by dialing (202) 208–1781. The full text of this notice will be available on CIPS for 30 days from the date of issuance. The complete text on diskette in WordPerfect format may also be purchased from the Commission's copy contractor, La Dorn Systems Corporation, also located in room 3104, 941 North Capitol Street NE., Washington, DC 20426.

On April 19, 1994, the Commission issued a Notice of Consolidation of Electronic Bulletin Board Working Groups. The member of the interim steering committee from the producer sector was incorrectly identified. The correct name and address is:

Randy D. Mills, Chevron USA Production, 1301 McKinney, Houston, TX 77252, Phone 713–754–2563, FAX 713–754–3840.

Lois D. Cashell,

Secretary.

[FR Doc. 94–10531 Filed 5–2–94; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the