

good cause exists for making some SIAPs effective in less than 30 days.

Conclusion

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 August 4, 2000.

L. Nicholas Lacey,

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 is revised to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120, 44701; and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, and 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

* * * Effective October 5, 2000

Walnut Ridge, AR, Walnut Ridge Regional, VOR-A, Amdt 16

Walnut Ridge, AR, Walnut Ridge Regional, VOR/DME RWY 22, Amdt 13

Walnut Ridge, AR, Walnut Ridge Regional, LOC RWY 18, Amdt 3

Walnut Ridge, AR, Walnut Ridge Regional, NDB RWY 18, Amdt 4

Jacksonville, FL, Cecil Field, VOR RWY 9R, Orig

Alton/St. Louis, IL, St. Louis Regional, NDB OR GPS RWY 29, Amdt 10B

Carbondale/Murphysboro, IL, Southern Illinois, NDB OR GPS RWY 18L, Amdt 12C

Champaign-Urbana, IL, University of Illinois-Willard, NDB OR GPS RWY 32L, Amdt 10B

Danville, IL, Vermilion County, VOR/DME OR GPS RWY 3, Amdt 11B

Effingham, IL, Effingham County Memorial, LOC RWY 29, Amdt 1B

Galesburg, IL, Galesburg Muni, VOR OR GPS RWY 21, Amdt 6B

Macomb, IL, Macomb Muni, NDB OR GPS RWY 27, Amdt 2D

Pekin, IL, Pekin Muni, VOR/DME RNAV OR GPS RWY 9, Amdt 5A

Peoria, IL, Greater Peoria Regional, NDB OR GPS RWY 31, Amdt 14A

South Bend, IN, South Bend Regional, VOR OR GPS RWY 18, Amdt 7B

South Bend, IN, South Bend Regional, NDB OR GPS RWY 27L, Amdt 28C

Hays, KS, Hays Regional, RNAV RWY 34, Orig

Frenchville, ME, Northern Aroostock Regional, NDB RWY 32, Amdt 6

Frenchville, ME, Northern Aroostock Regional, RNAV RWY 14, Orig

Frenchville, ME, Northern Aroostock Regional, RNAV RWY 32, Orig

College Park, MD, College Park, RNAV RWY 15, Orig

College Park, MD, College Park, VOR/DME RNAV RWY 15, Amdt 3

Gaithersburg, MD, Montgomery County Airpark, VOR RWY 14, Amdt 3

Gaithersburg, MD, Montgomery County Airpark, NDB RWY 14, Amdt 1

Gaithersburg, MD, Montgomery County Airpark, RNAV RWY 14, Orig

Gaithersburg, MD, Montgomery County Airpark, VOR/DME RNAV RWY 14, Amdt 4, CANCELLED

Stevensville, MD, Bay Bridge, VOR/DME RWY 29, Amdt 1

Stevensville, MD, Bay Bridge, RNAV RWY 11, Orig

Stevensville, MD, Bay Bridge, GPS RWY 11, Orig, CANCELLED

Stevensville, MD, Bay Bridge, RNAV RWY 29, Orig

Westminster, MD, Carroll County Reg/Jack B. Poage Field, VOR-A, Amdt 1

Westminster, MD, Carroll County Reg/Jack B. Poage Field, VOR RWY 34, Amdt 4

Westminster, MD, Carroll County Reg/Jack B. Poage Field, RNAV RWY 16, Orig

Westminster, MD, Carroll County Reg/Jack B. Poage Field, RNAV RWY 34, Orig

Westminster, MD, Clearview Airpark, VOR-A, Amdt 4

Westminster, MD, Clearview Airpark, RNAV RWY 14, Orig

Chillicothe, OH, Ross County, VOR RWY 23, Amdt 3B

Columbus, OH, Bolton Field, NDB OR GPS RWY 4, Amdt 6B

Columbus, OH, Rickenbacker Intl, NDB OR GPS RWY 23L, Orig-A

Findlay, OH, Findlay, GPS RWY 18, Amdt 1A

Fremont, OH, Sandusky County Regional, GPS RWY 6, Orig-A

Fremont, OH, Sandusky County Regional, GPS RWY 24, Orig-A

Lancaster, OH, Fairfield County, LOC RWY 28, Amdt 1A

Lancaster, OH, Fairfield County, NDB OR GPS RWY 28, Amdt 8A

Lancaster, OH, Fairfield County, VOR/DME RNAV OR GPS RWY 10, Amdt 10A

Lima, OH, Lima Allen County, VOR OR GPS RWY 27, Amdt 14B

Marion, OH, Marion Muni, GPS RWY 24, Orig-A

Mount Vernon, OH, Knox County, VOR/DME RNAV OR GPS RWY 28, Amdt 2B

Springfield, OH, Springfield-Beckley Muni, NDB OR GPS RWY 24, Amdt 16A

Wapakoneta, OH, Neil Armstrong, LOC RWY 26, Amdt 3C

Wapakoneta, OH, Neil Armstrong, VOR/DME RNAV OR GPS RWY 26, Amdt 5C

Springfield, TN, Springfield-Robertson County, LOC RWY 4, Orig

Springfield, TN, Springfield-Robertson County, NDB RWY 4, Orig

Corsicana, TX, C. David Campbell Field-Corsicana Muni, VOR/DME-A, Amdt 1

Corsicana, TX, C. David Campbell Field-Corsicana Muni, VOR/DME-B, Amdt 1

Corsicana, TX, C. David Campbell Field-Corsicana Muni, NDB RWY 14, Amdt 4

Corsicana, TX, C. David Campbell Field-Corsicana Muni, NDB RWY 32, Amdt 3

Corsicana, TX, C. David Campbell Field-Corsicana Muni, RNAV RWY 14, Orig

Corsicana, TX, C. David Campbell Field-Corsicana Muni, RNAV RWY 32, Orig

Charlotte Amalie, VI, Cyril E King, GPS RWY 10, Orig, CANCELLED

Charlotte Amalie, VI, Cyril E King, RNAV RWY 10, Orig

[FR Doc. 00-20275 Filed 8-9-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

15 CFR Part 287

[Docket No. 981222315-0219-02]

RIN 0693-AB49

Guidance on Federal Conformity Assessment Activities

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

ACTION: Final policy guidance.

SUMMARY: This document contains final policy guidance on Federal agency use of conformity assessment activities. The provisions are solely intended to be used as guidance for agencies in their conformity assessment activities and do not preempt the agencies' authority and responsibility to make regulatory

procurement decisions authorized by statute or required to meet programmatic objectives and requirements.

DATES: This guidance becomes effective August 10, 2000.

FOR FURTHER INFORMATION CONTACT: Dr. Belinda Collins, Director, Office of Standards Services, National Institute of Standards and Technology, Building 820, MS 2100, Room 282, Gaithersburg, MD 20899. Phone: (301) 975-4000.

SUPPLEMENTARY INFORMATION:

Background

This guidance outlines Federal agencies' responsibility for evaluating the efficacy and efficiency of their conformity assessment activities. Each agency is responsible for coordinating its conformity assessment activities with those of other appropriate government agencies and with those of the private sector to make more productive use of the increasingly limited Federal resources available for the conduct of conformity assessment activities and to reduce unnecessary duplication.

This guidance applies to all agencies, which set policy for, manage, operate, or use conformity assessment activities and results, both domestic and international, except for activities carried out pursuant to treaties. "Agency" means any Executive Branch Department, independent commission, board, bureau, office, agency, government-owned or controlled corporation, or other establishment of the Federal government. It also includes any regulatory commission or board, except for independent regulatory commissions subject to separate statutory requirements regarding policy setting, management, operation, and use of conformity assessment activities. It does not include the legislative or judicial branches of the Federal government.

History of the Guidance

In February 1996, The National Technology Transfer and Advancement Act (NTAA) of 1995 was enacted by Congress. Section 12 of the Act directed NIST to coordinate conformity assessment activities of Federal, state and local entities with private sector technical standards activities and conformity assessment activities with the goal of eliminating any unnecessary duplication of conformity assessment activities. The Office of Management and Budget (OMB) Circular A-119, revised February 19, 1998 directed the Secretary of Commerce to issue guidance to the agencies to ensure effective coordination of Federal

conformity assessment activities. The Director of the National Institute of Standards and Technology (NIST), United States Department of Commerce, published proposed guidance in the **Federal Register** on Federal conformity assessment activities on November 3, 1999 (64 FR 59691 (1999)). Closing date for comments was January 18, 2000.

Summary of Public Comments Received by the Agency in Response to the November 3, 1999 Request for Public Comments, and the Agency's Response to the Comments

NIST received comments from nine commentors, including: one national standards coordinating and conformity assessment accreditation body, one government agency, one international company, one laboratory accreditation body, one certification body, one consulting organization, and three trade associations in response to its request. In addition, in September 1999, the U.S. General Accounting Office (GAO) published a report, entitled "GAO/GGD-99-170—Certification Requirements: New Guidance Should Encourage Transparency in Agency Decisionmaking," which contained a recommendation for including a section in the guidance on the issue of transparency in agency certification decisionmaking. The 51 comments as well as the GAO recommendation were considered in finalizing the guidance. The following summarizes the comments received and the agency's response to the comments.

General Comments

One national standards coordinating and conformity assessment accreditation body commented that the guidance should task only NIST with substantive objectives and identify the approach and procedures for accomplishing them.

Response: In OMB Circular A-119, OMB stated that "(t)o ensure effective coordination, the Secretary of Commerce must issue guidance to the agencies." This guidance is a response to that mandate. The suggested approach would not be consistent with OMB's mandate.

One laboratory accreditation body commented the proposed rule should be withdrawn and that the guidance be issued as an annex to OMB Circular A-119.

Response: This document is intended to serve as guidance for Federal agencies in implementing their responsibilities under the NTTAA, and is not a rule. The guidance was issued at the direction of OMB, which chose not to include conformity assessment in OMB

Circular A-119. This comment has been forwarded to OMB for consideration during the next revision of the Circular.

One government agency commented that while the examples in the guidance were helpful in describing how the guidance may be implemented, they should remain examples in the final version of the guidance.

Response: NIST agrees with this comment.

One government agency commented that Federal regulatory programs that engage in conformity assessment must apply a high degree of scrutiny to ensure that requirements are met. Therefore, it may be very difficult to rely on the work of private sector organizations, which understandably perform their activities for other motives and perhaps to a lesser degree of scrutiny. The guidance should present the option that private sector organizations rely on the conformity assessment activities of a Federal agency. This option would also promote the objectives under the proposed Section 287.1.

Response: Elimination of unnecessary duplication and complexity in conformity assessment activities can be accomplished by relying on private sector conformity assessment programs and activities. However, reduction in duplication and complexity can also be accomplished by Federal agency reliance on other governmental conformity assessment activities, by reliance on supplier's declaration of conformity, or by encouraging the private sector to rely on governmental activities. The NTTAA does not indicate a preference for any specific approach. The determination of which approach best meets agency objectives is the responsibility of the agency.

Comments on Section 287.1

One national standards coordinating and conformity assessment accreditation body commented that Section 287.1 should provide more information on the evaluation procedures to be used to evaluate the efficacy and efficiency of Federal conformity assessment activities.

Response: The variety of conformity assessment activities conducted by different Federal agencies precludes development of specific evaluation techniques that would apply to all agencies. Guidance on how to measure certain aspects of performance (regulatory burden, cost-benefit issues, etc.) is available from the Office of Management and Budget (OMB) and from other sources within the Federal government, but this guidance must usually be tailored to reflect the type of

activities a given agency undertakes. NIST believes that evaluations of only one aspect of program performance can be misleading. Evaluations of program performance/effectiveness should consider all programmatic aspects, including an agency's legislative mandates, program objectives and resource availability.

One laboratory accreditation body commented that the second and third sentences of Section 287.1 should be replaced by: "Each agency should seek ways in which it can use existing conformity assessment activities of the private sector instead of creating or maintaining their own activities."

Response: The purpose and scope, as currently written in Section 287.1, best reflects the intent stated in the Act, which is to eliminate "unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures." This can be accomplished in a number of ways. Using the results of private sector conformity assessment activities is only one method.

One laboratory accreditation body commented that the last sentence of Section 287.1 should be revised to cite the role of the U.S. Trade Representative (USTR) in overseeing the implementation of the U.S. trade obligations including commitments under the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT).

Response: The guidance is not intended to address U.S. obligations or the USTR's role in implementing the WTO Agreement or in other trade agreements. This guidance addresses only matters covered in the NTTAA. The Federal government's obligations under the World Trade Organization Agreement and other trade agreements are addressed elsewhere.

One consulting organization commented that NIST should state its position on who is responsible for accreditation in the United States.

Response: Accreditation activities can be conducted by either the public and/or the private sector. The appropriate sector to be assigned responsibility for accreditation should be determined on a case-by-case basis. The need for accreditation also needs to be determined on a case-by-case basis. There is no one-size-fits-all solution to this issue.

One certification body commented that the Interagency Committee on Standards Policy (ICSP) should be opened to regular participation and attendance by private sector standards developers and organizations providing

conformity assessment services to facilitate cooperation and confidence between the government and private sector conformity assessment organizations.

Response: The ICSP has invited a number of standards developers and conformity assessment organizations to present information and viewpoints on topics of interest to the ICSP. However, the ICSP is an interagency committee. Membership is restricted to the Federal departments and agencies listed in its charter.

One certification body commented that the promotion of accreditation and/or recognition organizations that have not demonstrated added value to the marketplace should be discouraged.

Response: NIST agrees with this comment. Agencies are responsible for meeting programmatic objectives in a cost-effective manner. However, it is the responsibility of each agency to determine which approach best meets its needs.

One certification body commented that no single mechanism can meet the needs of all suppliers or acceptance authorities around the globe. New mechanisms that facilitate trade, provide regulatory confidence and protect public safety should be considered as they are developed and proven effective to meet the needs of supplier and acceptance authorities.

Response: NIST agrees with this comment. However, it remains the responsibility of each agency to determine which mechanisms are appropriate for application within its programs.

One trade association commented that the following objectives should be included in the proposed guidance:

- Eliminate the cost to government of conducting (developing) its own conformity assessment activities and thereby decrease the cost of goods procured and the burden of complying with agency regulation;
- Provide incentives and opportunities (to whom) to establish conformity assessment programs that serve national needs;
- Encourage long term growth of U.S. enterprises and promote efficiency and economic competition through harmonization of conformity assessment activities; and
- Further the policy of reliance upon the private sector to supply the government need for goods and services.

Response: While the statements listed above are a partial list of potential benefits from implementation of the guidance, the objective of the guidance was clearly and succinctly defined in the NTAA—to eliminate "unnecessary

duplication and complexity in the development and promulgation of conformity assessment requirements and measures."

Comments on Section 287.2

One national standards coordinating and conformity assessment accreditation body commented that the definition of recognition is too narrow in section 287.2 and is inconsistent with the way it is used in the example in section 287.4.

Response: While the definition for the term "recognition" in Section 287.2 is appropriate; the term has been changed in the example.

One national standards coordinating and conformity assessment accreditation body and one trade association commented that the definitions in the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) Guide 2 should be cited without modification.

Response: The definitions in section 287.2 were based on ISO/IEC Guide 2, but the definitions have been modified to better address the nature of Federal government conformity assessment activities. Definitions were considered necessary because agencies do not use consistent terminology in their regulatory and procurement conformity assessment programs. This inconsistent use of terminology could create potential confusion for agencies reading the guidance. NIST decided to define only those terms which were considered to be necessary to understand the guidance.

One laboratory accreditation body commented that the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT) definition of conformity assessment should be referenced and "mandatory administrative procedures" should not be excluded from the definition.

Response: ISO/IEC Guide definitions have been used in accordance with the NTTAA's requirements that preference be given to the use of voluntary consensus standards. There is also no evidence in the Act or legislative history that Congress intended to include mandatory administrative procedures.

The Occupational Safety and Health Administration (OSHA) commented that some of the key definitions in the notice do not correctly depict the Occupational Safety and Health Administration's (OSHA's) National Recognized Testing Laboratory (NRTL) Program. OSHA recognizes a testing/certification body under the NRTL Program, not an accreditation body. In addition, the agency commented that OSHA's

recognition does not mean that an organization is "competent" in testing or in certification to the extent that "competent" means adept, proficient or a similar term. To obtain recognition, an organization must demonstrate that it meets the requirements in 29 CFR 1910.7, but this regulation does not include requirements for proficiency or other criteria to judge "competence."

Response: NIST agrees that agencies do not use standardized terminology in their conformity assessment activities. In defining key terms, NIST intended to let the reader know what is meant by that term within the context of the guidance. NIST recognizes that the same term may be used by different agencies to mean very different types of activities. A footnote will be added to the definition for "accreditation" to accommodate OSHA's activities.

OSHA also commented that the definition of conformity assessment describes requirements as being applicable to "products, services, and systems," but not to "organizations" and requested that the word "organizations" be added.

Response: The word "organizations" has been added.

One international company, one laboratory accreditation body, and one trade association commented that the guidance should identify supplier's declaration as an appropriate option for agencies to consider in their conformity assessment policies, taking into account the appropriate balance of risks and benefits of first party (supplier), second party, and third party conformity assessment for specific products and services. The same trade association recommended that NIST amend the definition in the proposed Section 287.2 as follows: In the definition of conformity assessment, add "suppliers declaration of conformity" after "inspection" and add a definition for "supplier's declaration of conformity."

Response: The guidance now includes reference to first, second and third party conformity assessment activities and procedures. The definition of conformity assessment has been amended to include "supplier's declaration of conformity." A definition of "supplier's declaration of conformity" has also been included. However, the guidance does not intend to suggest that any one method or activity is preferable. It is the responsibility of each agency to select the conformity assessment activities and procedures, which will best meet its legislative mandates and programmatic objectives in the most cost-effective and efficient manner.

Comments on Section 287.3

One national standards coordinating and conformity assessment accreditation body commented that NIST should be charged in section 287.3 with ensuring that other agencies are aware of their obligation to adopt policies needed to accomplish the purpose of this guidance.

Response: While NIST is charged with coordinating conformity assessment activities, agencies remain responsible for their own conformity assessment activities, including the adoption of any policies that agencies feel are needed to operate in accordance with their statutory mandates. NIST is available and willing to assist agencies in carrying out this responsibility and to provide guidance as needed.

One national standards coordinating and conformity assessment accreditation body and one trade association commented that some attention should be given in section 287.3 to NIST's obligations beyond the Federal level, especially to its obligations at the state level.

Response: NIST partially agrees with this comment. The language in the Act is unclear as to what Congress intended NIST to do with regard to state conformity assessment activities. However, in the Congressional House Record of 2/27/96 for The National Technology Transfer and Advancement Act (NTTAA), Representative Morella stated that: "Section 12 Standards Conformity. Restates existing authorities for the National Institute of Standards and Technology (NIST) activities in standards and conformity assessment. Requires NIST to coordinate among Federal agencies, survey existing state and Federal practices, and report back to Congress on recommendations for improvements in these activities." NIST is undertaking studies of existing state conformity assessment practices, subject to resource limitations. NIST also plans to undertake additional activities with the states as resources become available. Any activities undertaken by NIST will be conducted in a manner that respects state sovereignty issues. NIST has added the following statement to the guidance: "To the extent that resources are available, NIST will develop information on existing state conformity assessment practices; and, upon request by a state government agency, will work with that agency to reduce duplication and complexity in state conformity assessment activities."

One laboratory accreditation body commented that a new clause should be added to section 287.3 so that NIST would also "encourage government

participation and use of private sector, conformity assessment activities to the maximum extent practical."

Response: NIST disagrees. NIST is obligated to assist other Federal agencies in reducing duplication and complexity in their conformity assessment activities. The use of private sector conformity assessment activities is only one of a number of methods that can be used by an agency to accomplish this goal. It remains the responsibility of the agency to determine which method is most appropriate for its specific applications.

Comments on Section 287.4

One national standards coordinating and conformity assessment accreditation body commented that the example in section 287.4, which uses the term "recognition," does not support the use of the qualifier "mutual."

Response: The agency agrees with this comment. The qualifier "mutual" has been removed and the term "recognition" has been replaced.

One national standards coordinating and conformity assessment accreditation body and one laboratory accreditation body commented that a list of references, containing the documents of the organizations cited in section 287.4 should be inserted in this section or that NIST should provide a list of specific conformity assessment guides and standards, perhaps as a separate document.

Response: NIST believes that a better solution is to address an agency's need for a list of applicable standards on a case-by-case basis. NIST's National Center for Standards and Certification Information (NCSCI) assists agencies to identify possible conformity assessment standards/guides, which may be of interest for a specific application. The organizations listed in the guidance are examples, and are not intended to represent a comprehensive list of organizations that develop standards and guidance in the conformity assessment area. A specific list could omit standards of potential interest to agencies in conformity assessment related areas or from other organizations not included as examples. In addition, such a list would rapidly become outdated as ISO guides and standards in the conformity assessment area are revised, reissued, or removed. Lastly, standards that appear on such a list might be presumed by some to have a "special blessing" by NIST, which could create misunderstanding. Agencies can contact NCSCI for a list of standards in their area of interest.

One national standards coordinating and conformity assessment accreditation body commented that section 287.4 should be rewritten to address the policies and procedures that should be adopted by agencies through the mechanism of the Interagency Committee on Standards Policy (ICSP). The development of a policy on conformity assessment might be stipulated that would address the roles of supplier's declaration, third parties, and accreditors.

Response: As noted in section 287.3(a), NIST will assist "the ICSP in developing policies and guidance on conformity assessment issues." Agency Standards Executives serving on the ICSP are responsible for determining which policies and procedures the ICSP should develop, which might be useful for consideration within their agencies. However, the individual agency is responsible for the final selection and implementation of the policies and procedures needed by the agency to implement the goals of the NTTAA.

One national standards coordinating and conformity assessment accreditation body commented that the ICSP Agency Standards Executives' suitability for serving as change agents with respect to the conformity assessment activities of the Federal government should be reconsidered.

Response: The selection of the ICSP Agency Standards Executives is the responsibility of the Agency, as noted in section 287.4(n). The agency is responsible for selecting an individual who is capable of carrying out the guidance in OMB Circular A-119 as well as the guidance in this document. If needed, the Agency is free to assign additional personnel to assist the Agency Standards Executive in carrying out these responsibilities.

One international company commented that the examples listed in section 287.4(g) are limited to laboratory issues and organizations that are close to the Federal process. It would be appropriate to list some other organizations such as the American National Standards Institute (ANSI) or the International Organization for Standardization's (ISO) Committee on Conformity Assessment (CASCO) to indicate the broader direction that is intended.

Response: The examples cited have been included in the guidance.

One international company commented that organizations, such as the American National Standards Institute (ANSI) or the International Organization for Standardization's (ISO) Committee on Conformity Assessment (CASCO) be listed in section 287.4(j) to

indicate the broader direction that is intended.

Response: Section 287.4(j) does not list examples. Participation in the development of any private sector conformity assessment standards (consistent with the mission and objectives of the agency) would be included in this section. ANSI does not develop standards, so it would not be included in this section. ISO is a private sector organization, which develops conformity assessment standards, so participation in ISO CASCO is included in this section.

One laboratory accreditation body commented that in section 287.4(c), agencies need to consider ways to use not only conformity assessment results of others (both domestic and foreign), but the conformity assessment activities themselves as a replacement for their own activities.

Response: This comment addresses matters beyond the scope of this guidance. Regulatory and procurement obligations of Federal agencies have been authorized by Congress, and such activities/systems cannot be replaced by private sector activities/systems without congressional approval or legislative change.

One laboratory accreditation body commented that the examples in sections 287.4(e) and (h) are weak as they only suggest an agency might supplement (not replace) its own activities with outside conformity assessment activities mainly administered by other government agencies.

Response: In section 287.4(e), NIST will include the example of the Federal Communications Commission's FCC Telecommunications Certification Body (TCB) program, which allows designated private entities to issue telecommunications equipment approvals for specified regulatory requirements in essentially the same manner as the FCC. FCC has also replaced requirements for premarketing approval with supplier's declaration of conformity for certain types of equipment.

One laboratory accreditation body commented that in section 287.4(f), it is not clear why "mutual recognition" is necessary or desirable between agencies when one-way recognition may also be appropriate.

Response: This section has been reworded.

One laboratory accreditation body commented that section 287.4(g) should delete any reference to the National Environmental Laboratory Accreditation Conference (NELAC) because NELAC specifically prohibits private sector

laboratory accreditation bodies from being part of NELAC by suggesting that accreditation is an inherent government function. This is contrary to the intent of the NTTAA, which encourages use of private sector conformity assessment activities.

Response: The purpose of the NTTAA is to eliminate unnecessary duplication and complexity in conformity assessment activities. While this can be done by relying on private sector conformity assessment programs and activities, it can also be accomplished by relying on other governmental activities, by relying on a supplier's declaration of conformity, or by encouraging the private sector to rely on governmental activities. While agencies should consider alternative approaches in their rulemaking and procurement activities, the determination of which approach best meets agency objectives is the responsibility of the agency.

One laboratory accreditation body and one trade association commented that sections 287.4(i) should cite the USTR's role in trade policy. The same trade association commented that sections 287.4(j) should also cite the USTR's role.

Response: While NIST recognizes the important role that the USTR has in developing trade related policies, as well as the responsibilities placed on Federal agencies as a result of trade agreements, such as the WTO Agreement, these roles and responsibilities are defined in other legislation and related documents. This guidance addresses only matters covered in the NTTAA.

One laboratory accreditation body commented that there is no need for separate government recognition systems if equivalent systems exist in the private sector that provide equivalent recognition. Government recognition systems would add cost without adding value and would create unnecessary duplication and complexity, the opposite intent of the NTTAA.

Response: In trade agreements, the need for government recognition of conformity assessment bodies is determined not only by the U.S. Government, but also by the other countries signatory to such an agreement. Since some governments do not deem the use of private sector systems to be adequate proof of competence in the absence of governmental recognition, such recognition becomes a requirement under the terms of the specific agreement. For domestic regulatory and procurement issues, it is the responsibility of each Federal agency to

determine whether use of a private sector system can adequately address all of its programmatic objectives and any relevant legislative mandates in a cost-effective manner.

One trade association commented that while the reference to the National Cooperation for Laboratory Accreditation (NACLA) and the National Environmental Laboratory Accreditation Conference (NELAC) in section 287.4(g) begins to address the issue of duplication of accreditations for testing programs, the proposed guidance should also provide direction related to other forms of conformity assessment, such as certification and registration.

Response: The organizations listed in section 287.4(g) are intended to serve only as examples of activities in which agencies should consider participation. The activities of ANSI have been added to the list of examples to better illustrate the broad range of activities where Federal participation is encouraged.

One trade association commented that the wording in section 287.4(c) should strongly encourage the use of private sector conformity assessment programs in lieu of the development of government programs. The same trade association commented that Section 287.4(e) include a requirement that NIST provide a centralized coordinating function in the determination of acceptable private sector conformity assessment practices. To allocate the responsibility to each agency only continues the duplication of accreditation and approval processes. NIST should advocate the use of private sector accreditation bodies that comply with national and international criteria as the tool to be used for determination of acceptance. The same trade association also commented that in section 287.4(f), mutual recognition of private sector procedures should be recommended for all agencies.

Response: The purpose of the NTTAA is to eliminate unnecessary duplication and complexity in conformity assessment activities. While this can be done by relying on private sector conformity assessment programs and activities, it can also be accomplished by relying on other governmental activities, by relying on a supplier's declaration of conformity, or by encouraging the private sector to rely on governmental activities. While agencies should consider alternative approaches in their rulemaking and procurement activities, the determination of which approach best meets agency objectives is the responsibility of the agency.

One trade association commented that in section 287.4(j), agencies should be encouraged to participate in the

development of private sector conformity assessment procedures and programs as well as the development of standards. *RESPONSE:* NIST partially agrees with this comment. The responsibility for participation in conformity assessment programs and activities, as distinct from standards development, is covered in section 287.4(g). The examples in this section will be expanded to include participation in ANSI's conformity assessment related activities to better illustrate the intention of this section.

GAO Recommendation: GAO recommended that the guidance include a section that "specifically addresses the transparency of agencies' certification decisionmaking." GAO recommended that the guidance "should encourage agencies to publicly explain why particular certification decisions were made or how certification decisions in the future will be made."

Response: A new item has been added to section 287.4 of the guidance to address this issue.

Comments on Section 287.5

One national standards coordinating and conformity assessment accreditation body commented that section 287.5 places responsibility for both standards and conformity assessment with one representative from each agency and noted that a significant majority of persons with major responsibilities for standards have no responsibility or knowledge of conformity assessment.

Response: NIST partially disagrees with this comment. The Office of Management and Budget (OMB) A-119 indicates that more than one Standards Executive was not contemplated by OMB. That is, the Circular speaks of "a" Standards Executive (14(c)) and "the" Standards Executive (14(d)), etc. NIST and OMB believe that having only one Standards Executive would facilitate better coordination and communication for both standards and their related conformity assessment activities.

However, both also recognize that because responsibility for an agency's conformity assessment activities may cut across organizational boundaries, it may be necessary to assign additional agency personnel to carry out these new responsibilities. The agency must ensure that these responsibilities are coordinated and should carefully define each staff member's responsibilities to ensure that the duties defined under this guidance and under OMB Circular A-119 are effectively carried out.

One laboratory accreditation body commented that section 287.5 should contain reporting requirements for the

annual agency reports to NIST and OMB, including whether each agency gave consideration to the use of relevant private sector, conformity assessment activities and the reason for not using them—similar to agencies' reporting under OMB Circular A-119. NIST itself should be required to make similar reports justifying its own conformity assessment activities.

Response: Mandatory agency reporting requirements regarding conformity assessment activities were not specified in the NTTAA. Conformity assessment reporting requirements for all agencies, including NIST, remain voluntary.

One government agency commented that the guidance states that each agency "should coordinate its * * * activities" to make "more productive use of * * * limited Federal resources * * *." However, the "responsibilities" under the proposed Section 2987.5 and the actual coordination could demand resources that may more than offset any gains expected from the coordination.

Response: The guidance does not recommend that agencies undertake activities where the costs involved are likely to exceed the benefits realized. While coordination is often beneficial and should always be considered, the agencies themselves are responsible for the final decision as to the appropriate level of coordination and commitment of resources to the agency's conformity assessment activities.

One trade association commented that a new responsibility should be added to this section— "To use private sector conformity assessment program results in all agency assessment programs."

Response: The goal of the guidance, which is spelled out in the NTTAA, can be accomplished in a number of ways. It is the responsibility of each agency to determine which option or set of procedures is most appropriate for its application.

Purpose of This Guidance

This guidance outlines Federal agencies' responsibility for evaluation of the efficacy and efficiency of their conformity assessment activities. Each agency is responsible for coordinating its conformity assessment activities with those of other appropriate government agencies and with those of private sector to make more productive use of the increasingly limited Federal resources available for the conduct of conformity assessment activities and to reduce unnecessary duplication.

Applicability of This Guidance

This guidance applies to all agencies, which set policy for, manage, operate, or

use conformity assessment activities and results, both domestic and international, except for activities carried out pursuant to treaties. "Agency" means any Executive Branch Department, independent commission, board, bureau, office, agency, government-owned or controlled corporation, or other establishment of the Federal government. It also includes any regulatory commission or board, except for independent regulatory commissions subject to separate statutory requirements regarding policy setting, management, operation, and use of conformity assessment activities. It does not include the legislative or judicial branches of the Federal government.

Rulemaking Requirements

Under 5 U.S.C. 553(b)(A), this guidance is not subject to the notice and comment requirements of the Administrative Procedure Act. Furthermore, pursuant to 5 U.S.C. 553(d)(2), this guidance is not subject to the delayed effective date requirement of the Act. The Director has chosen to publish this document for comment only to obtain input from persons who may be affected by the guidance.

PRA Clearance

This policy statement does not contain a collection of information for purposes of the Paperwork Reduction Act.

Executive Order 12866

It has been determined that this action is significant for purposes of Executive Order 12866.

Regulatory Flexibility Act

This action is exempt from the analytical requirements of the Regulatory Flexibility Act because notice and comment are not required for this action by section 553 of the Administrative Procedure Act or any other law.

List of Subjects in 15 CFR Part 287

Conformity assessment, Procurement, Reporting and recordkeeping requirements.

Dated: August 4, 2000.

Karen H. Brown,
Deputy Director.

For the reasons set forth in the preamble, Part 287 is added to subchapter J of chapter II in Title 15 of the Code of Federal Regulations (CFR) to read as follows:

PART 287—GUIDANCE ON FEDERAL CONFORMITY ASSESSMENT

Sec.

287.1 Purpose and scope of this guidance.

287.2 Definitions.

287.3 Responsibilities of the National Institute of Standards and Technology.

287.4 Responsibilities of Federal agencies.

287.5 Responsibilities of an Agency Standards Executive.

Authority: Sec. 12, Pub. L. 104–113, 110 Stat. 782 (15 U.S.C. 272).

§ 287.1 Purpose and scope of this guidance.

(a) This part provides guidance for each Federal agency to use in evaluating the efficacy and efficiency of its conformity assessment activities. Each agency should coordinate its conformity assessment activities with those of other appropriate government agencies and with those of the private sector to reduce unnecessary duplication. This guidance is intended to help Federal agencies improve the management and coordination of their own conformity assessment activities with respect to other government entities and the private sector. This will help ensure more productive use of the increasingly limited Federal resources available to conduct conformity assessment activities. This will also support the role of the U.S. Government in pursuing international trade and other related negotiations and agreements with foreign countries and U.S. industry in pursuing agreements with foreign national and international private sector organizations.

(b) This guidance applies to all agencies, which set policy for, manage, operate, or use conformity assessment activities and results, both domestic and international, except for activities carried out pursuant to treaties.

(c) This guidance does not preempt the agencies' authority and responsibility to make regulatory or procurement decisions authorized by statute or required to meet programmatic objectives and requirements. These decision-making activities include: determining the level of acceptable regulatory or procurement risk; setting the level of protection; balancing risk, cost and availability of technology (where statutes permit) in establishing regulatory and procurement objectives; and determining or implementing procurement or regulatory requirements necessary to meet programmatic or regulatory objectives. Each agency retains broad discretion in its selection and use of regulatory and procurement conformity assessment practices and may elect not to use or recognize alternative

conformity assessment practices if the agency deems them to be inappropriate, inadequate, or inconsistent with statutory criteria or programmatic objectives and requirements. Nothing contained herein shall give any party any claim or cause of action against the Federal government or any agency thereof. Each agency remains responsible for representation of the agency's views on conformity assessment in matters under its jurisdiction. Each agency also remains the primary point of contact for information on the agency's regulatory and procurement conformity assessment actions.

§ 287.2 Definitions.¹

Accreditation means a procedure used to provide formal notice that a body or person is competent to carry out specific tasks. These tasks include: sampling and testing; inspection; certification; and registration.²

Agency means any Executive Branch Department, independent commission, board, bureau, office, agency, government-owned or controlled corporation, or other establishment of the Federal government. It also includes any regulatory commission or board, except for independent regulatory commission subject to separate statutory requirements regarding policy setting, management, operation, and use of conformity assessment activities. It does not include the legislative or judicial branches of the Federal government.

Agency Standards Executive means an official designated by an agency as its representative on the Interagency Committee for Standards Policy (ICSP) and delegated the responsibility for agency implementation of OMB Circular A–119 and the guidance in this part.

Certification means a procedure used to provide written assurance that a product, process, service, or person's qualifications conforms to specified requirements.

Conformity assessment means any activity concerned with determining directly or indirectly that requirements are fulfilled. Requirements for products,

¹ Definitions of accreditation, certification, conformity assessment, inspection, supplier's declaration of conformity, registration and testing are based on the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC), Guide 2 (1996). In certain industrial sectors, it is recognized that organizations other than ISO or IEC may issue definitions relevant to conformity assessment, such as the Codex Alimentarius Commission with respect to the food industry sector.

² For some agencies, accreditation may mean that a body or person meets requirements defined in a specific section(s) of the CFR. The referenced section(s) may include only limited requirements for demonstration of technical competency.

services, systems, and organizations are those defined by law or regulation or by an agency in a procurement action. Conformity assessment includes: sampling and testing; inspection; supplier's declaration of conformity; certification; and quality and environmental management system assessment and registration. It also includes accreditation and recognition. Conformity assessment does not include mandatory administrative procedures (such as registration notification) for granting permission for a good or service to be produced, marketed, or used for a stated purpose or under stated conditions. Conformity assessment activities may be conducted by the supplier (first party) or by the buyer (second party) either directly or by another party on the supplier's or buyer's behalf, or by a body not under the control or influence of either the buyer or the seller (third party).

Inspection is defined as the evaluation by observation and judgment accompanied as appropriate by measurement, testing or gauging of the conformity of a product, process or service to specified requirements.

NIST means the National Institute of Standards and Technology, an agency within the United States Department of Commerce.

Recognition means a procedure used to provide formal notice that an accreditation body is competent to carry out specific tasks. These tasks include: the accreditation of testing laboratories and inspection, certification, and registration bodies. A governmental recognition system is a set of one or more procedures used by a Federal agency to provide recognition.

Registration means a procedure used to give written assurance that a system conforms to specified requirements. Such systems include those established for the management of product, process or service quality and environmental performance.

Sampling means the selection of one or more specimens of a product, process, or service for the purpose of evaluating the conformity of the product, process or service to specified requirements.

Supplier's declaration of conformity means a procedure by which a supplier gives written assurance that a product, process, service or organization conforms to specified requirements.

Testing means the action of carrying out one or more technical operations (tests) that determine one or more characteristics or performance of a given product, material, equipment, organism, person's qualifications, physical phenomenon, process, or service

according to a specified technical procedure (test method).

§ 287.3 Responsibilities of the National Institute of Standards and Technology.

(a) Work with agencies through the Interagency Committee on Standards Policy (ICSP) to coordinate Federal, state and local conformity assessment activities with private sector conformity assessment activities. NIST chairs the ICSP; assists the ICSP in developing and publishing policies and guidance on conformity assessment related issues; collects and disseminates information on Federal, state and private sector conformity assessment activities; and increases public awareness of the importance of conformity assessment and nature and extent of national and international conformity assessment activities.

(b) Encourage participation in the ICSP by all affected agencies and ensure that all agency views on conformity assessment are considered.

(c) To the extent that resources are available, develop information on state conformity assessment practices; and, upon request by a state government agency, work with that state agency to reduce duplication and complexity in state conformity assessment activities.

(d) Review within three years from August 10, 2000, the effectiveness of the final guidance and recommend modifications to the Secretary as needed.

§ 287.4 Responsibilities of Federal agencies.

Each agency should:

(a) Implement the policies contained in the guidance in this part.

(b) Provide a rationale for its use of specified conformity assessment procedures and processes in rulemaking and procurement actions to the extent feasible. Further, when notice and comment rulemaking is otherwise required, each agency should provide the opportunity for public comment on the rationale for the agency's conformity assessment decision.

(c) Use the results of other governmental agency and private sector organization conformity assessment activities to enhance the safety and efficacy of proposed new conformity assessment requirements and measures. An example of this would be to collect and review information on similar activities conducted by other Federal, state and international organizations and agencies and private sector organizations to determine if the results of these activities can be used to improve the effectiveness of a proposed Federal agency conformity assessment activity.

(d) Use relevant guides or standards for conformity assessment practices published by domestic and international standardizing bodies as appropriate in meeting regulatory and procurement objectives. Guides and standards for sampling, testing, inspection, certification, quality and environmental management systems, management system registration and accreditation are issued by organizations which include, but are not limited to, the American National Standards Institute, the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), the International Telecommunications Union (ITU) and the Organization for Economic Cooperation and Development (OECD), the World Health Organization (WHO), and the Codex Alimentarius Commission. Each agency retains responsibility for determining which, if any, of these documents are relevant to its needs.

(e) Identify appropriate private sector conformity assessment practices and programs and consider the results of such practices and/or programs as appropriate in existing regulatory and procurement actions. Responsibility for the determination of appropriateness rests with each agency. Examples: an agency could use the results of private sector or other governmental conformity assessment activities to schedule procurement type audits more effectively. This could allow agencies to reduce the number and extent of audits conducted at companies which are performing in accordance with contract specifications and which are under review by a third party or another agency and to concentrate agency audit efforts on companies which have shown problems in conforming to contract specifications. Another example is the Federal Communications Commission's (FCC) Telecommunication Certification Body (TCB) program, which allows designated private entities to issue telecommunications equipment approvals for specified regulatory requirements. In addition, under Part 15, FCC premarketing approval requirements for certain types of equipment have been replaced with suppliers declaration of conformity to the regulations, provided test results supporting the declaration are obtained from an accredited testing lab.

(f) Consider using the results of other agencies' conformity assessment procedures. Example: An agency could use the results of another agency's inspection/audit of a supplier to eliminate or reduce the scope of its own inspection/audit of that supplier.

(g) Participate in efforts designed to improve coordination among governmental and private sector conformity assessment activities. These efforts include, but are not limited to, the National Cooperation for Laboratory Accreditation (NACLA) organization, the National Environmental Laboratory Accreditation (NELAC), the International Organizations for Standardization's (ISO) Committee on Conformity Assessment (CASCO), conformity assessment related activities of the American National Standards Institute (ANSI), and ICSP working groups dealing with conformity assessment issues.

(h) Work with other agencies to avoid unnecessary duplication and complexity in Federal conformity assessment activities. Examples: An agency can participate in another agency's conformity assessment activities by conducting joint procurement audits/inspections of suppliers that sell to both agencies. An agency can share conformity assessment information with other agencies. An agency can use conformity assessment information provided by other agencies to the extent appropriate to improve the effectiveness and efficiency in its own conformity assessment activities. Conformity assessment information may include: Conformity assessment procedures and results, technical data on the operation of conformity assessment programs, processing methods and requirements for applications, fees, facility site data, complaint review procedures, and confidentiality procedures.

(i) Encourage domestic and international recognition of U.S. conformity assessment results by supporting the work of the U.S. Government in international trade and related negotiations with foreign countries and U.S. industry in pursuing agreements with foreign national and international private sector organizations and any resulting activities/requirements resulting from those negotiations/agreements.

(j) Participate in the development of private sector conformity assessment standards to ensure that Federal viewpoints are represented.

(k) Work with other agencies to harmonize Federal requirements for quality and environmental management systems for use in procurement and regulation, including provisions which will allow the use of one quality or environmental management system per supplier facility in the Federal procurement process and the sharing and usage of audit results and related information as appropriate.

(l) Work with other ICSP members, NIST, and the private sector to develop national infrastructures for coordinating and harmonizing U.S. conformity assessment needs, practices and requirements in support of the efforts of the U.S. Government and U.S. industry to increase international market access for U.S. products.

(m) Work with other ICSP members, NIST, and the private sector as necessary and appropriate to establish criteria for the development and implementation of governmental recognition systems to meet government recognition requirements imposed by other nations and regional groups to support the efforts of the U.S. Government to facilitate international market access for U.S. products.

(n) Assign an Agency Standard Executive responsibility for coordinating the agency-wide implementation of the guidance in this part.

§ 287.5 Responsibilities of an Agency Standards Executive.

In addition to carrying out the duties described in OMB Circular A-119 related to standards activities, an Agency Standards Executive should:

- (a) Promote the following goals:
- (1) Effective use of agency conformity assessment related resources and participation in conformity assessment related activities of agency interest.
 - (2) Development and dissemination of agency technical and policy positions.
 - (3) Development of agency positions on conformity assessment related issues that are in the public interest.
- (b) Ensure that agency participation in conformity assessment related activities is consistent with agency missions, authorities, priorities, and budget.
- (c) Cooperate with NIST in carrying out agency responsibilities under the guidance in this part.
- (d) Consult with NIST, as necessary, in the development and issuance of internal agency procedures and guidance implementing the policies in this part.

(e) Establish an ongoing process for reviewing his/her agency's existing conformity assessment activities and identifying areas where efficiencies can be achieved through coordination with other agency and private sector conformity assessment activities.

(f) Work with other parts of his/her agency to develop and implement improvements in agency conformity assessment related activities.

(g) Report to NIST, on a voluntary basis, on agency conformity assessment activities for inclusion in the annual report to the Office of Management and

Budget (OMB) on the agency's implementation of OMB Circular A-119.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 310, and 344

[Docket No. 77N-334S]

RIN 0910-AA01

Topical Otic Drug Products for Over-the-Counter Human Use; Products for Drying Water-Clogged Ears; Amendment of Monograph; Lift of Partial Stay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; lift of partial stay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule amending the monograph for over-the-counter (OTC) topical otic drug products (the regulation that establishes conditions under which these drug products are generally recognized as safe and effective and not misbranded). The amendment adds conditions for marketing topical otic drug products for drying water-clogged ears and includes labeling in the new OTC drug format. The agency is amending its final regulations for OTC drug labeling requirements to include the new flammability warning for topical otic drug products for drying water-clogged ears. The agency is also lifting a partial stay of the effective date of certain provisions of the regulations for topical otic drug products for the drying of water clogged ears. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

DATES:

Effective Date: This rule is effective May 17, 2002. The stay of § 310.545 (a)(15)(ii) for topical otic drug products for the drying of water-clogged ears that published at 60 FR 42436 on August 16, 1995, and effective June 22, 1995, is lifted effective September 11, 2000.

Compliance Date: The compliance date for products with annual sales less than \$25,000 is May 17, 2003. The compliance date for all other OTC drug products is May 17, 2002.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600