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NIST
PUBLICATIONS

NIST Special Publication

Proceedings of the NIST Workshop on Conformity Assessment for a Changing Government

Mary Jo DiBernardo, Editor

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NIST
National Institute of Standards and Technology
Technology Administration, U.S. Department of Commerce

The National Institute of Standards and Technology was established in 1988 by Congress to "assist industry in the development of technology . . . needed to improve product quality, to modernize manufacturing processes, to ensure product reliability . . . and to facilitate rapid commercialization . . . of products based on new scientific discoveries."

NIST, originally founded as the National Bureau of Standards in 1901, works to strengthen U.S. industry's competitiveness; advance science and engineering; and improve public health, safety, and the environment. One of the agency's basic functions is to develop, maintain, and retain custody of the national standards of measurement, and provide the means and methods for comparing standards used in science, engineering, manufacturing, commerce, industry, and education with the standards adopted or recognized by the Federal Government.

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- Information Access
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- Information Services and Computing
- Software Diagnostics and Conformance Testing
- Statistical Engineering

¹ At Boulder, CO 80303.

² Some elements at Boulder, CO.

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Standards Services Division

Technology Services

National Institute of Standards and Technology

Gaithersburg, MD 20899-0001

May 2003



U.S. Department of Commerce

Donald L. Evans, Secretary

Technology Administration

Phillip J. Bond, Under Secretary for Technology

National Institute of Standards and Technology

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Abstract:

The National Institute of Standards and Technology (NIST) sponsored the NIST Conformity Assessment for a Changing Government Workshop on December 3, 2001. The National Technology Transfer and Advancement Act (NTTAA) of 1995 instructs NIST to work with other Federal agencies and with private sector organizations to coordinate testing, certification, inspection, laboratory accreditation, and other conformity assessment activities in the United States with the goal of reducing duplication and complexity. This publication is a compilation of speeches and presentations from multiple speakers on various conformity assessment-related topics including laboratory accreditation, testing, third party certification, supplier's declaration of conformity, and quality management and registration systems.

Key Words:

Accreditation, Calibration, Certification, Conformity Assessment, ISO 9000, ISO 14000, Interagency Committee on Standards Policy, ICSP, Laboratory Accreditation, NACLA, NTTAA, National Technology Transfer and Advancement Act, Quality Management and Registration Systems, Suppliers Declaration of Conformity, Standards, Testing, Third Party Product Certification.

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On December 3, 2001, the following people served as panel moderators: 1) James Walters, Director, International Standards, Air-Conditioning and Refrigeration Institute; 2) Mary Saunders, NIST; 3) Roberta Breden, Director, Technical Regulatory Affairs, Telecommunications Industry Association; 4) Joseph Dunbeck, Chief Executive Officer, Registrar Accreditation Board; 5) Belinda Collins, NIST.

Conformity Assessment for a Changing Government

December 3, 2001

Foreword

Eliminating unnecessary duplication of effort and improving operational efficiency are aims of any organization, private or public. These aims motivated passage of the National Technology Transfer and Advancement Act (NTTAA) of 1995, which instructs the National Institute of Standards and Technology (NIST) to work with other Federal agencies and with private sector organizations to coordinate testing, certification, inspection, laboratory accreditation, and other conformity assessment activities in the United States with the goal of reducing duplication and complexity.

Several agencies and their customers realize the benefits that derive from streamlining, coordination, and faster approval times, all of which result in cost savings and opportunities to redirect organizational resources. For some agencies, these benefits are the products of partnerships with private sector organizations and other Federal and state agencies with corresponding interests. For others, newly realized advantages stem from internal adjustments motivated by the NTTAA.

December 3, 2001, was a day of instructive, thought-provoking presentations and discussions on how various Federal agencies are successfully following the letter and the spirit of the Act. Agency representatives described the processes that they use to evaluate conformity assessment alternatives and prospective partners, and to ensure a good fit with their missions, regulatory responsibilities, and procurement activities.

This workshop was organized by NIST in accordance with the NTTAA mandate. With the similar goal of eliminating unnecessary duplication in conformity assessment processes, the Office of Management and Budget (OMB) Circular A-119 directs the Secretary of Commerce to issue guidance to Federal agencies to ensure effective coordination of their conformity assessment activities. NIST, with the assistance of the

Interagency Committee on Standards Policy, published guidance on Federal conformity assessment activities in the Federal Register on August 10, 2000 (Volume 65, Number 155).

As explained in the NIST guidance document, each Federal agency is responsible for coordinating its conformity assessment activities with those of other relevant government agencies and with those of the private sector to make more efficient use of Federal resources. This guidance applies to all agencies that set policy for, manage, operate, or use conformity assessment activities and results, both domestic and international. It does not apply to activities carried out pursuant to treaties.

At the workshop, standards executives, managers and staff members of regulatory agencies, and procurement personnel reviewed various options for trimming "red tape" by using private sector conformity assessment programs or other cooperative approaches. A general overview of the NTTAA was presented, and the NIST guidance to Federal Agencies on Conformity Assessment was discussed. Panel discussions dealt with topics ranging from private sector programs in support of Federal agencies to testing, calibration, and certification, suppliers' declarations of conformity, and registration. Participants heard the insights of top-level government officials from the Consumer Product Safety Commission, Environmental Protection Agency, Federal Communications Commission, NASA, NIST, the National Highway Traffic Safety Administration, Sandia National Laboratory, and the U.S. Postal Service. They were also briefed about the National Cooperation for Laboratory Accreditation (NACLA), a nonprofit corporation established to coordinate laboratory accreditation activities within the United States and to serve as the U.S. link to the worldwide lab accreditation system.

This report presents the viewgraphs used by speakers.

Opening Remarks

Karen Brown

Acting Director, NIST

Good morning and welcome to NIST. It's good to see such a great turnout for this workshop.

We're looking forward to an instructive, thought-provoking day. Both government and private sector representatives will discuss how federal agencies are implementing the National Technology Transfer and Advancement Act, which calls for reducing complexity and duplication in conformity assessment activities.

Before we get into the details of the program today, let me say a few words about NIST.

Our mission is to develop and promote measurement, standards, and technology to enhance productivity, facilitate trade, and improve the quality of life.

We provide a variety of services to our customers—ranging from calibrations, standard reference materials, and standard reference data to measurement quality assurance programs and laboratory accreditation services.

These NIST services are essential to the nation's measurement infrastructure. In turn, that infrastructure is critical to the effective operation of conformity assessment programs in both the government and the private sector.

Accurate measurements made on the factory floor mean less rework and less waste. Customers can rely on the results of tests performed in accredited laboratories, whose measurements are traceable to NIST, where required.

All of this contributes to improving quality and increasing production efficiency, and to increasing regulators' confidence in the performance of regulated industries.

Eliminating unnecessary duplication of effort and improving operational efficiency are important to any organization, private or public. These aims motivated passage of the National Technology Transfer and Advancement Act, or NTAA, five years ago.

Under the Act, NIST is responsible for facilitating federal agency use of and participation in private voluntary standards. We also coordinate conformity assessment activities of Federal, state and local agencies with private sector activities.

What better way to facilitate sharing of information than to bring together standards executives, managers and staff members of federal agencies with private

sector experts to talk about different approaches to conformity assessment activities?

We have an opportunity here today to look at various options for trimming "red tape" and reducing costs through greater governmental use of private sector conformity assessment programs, along with other cooperative approaches.

At a time of tight budgets and increasing demands on resources, we are all looking at ways to leverage our limited resources to provide better service to our customers. At NIST, we are engaged in a strategic planning effort intended to focus on those areas where NIST programs over the next several years can have the greatest impact.

Other federal agencies face similar challenges. Regulatory agencies need to allocate their resources effectively so that they can carry out their mandates from Congress to protect consumer safety, health, and the environment. Procurement personnel in all agencies need to apply cost-effective procedures; they also need to have confidence in the quality of the products and services that they purchase.

Several agencies and their customers have already realized the benefits of streamlining and coordination of conformity assessment activities: faster approval times, cost savings and opportunities to redirect organizational resources.

We'll hear from representatives of some of these agencies today, and also from managers of private sector programs that support agency regulatory and procurement activities.

This workshop is an important step in sharing information across the federal government on leveraging limited resources to carry out statutory responsibilities. We are very glad to have you all here with us to participate in this workshop.

Now I'd like to turn the floor over to Dr. Richard Kayser, Director of Technology Services. Rich will tell you a little more about how NIST is working with other federal agencies to carry out the NTAA. He will also give you an overview of what you can expect during the workshop today.

Again, welcome.



Opening Remarks

Richard F. Kayser

Director, Technology Services, NIST

As Karen mentioned, the NTTAA directs NIST, and I quote, "to coordinate Federal, State, and local technical standards activities and conformity assessment activities with private-sector technical standards activities and conformity assessment activities with the goal of eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures."

"Eliminating unnecessary duplication and complexity" sounds good, and it would enable Federal agencies to make more productive use of their resources, but how far should Federal agencies go and what specifically should they do to achieve this goal?

Well, as many of you may know, one of the sections of the NTTAA codified the policies of OMB Circular A-119: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities. Moreover, the most recent version of the Circular, issued in February 1998, directed NIST to issue guidance to Federal agencies outlining their responsibilities for evaluating, on an ongoing basis, the efficacy and efficiency of their conformity assessment activities. NIST issued its Guidance on Federal Conformity Assessment Activities in August of 2000. Copies of the Law, the Circular and the Guidance document are included in your workshop materials.

You'll be hearing more about the NTTAA, OMB Circular A-119, and the Guidance shortly, so I won't go

into detail. Suffice it to say that during 2002, NIST will be working with Federal agencies on government-wide coordination efforts in conformity assessment. We'll share information with each other and look for ways to reduce duplication and increase effectiveness of the conformity assessment activities carried out by, or on behalf of, Federal agencies. We will do this through the existing Interagency Committee on Standards Policy, which NIST chairs, and through meetings such as this.

In 2003, we will be reviewing the effectiveness of our Guidance on Federal Conformity Assessment Activities and recommending modifications to the Secretary of Commerce, as needed. We value your input to this process.

The first portion of today's workshop will focus on implementation and benefits of the NTTAA, including the Conformity Assessment Guidance. Following a break, we'll hear from the first of five panels, where speakers will provide practical examples of private-sector testing and certification programs that support Federal agency needs.

I'd now like to introduce our first speaker, Dr. Belinda Collins, Acting Deputy Director of Technology Services. Belinda will speak about the Law and OMB Circular, focusing on the role of the Interagency Committee on Standards Policy, which she chairs.

PART ONE

**NATIONAL TECHNOLOGY TRANSFER
AND ADVANCEMENT ACT
(NTTAA) OF 1995**

Overview of the NTTAA

The National Technology Transfer and Advancement Act and Conformity Assessment

Belinda L. Collins, Ph.D.
Deputy Director
Technology Services, NIST

SLIDE 1

National Technology Transfer and Advancement Act (NTTAA)

- Directs Federal Agencies to use consensus technical standards developed by voluntary consensus standards bodies
 - if agencies do not use these standards, must explain to OMB why they chose not to
- Encourages participation in voluntary consensus standards bodies when compatible with missions, authorities, etc.
- Directs NIST to coordinate Federal standards and conformity assessment activities with those of the private sector

SLIDE 2

NIST Role Under the NTTAA

- Provide Annual Reports to Congress through OMB to track progress on NTTAA and implementation of OMB Circular A-119
- Chair the Interagency Committee on Standards Policy (ICSP); provide secretariat
 - Ensure effective participation in and use of standards
 - Meets at least 3 times a year; subcommittees more frequently
 - Improve coordination in conformity assessment to "eliminate unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures"

SLIDE 3

NTTAA Accomplishments

- Annual Reports on Federal Activities
- ANSI/NIST MOU
- NTTAA Website
 - Conformity Assessment Network and Website
 - NIST SP 739: Directory of Federal Government Certification and Related Programs
- Conformity Assessment Guidance (Federal Register - Aug 2000)
 - Agencies to ensure effective coordination of conformity assessment activities to eliminate unnecessary duplication and complexity
 - <http://www.ts.nist.gov/ca>

SLIDE 4

What is Conformity Assessment?

- Conformity assessment is any activity that helps ensure that products, services, or systems have required, consistent characteristics.
- Conformity assessment activities include:
 - Sampling and testing
 - Inspection
 - Certification (products, services and personnel)
 - Management system registration (ISO 9000/14000)
- Accreditation verifies competence of conformity assessment activities

SLIDE 5

Product Certification in the United States

- Largely a private sector activity to meet regulatory, industry and customer needs
- Government agencies play a variety of roles:
 - Direct certification (FDA, USDA)
 - Recognition of private sector third party certification (OSHA)
 - Recognition of manufacturer declaration of conformity (FCC; DOT)
 - Recognition of laboratory accreditation bodies (NIST)

SLIDE 6

Federal Government Programs

- There are about 28 Federal conformity assessment programs in various agencies:
 - Department of Agriculture: food safety, grain inspection, etc.
 - EPA: drinking water, vehicle emissions, etc.
 - NIST: laboratory accreditation required by FCC, HUD, DOE, EPA, NRC, etc.

SLIDE 7

U.S. Laboratory Accreditation

- Historically, a mix of programs
 - No formal recognition between/among programs
 - Overlapping and redundant assessments
- National Cooperation for Laboratory Accreditation created in 1998 under NTTAA
 - NIST MOU with NACLA recognizes process for recognizing competent laboratory accreditation bodies - supports Trade Agreements
 - DOT chairs recognition committee
- Mutual Recognition Arrangement (MRA) among 3 U.S. bodies provides framework for recognizing technical competence
 - Stakeholder members of ILAC

SLIDE 8

Desired NTTAA Outcomes


- Increased Federal use of standards; greater coordination with private sector
- Improved participation in relevant standards and conformity assessment activities
- Web access to standards referenced in regulations
- Coordination of Federal conformity assessment activities to reduce duplication
- Improved linkage with state activities

SLIDE 9

Planned NTTAA Activities for 2002

- Workshops and Training
 - NTTAA Workshop - Oct 11
 - Conformity Assessment Workshop - Dec 3
 - How to participate in standards - for NIST/DOC staff
- Federal Level
 - Impart understanding, improve compliance for all member agencies
 - Coordinate activities in conformity assessment, including support for NACLA
- Outreach to states
 - Evaluate needs, effort; Use California as test case

SLIDE 10



Federal Agency Obligations under OMB Circular A-119 and Benefits of The NTTAA

Kevin McIntyre
Senior Standards Specialist
Office of Standards Services, NIST


SLIDE 1



Commerce/NIST's Role

- Coordinate federal implementation of the Circular and provide administrative guidance
- Chair the ICSP; serve as secretariat
- Report to OMB on implementation of the Circular
- Establish procedures for developing participant directories
- Issue Conformity Assessment guidance

SLIDE 2



Responsibilities of Agency Heads

- Implement policies of the Circular
- Ensure agency compliance
- Appoint a Standards Executive to serve on the ICSP
- Transmit information to NIST for the annual report to OMB


SLIDE 3



Responsibilities of Standards Executives

- Promote effective use of agency resources and participation
- Promote development of appropriate agency positions on standards that
 - Are clearly defined
 - Do not conflict with each other
 - Are in the public interest
 - Are consistent with administration policy

SLIDE 4



Responsibilities of Standards Executives (cont.)

- Assure agency participation consistent with agency mission, authority, goals, and budget
- Assure that agency participants understand and accurately represent agency positions
- Coordinate multi-agency committee participation
- Assure that necessary internal policies are in place for managing standards use and participation

SLIDE 5



Responsibilities of Standards Executives (cont.)

- Cooperate with DOC/NIST in implementing the Circular, including participant database
- Prepare agency input to OMB report
- Develop processes for ongoing review and update of agency standards use
- Develop processes to ensure that participation is properly reviewed (legal, budgetary) for compliance with applicable law

SLIDE 6

General Agency Requirements

- Use voluntary consensus standards (VCS) in lieu of government-unique standards except where inconsistent with law or otherwise impractical
- Participate in standards bodies where appropriate to agency mission
- Report on use of government-unique standards
- Report on participation in the development and use of voluntary consensus standards

SLIDE 7

Participation in Standards Bodies

Agencies must:

- Consult with voluntary consensus bodies, both domestic and international
- Participate in standards development when
 - In the public interest
 - Compatible with agency mission, authority, priorities, budget resources

SLIDE 8

Agency Support of VCS Activities

- Must not be contingent on the outcome of the activity
- Can be no greater than that of other participants except when
 - In the direct and predominant interest of the government
 - Development or revision is otherwise unlikely
- Forms of Support
 - Participation of agency personnel
 - Joint planning with SDCs to identify needed standards
 - Direct financial, administrative, technical

SLIDE 9

Limitations on Agency Participation

Agencies must not:

- Get involved in internal management issues
- Dominate standards activities
- Exert undue influence

Participation must be in compliance with all applicable federal laws

SLIDE 10

Annual Reporting Requirements

- List of government-unique standards used in lieu of voluntary standards
- Number of bodies in which agency participates
- Number of agency participants
- Number of voluntary standards used
- Identification of voluntary standards substituted for government-unique standards
- Evaluation of the effectiveness of the Circular

SLIDE 11

Successful Implementation Strategies

- Several presented at ANSI World Standards Week workshop
 - Defense
 - Energy
 - NASA
 - NRC
 - NIST
- Presentations available on-line
 - NTTAA website: <http://ts.nist.gov/ts/htdocs/210/nttaa/nttaa.htm>
 - ANSI Online: <http://www.ansi.org>

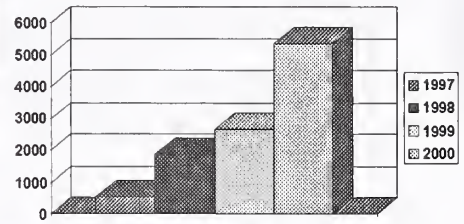
SLIDE 12

Results of NTTAA Efforts Thus Far

- Greater use of voluntary consensus standards
- Federal agency activity levels increasing
- Greater knowledge of standards
- More focused participation in specific, relevant standards activities
- Greater involvement with SDOs
- Mounting anecdotal evidence of positive outcomes

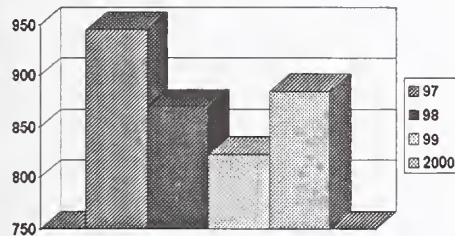
SLIDE 13

Number of Voluntary Standards Used by Federal Agencies



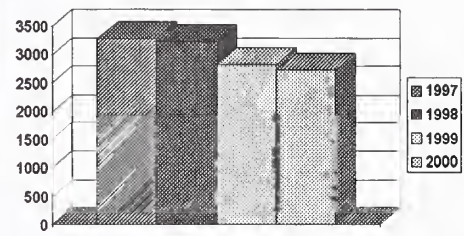
SLIDE 14

Voluntary Standards Bodies in Which Agencies Participate



SLIDE 15

Agency Employees Participating on SDO Committees



SLIDE 16

OMB Circular: Goals for Government Use of Voluntary Consensus Standards

- Eliminate costs of developing in-house standards
- Decrease the cost of goods procured
- Minimize burden of complying with agency regulation
- Provide incentives/opportunities to establish standards that serve national needs
- Encourage long-term growth for US enterprises
- Promote efficiency and economic competition
- Further policy of reliance upon the private sector

SLIDE 17

Significant Procurement Cost Savings

Case studies - DoD

- Aircraft batteries
 - Total reported savings \$454.7 million
 - Total investment \$9.3 million
- Mechanically attached pipe fittings
 - Total 10-year savings - over \$58 million
 - Investment during the same period - \$750,000

SLIDE 18



Additional Benefits

- **Decreased in-house costs**
 - Attention shifted from regulatory process to technical issues
 - Reduced time spent in preparation of regulations
 - Agencies can focus more on mission oriented activities
- **Improved communications with standards developing organizations**
 - Process of replacing government-unique standards
 - Strategic alliances with SDOs
 - DOT/ITS with AASHTO, ASTM, IEEE, ITE, SAE

SLIDE 19

Conformity Assessment Guidance Training

GUIDANCE ON FEDERAL CA ACTIVITIES

MAUREEN BREITENBERG
OSS/NIST



SLIDE 1

OBLIGATIONS UNDER NTTAA

- SECTION 12 OF NTTAA AUTHORIZED NIST TO COORDINATE FEDERAL, STATE AND LOCAL CONFORMITY ASSESSMENT (CA) ACTIVITIES WITH PRIVATE SECTOR CONFORMITY ASSESSMENT ACTIVITIES.
- GOAL OF NTTAA IS ELIMINATION OF UNNECESSARY DUPLICATION AND COMPLEXITY IN DEVELOPMENT/PROMULGATION OF CONFORMITY ASSESSMENT REQUIREMENTS AND MEASURES.

SLIDE 2

MYTH 1 - IT'S NIST's PROBLEM

- **MYTH:** OUR AGENCY DOESN'T HAVE TO DO ANYTHING -- ONLY NIST DOES.
- **REALITY:** EACH FEDERAL AGENCY MUST EVALUATE EFFICACY AND EFFICIENCY OF THEIR CA ACTIVITIES TO REDUCE UNNECESSARY DUPLICATION AND COMPLEXITY.
- NIST STANDS READY TO HELP, BUT EACH AGENCY IS RESPONSIBLE FOR COORDINATING ITS CA ACTIVITIES WITH THOSE OF OTHER GOV'T AGENCIES/ PRIVATE SECTOR TO MAKE MORE PRODUCTIVE USE OF LIMITED FED. RESOURCES AVAILABLE FOR CA ACTIVITIES.

SLIDE 3

MYTH 2 - MY AGENCY ONLY NEEDS TO COMPLY WITH NTTAA

- **MYTH:** ALL MY AGENCY HAS TO DO IS COMPLY WITH NTTAA AND WE HAVE FULFILLED OUR CA OBLIGATIONS.
- **REALITY:** AGENCIES HAVE *MANY* DOMESTIC/INT'L. OBLIGATIONS AFFECTING CONFORMITY ASSESSMENT -- NTTAA IS ONLY ONE OF THEM.
- **EXAMPLE:** VARIOUS RULEMAKING REQUIREMENTS AFFECT ALL REGULATORY ACTIVITIES, INCLUDING CA PROCEDURES AND REQUIREMENTS.
- **EXAMPLE:** U.S. IS SIGNATORY TO INTERNATIONAL TRADE AGREEMENTS (WTO AGREEMENT, NAFTA, ETZ.)

SLIDE 4

WTO OBLIGATIONS

- **WTO AGREEMENT:**
 - REQUIRES EQUAL TREATMENT FOR DOMESTIC PRODUCTS AND PRODUCTS FROM SIGNATORY COUNTRIES.
 - ENCOURAGES GOVERNMENTS TO PERMIT EQUAL PARTICIPATION FOR DOMESTIC CA BODIES AND CA BODIES LOCATED IN TERRITORIES OF OTHER MEMBERS.

SLIDE 5

MYTH 3 - IT'S A RULE

- **MYTH:** GUIDANCE IS A RULE SINCE IT'S IN THE CFR. WE HAVE TO FOLLOW EVERYTHING IN IT.
- **REALITY:** THE GUIDANCE IS GUIDANCE. *IT'S NOT A RULE.* OMB CIRCULAR A-119 DIRECTED DOC SECRETARY TO ISSUE GUIDANCE TO AGENCIES TO ENSURE EFFECTIVE COORDINATION OF FEDERAL CA ACTIVITIES.
- GUIDANCE PUBLISHED IN 15 CFR PART 287 TO MAKE IT EASIER TO FIND.
- PROVISIONS OF 15 CFR PART 287 ARE INTENDED TO BE USED AS GUIDANCE -- *IT'S NOT A RULE!*

SLIDE 6

MYTH 4 - APPLICABILITY

- **MYTH: NTTAA/GUIDANCE DOESN'T APPLY TO OUR AGENCY.**
- **REALITY: IT APPLIES TO ALL AGENCIES, WHICH SET POLICY FOR, MANAGE, OPERATE, OR USE CA ACTIVITIES AND RESULTS, BOTH DOMESTIC AND INTERNATIONAL, EXCEPT FOR ACTIVITIES CARRIED OUT PURSUANT TO TREATIES.**
- **"AGENCY" MEANS ANY EXEC. BRANCH DEPT., INDEPENDENT COMMISSION, BOARD, BUREAU, OFFICE, AGENCY, GOV'T-OWNED OR CONTROLLED CORPORATION, OR OTHER ESTABLISHMENT OF THE FED. GOV'T. DOES NOT INCLUDE LEGISLATIVE OR JUDICIAL BRANCHES.**

SLIDE 7

MYTH 5 - PREEMPTION

- **MYTH: NIST WILL TAKE OVER AGENCY'S CA RESPONSIBILITIES.**
- **REALITY: GUIDANCE DOES NOT PREEMPT AGENCIES' AUTHORITY/ RESPONSIBILITY TO MAKE REGULATORY OR PROCUREMENT DECISIONS AUTHORIZED BY STATUTE OR REQUIRED TO MEET PROGRAMMATIC OBJECTIVES AND REQUIREMENTS.**
- **DECISION-MAKING ACTIVITIES INCLUDE:**
 - DETERMINING LEVEL OF ACCEPTABLE REGULATORY OR PROCUREMENT RISK;
 - SETTING LEVEL OF PROTECTION;
 - BALANCING RISK, COST AND AVAILABILITY OF TECHNOLOGY (WHERE STATUTES PERMIT) IN ESTABLISHING REGULATORY AND PROCUREMENT OBJECTIVES; AND
 - DETERMINING/IMPLEMENTING PROCUREMENT OR REGULATORY REQUIREMENTS NECESSARY TO MEET PROGRAMMATIC OR REGULATORY OBJECTIVES

SLIDE 8

- **AGENCIES RETAIN BROAD DISCRETION IN SELECTION/ USE OF REGULATORY/PROCUREMENT CA PRACTICES.**
- **AGENCIES MAY ELECT NOT TO USE ALTERNATIVE CA PRACTICES IF AGENCY DEEMS THEM INAPPROPRIATE, INADEQUATE, OR INCONSISTENT WITH STATUTORY CRITERIA OR PROGRAMMATIC OBJECTIVES AND REQUIREMENTS.**
- **GUIDANCE DOES NOT GIVE ANY PARTY ANY CLAIM OR CAUSE OF ACTION AGAINST ANY FED. GOV'T AGENCY**
- **EACH AGENCY RESPONSIBLE FOR REPRESENTATION OF ITS VIEWS ON CA IN MATTERS UNDER ITS JURISDICTION.**
- **EACH AGENCY IS PRIMARY POINT OF CONTACT FOR INFO. ON ITS REGULATORY/ PROCUREMENT CA ACTIONS.**

SLIDE 9

MYTH 6 - NIST IS TAKING OVER ANSI's ROLE

- **MYTH: NIST WILL COORDINATE PRIVATE SECTOR CA ACTIVITIES.**
- **REALITY: NIST HAS RESPONSIBILITY FOR HELPING TO COORDINATE ACTIVITIES OF PUBLIC SECTOR.**
- **NIST WILL WORK WITH ANSI AND PRIVATE SECTOR AS APPROPRIATE.**
- **GUIDANCE REAFFIRMS ANSI'S ROLE IN COORDINATION OF PRIVATE SECTOR STANDARDS ACTIVITIES AS SPELLED OUT IN MOU BETWEEN NIST AND ANSI.**

SLIDE 10

MYTH 7: USE OF THIRD PARTIES IS REQUIRED

- **MYTH: AGENCIES MUST USE PRIVATE SECTOR CA PROGRAMS IN THEIR ACTIVITIES.**
- **REALITY: REDUCTION IN DUPLICATION AND COMPLEXITY MAY BE ACHIEVED BY**
 - RELYING ON PRIVATE SECTOR CONFORMITY ASSESSMENT PROGRAMS AND ACTIVITIES;
 - RELYING ON OTHER GOVERNMENTAL ACTIVITIES;
 - RELYING ON SUPPLIER'S DECLARATION OF CONFORMITY; OR
 - BY ENCOURAGING PRIVATE SECTOR TO RELY ON GOVERNMENTAL ACTIVITIES.

SLIDE 11

- **AGENCIES SHOULD CONSIDER ALTERNATIVE APPROACHES IN RULEMAKING/PROCUREMENT.**
- **HOWEVER, AGENCY IS RESPONSIBLE FOR FINAL DETERMINATION OF WHICH APPROACH(ES) BEST MEET AGENCY OBJECTIVES.**

SLIDE 12

MYTH 8 - WE HAVE TO USE GUIDANCE's DEFINITIONS

- **MYTH: OUR AGENCY HAS TO USE THE GUIDANCE's TERMS AND DEFINITIONS IN ITS PROGRAMS.**
- **REALITY: IT WOULD BE NICE, BUT**
- **TERMS AND DEFINITIONS WERE ONLY INCLUDED TO HELP READERS UNDERSTAND GUIDANCE BECAUSE AGENCIES DO NOT USE CONSISTENT TERMINOLOGY.**
- **DEFINITIONS BASED ON ISO/IEC GUIDE 2. MODIFIED TO ADDRESS UNIQUE NATURE OF FEDERAL GOVERNMENT CA ACTIVITIES.**

SLIDE 13

MYTH 9 - SUPPLIER'S DECLARATION ISN'T INCLUDED

- **MYTH: SUPPLIER'S DECLARATION IS NOT RECOGNIZED IN GUIDANCE.**
- **REALITY: GUIDANCE RECOGNIZES 1ST, 2ND AND 3RD PARTY CA ACTIVITIES AND PROCEDURES IN DEFINITION OF CA.**
- **GUIDANCE DOES NOT SUGGEST ANY ONE METHOD/ACTIVITY IS PREFERABLE.**
- **EACH AGENCY MUST SELECT CA ACTIVITIES AND PROCEDURES, WHICH BEST MEET LEGISLATIVE MANDATES AND PROGRAMMATIC OBJECTIVES IN MOST COST-EFFECTIVE AND EFFICIENT MANNER.**

SLIDE 14

DEFINITIONS -CA

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

SLIDE 15

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*).

SLIDE 16

MYTH 10 -- AGENCIES CAN'T SAY NO

- **MYTH: GUIDANCE REQUIRES THAT AGENCIES UNDERTAKE ALL COORDINATION ACTIVITIES EVEN WHERE COSTS INVOLVED ARE LIKELY TO EXCEED BENEFITS.**
- **REALITY: WHILE COORDINATION IS OFTEN BENEFICIAL AND SHOULD ALWAYS BE CONSIDERED, AGENCIES ARE RESPONSIBLE FOR FINAL DECISION AS TO APPROPRIATE LEVEL OF COORDINATION AND COMMITMENT OF RESOURCES.**

SLIDE 17

MYTH 11 - MANDATORY REPORTING

- **MYTH : REPORTING IS MANDATORY.**
- **REALITY: MANDATORY AGENCY REPORTING REQUIREMENTS REGARDING CA ACTIVITIES WAS NOT SPECIFIED IN NTTAA. CA REPORTING FOR ALL AGENCIES IS VOLUNTARY.**
- **HOWEVER, IT IS AN OPPORTUNITY TO TAKE CREDIT FOR WHAT AGENCY IS DOING.**
- **VOLUNTARY REPORT TO NIST ON AGENCY CA ACTIVITIES IS TO BE INCLUDED IN ANNUAL REPORT ON AGENCY'S IMPLEMENTATION OF OMB CIRCULAR A-119.**

SLIDE 18

MYTH 12 – ONLY ONE STDS. EXECUTIVE ALLOWED

- MYTH: UNDER NO CIRCUMSTANCES CAN THERE BE MORE THAN ONE STDS EXECUTIVE.
- REALITY: OMB A-119 INDICATES MORE THAN ONE STDS. EXECUTIVE WAS NOT CONTEMPLATED.
- NIST/OMB BELIEVE ONE STDS. EXECUTIVE FOR STDS. AND CA FACILITATES BETTER COORDINATION AND COMMUNICATION.
- HOWEVER, OMB AND NIST RECOGNIZE IT *MAY* BE NECESSARY TO ASSIGN ADDITIONAL STAFF TO CARRY OUT CA RESPONSIBILITIES.
- AGENCY MUST ENSURE RESPONSIBILITIES ARE COORDINATED AND EFFECTIVELY CONDUCTED!

SLIDE 19

NIST RESPONSIBILITIES

- WORK WITH AGENCIES THROUGH (ICSP) TO COORDINATE FEDERAL, STATE, AND LOCAL CA ACTIVITIES WITH PRIVATE SECTOR CA ACTIVITIES.
- CHAIR ICSP AND ASSIST ICSP IN DEVELOPING POLICIES/GUIDANCE ON CA ISSUES.
- COLLECT/DISSEMINATE INFO. ON FEDERAL, STATE AND PRIVATE SECTOR CA ACTIVITIES.
- INCREASE PUBLIC AWARENESS OF IMPORTANCE OF CA AND NATURE/EXTENT OF NAT'L AND INT'L CA ACTIVITIES.
- ENCOURAGE ICSP PARTICIPATION BY ALL AGENCIES AND ENSURE AGENCY VIEWS ARE CONSIDERED.
- TO EXTENT RESOURCES ARE AVAILABLE, DEVELOP INFO. ON STATE CA PRACTICES; AND, UPON REQUEST BY STATE AGENCY, WORK WITH AGENCY TO REDUCE DUPLICATION/COMPLEXITY IN STATE CA ACTIVITIES.
- REVIEW GUIDANCE WITHIN THREE YEARS OF ISSUANCE.

SLIDE 20

AGENCY RESPONSIBILITIES

- IMPLEMENT POLICIES IN NTTAA/ GUIDANCE.
- PROVIDE RATIONALE FOR USE OF CA PROCEDURES AND PROCESSES IN RULEMAKING/ PROCUREMENT TO EXTENT FEASIBLE.
- WHEN NOTICE/COMMENT RULEMAKING REQUIRED, PROVIDE OPPORTUNITY FOR PUBLIC COMMENT ON AGENCY'S CA DECISION.

SLIDE 21

- USE RESULTS OF OTHER GOV'T AGENCY AND PRIVATE SECTOR ORGANIZATIONS IN CA ACTIVITIES TO ENHANCE SAFETY/EFFICACY OF PROPOSED NEW CA REQUIREMENTS/MEASURES.
- *EXAMPLE:* COLLECT/ REVIEW INFORMATION ON SIMILAR ACTIVITIES CONDUCTED BY OTHER FEDERAL/STATE AGENCIES/PRIVATE SECTOR BODIES TO DETERMINE IF RESULTS CAN BE USED TO IMPROVE EFFECTIVENESS OF PROPOSED FED. AGENCY CA ACTIVITY.

SLIDE 22

- USE RELEVANT CA GUIDES/ RECOMMENDATIONS PUBLISHED BY DOMESTIC/INTERNATIONAL STDS. BODIES AS APPROPRIATE. [i.e., ISO, IEC, ITU, OECD, WHO, AND CODEX ALIMENTARIUS COMMISSION.]
- EACH AGENCY IS RESPONSIBLE FOR DETERMINING WHICH, IF ANY, DOCUMENTS ARE RELEVANT TO ITS NEEDS.
- NCSCI CAN HELP IDENTIFY PERTINENT STANDARDS/GUIDES.

SLIDE 23

- IDENTIFY APPROPRIATE PRIVATE SECTOR CA PRACTICES /PROGRAMS AND CONSIDER USING RESULTS IN *EXISTING* REGULATORY/ PROCUREMENT ACTIONS.
- *EXAMPLE:* AGENCY COULD USE RESULTS OF PRIVATE SECTOR/OTHER GOV'T. AGENCY CA ACTIVITIES TO SCHEDULE PROCUREMENT AUDITS MORE EFFECTIVELY. COULD ALLOW AGENCIES TO REDUCE NO./EXTENT OF AUDITS AT COMPANIES PERFORMING WELL AND UNDER REVIEW BY THIRD PARTY/ANOTHER AGENCY AND CONCENTRATE EFFORTS ON COMPANIES WHICH HAVE PROBLEMS CONFORMING TO CONTRACT SPECIFICATIONS.

SLIDE 24

■ **EXAMPLE:** FEDERAL COMMUNICATIONS COMMISSION'S (FCC) TELECOMMUNICATION CERTIFICATION BODY (TCB) PROGRAM AND FCC'S REPLACEMENT OF PREMARKETING APPROVAL REQUIREMENTS FOR CERTAIN TYPES OF EQUIPMENT WITH SUPPLIERS DECLARATION OF CONFORMITY, PROVIDED TEST RESULTS SUPPORTING DECLARATION ARE FROM ACCREDITED TESTING LAB.

SLIDE 25

- **CONSIDER USING RESULTS OF OTHER AGENCIES' CA PROCEDURES.**
- **EXAMPLE:** AGENCY COULD USE RESULTS OF ANOTHER AGENCY'S INSPECTION/AUDIT OF SUPPLIER TO ELIMINATE/REDUCE SCOPE OF ITS INSPECTION/AUDIT OF THAT SUPPLIER.
- **PARTICIPATE IN EFFORTS DESIGNED TO IMPROVE COORDINATION AMONG GOV'T. AND PRIVATE SECTOR CA ACTIVITIES.**
- **EXAMPLES:** NATIONAL COOPERATION FOR LABORATORY ACCREDITATION (NACLA) ORGANIZATION, NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE (NELAC), ISO/CASCO, ANSI'S CA ACTIVITIES), AND ICSP WGs DEALING WITH CA ISSUES.

SLIDE 26

- **WORK WITH OTHER AGENCIES TO AVOID UNNECESSARY DUPLICATION AND COMPLEXITY IN FED. CA ACTIVITIES.**
- **EXAMPLES:**
 - PARTICIPATE IN ANOTHER AGENCY'S CA ACTIVITIES BY CONDUCTING JOINT PROCUREMENT AUDITS/ INSPECTIONS OF SUPPLIERS WHICH SELL TO BOTH.
 - SHARE CA INFORMATION WITH OTHER AGENCIES.
 - USE CA INFO. PROVIDED BY OTHER AGENCIES TO IMPROVE EFFECTIVENESS/EFFICIENCY IN CA ACTIVITIES.
 - CA INFORMATION MAY INCLUDE: CA PROCEDURES/ RESULTS, TECHNICAL DATA ON OPERATION OF CA PROGRAMS, PROCESSING METHODS/REQUIREMENTS FOR APPLICATIONS, FEES, FACILITY SITE DATA, COMPLAINT REVIEW PROCEDURES, AND CONFIDENTIALITY PROCEDURES.

SLIDE 27

- **ENCOURAGE DOMESTIC/INT'L RECOGNITION OF U.S. CA RESULTS, INCLUDING PROVIDING SUPPORT FOR INT'L NEGOTIATIONS AND ANY RESULTING ACTIVITIES/REQUIREMENTS RESULTING FROM THOSE NEGOTIATIONS AND HELPING U.S. INDUSTRY IN PURSUE AGREEMENTS WITH FOREIGN NAT'L/ INT'L PRIVATE SECTOR ORGANIZATIONS.**
- **PARTICIPATE IN DEVELOPMENT OF PRIVATE SECTOR CA STDS. TO ENSURE FEDERAL VIEWPOINTS ARE REPRESENTED.**
- **WORK WITH OTHER AGENCIES TO HARMONIZE FEDERAL REQUIREMENTS FOR QUALITY/ ENVIRONMENTAL MGT. SYSTEMS FOR USE IN PROCUREMENT/REGULATION.**

SLIDE 28

- **WORK WITH OTHER ICSP MEMBERS, NIST, AND PRIVATE SECTOR AS NECESSARY/APPROPRIATE TO ESTABLISH CRITERIA FOR DEVELOPMENT/ IMPLEMENTATION OF GOV'T RECOGNITION SYSTEMS TO MEET GOV'T RECOGNITION REQUIREMENTS IMPOSED BY OTHER NATIONS/REGIONAL GROUPS TO FACILITATE INT'L MARKET ACCESS FOR U.S. PRODUCTS.**
- **ASSIGN AGENCY STDS EXECUTIVE RESPONSIBILITY FOR COORDINATING IMPLEMENTATION OF GUIDANCE.**

SLIDE 29

RESPONSIBILITIES OF AGENCY STANDARDS EXECUTIVE

- **CARRIES OUT DUTIES IN OMB CIRCULAR A-119 RELATED TO STDS.**
- **PROMOTES THE FOLLOWING GOALS:**
 - EFFECTIVE USE OF AGENCY CA RELATED RESOURCES AND PARTICIPATION IN CA ACTIVITIES OF AGENCY INTEREST.
 - DEVELOPMENT/DISSEMINATION OF AGENCY TECHNICAL AND POLICY POSITIONS.
 - DEVELOPMENT OF AGENCY POSITIONS ON CA RELATED ISSUES THAT ARE IN PUBLIC INTEREST.

SLIDE 30

OTHER DUTIES

- ENSURE AGENCY PARTICIPATION IN CA ACTIVITIES IS CONSISTENT WITH AGENCY MISSIONS, AUTHORITIES, PRIORITIES, AND BUDGET.
- COOPERATE WITH NIST IN CARRYING OUT AGENCY RESPONSIBILITIES UNDER GUIDANCE.
- CONSULT WITH NIST, AS NECESSARY, IN DEVELOPMENT/ISSUANCE OF INTERNAL AGENCY IMPLEMENTATION PROCEDURES AND GUIDANCE.
- ESTABLISH ONGOING PROCESS FOR REVIEWING AGENCY'S EXISTING CA ACTIVITIES AND IDENTIFYING AREAS WHERE EFFICIENCIES ARE POSSIBLE.
- WORK WITH OTHER PARTS OF AGENCY TO DEVELOP/IMPLEMENT IMPROVEMENTS IN AGENCY CA ACTIVITIES.

SLIDE 31

REPORT TO NIST, ON A VOLUNTARY BASIS, ON AGENCY CA ACTIVITIES FOR INCLUSION IN ANNUAL REPORT TO OMB ON AGENCY'S IMPLEMENTATION OF OMB CIRCULAR A-119

SLIDE 32

HELPFUL INFORMATION

NIST HAS CONFORMITY ASSESSMENT
WEBSITE AT:

[HTTP://TS.NIST.GOV/CA](http://ts.nist.gov/ca)

SLIDE 33

NCSCI CONTACT INFORMATION

NATIONAL CENTER FOR STANDARDS AND
CERTIFICATION INFORMATION (NCSCI)

NIST

100 BUREAU DRIVE, MS 2150
GAITHERSBURG, MD 20899-2150

PHONE: 301-975-4040

FAX: 301-926-1559

E-MAIL: NCSCI@NIST.GOV

SLIDE 34

PART TWO

**PUBLIC AND PRIVATE SECTOR
COOPERATION IN SUPPORT
OF REGULATION**

Private Sector Testing and Certification in Support of Federal Agency Needs

MEETING SAFETY and QUALITY NEEDS THROUGH THIRD PARTY CONFORMITY ASSESSMENT

Presented by:
Gordon Gillerman
Manager - Governmental Services
Underwriters Laboratories



SLIDE 1

What are the needs of:

Acceptance Interests - Confidence that a product or system meets requirements (Regulatory and Non-Regulatory)

Manufacturers/Service Providers- Effective/Efficient Conformity Assessment conducted locally and accepted without further evaluation



SLIDE 2

Meeting these needs simultaneously requires third parties Conformity Assessment Programs to:

- operate with integrity
- excel technically
- maintain objectivity
- be responsive
- be efficient
- be accredited - when needed



SLIDE 3

If the third party does not meet the confidence needs of the Acceptance Interests - the demand for the third party's services is not driven.

If the third party does not meet the needs of the Suppliers - other third parties are sought to provide conformity assessment services.



SLIDE 4

TYPICAL CONFORMITY ASSESSMENT PROGRAMS to ADDRESS THESE NEEDS

- Testing
- Product Certification
- Quality System Registration
- Inspection



SLIDE 5

Testing

- Conduct specified tests
- Deliver test results and methods



SLIDE 6

DELIVERING
Tomorrow's
SOLUTIONS
Today

Product Certification

Investigation

- Construction and Marking Review
- Testing Conducted
- Results Compared to Requirements
- Compliance or Non-Compliance Determined

Surveillance

- Unannounced, Frequent Product Inspections
- Witnessing of Production Tests
- Countercheck Testing
- Market Sampling

UL

SLIDE 7

DELIVERING
Tomorrow's
SOLUTIONS
Today

Quality Management System Registration

- Pre-assessment (procedure review)
- Assessment (on site implementation)
- Audit (verify continued implementation and identify potential improvements)

UL

SLIDE 8

DELIVERING
Tomorrow's
SOLUTIONS
Today

Commercial Testing and Inspection

Purpose is to Determine if Products meet Purchaser's/Procurement Specifications

- Useful if a full quality system is not in place or does not cover key aspects of product
- or if confidence needs of purchaser demand product specification inspection in addition to quality management systems

UL

SLIDE 9

DELIVERING
Tomorrow's
SOLUTIONS
Today

UL Governmental accreditation:

Federal Government Defense Logistics Agency US EPA FCC DoL OSHA FDA General Services Administration (GSA) National Institute of Justice United States Coast Guard US Department of Agriculture Forest Service	State and Local Government State of Arizona State of California State of Colorado State of Florida State of Iowa State of Indiana City of Los Angeles State of Massachusetts State of Maryland State of Maine State of Michigan State of Minnesota State of Missouri State of Montana State of North Carolina State of Nebraska State of New Hampshire	State of New York State of Ohio State of Oregon State of Pennsylvania, Department of Environmental Protection State of South Carolina State of Tennessee State of Texas State of Virginia State of Washington State of Wisconsin
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UL

SLIDE 10

DELIVERING
Tomorrow's
SOLUTIONS
Today

FDA Accredited Persons Program

- First Tier Review of Medical Device Manufacturer's Reports for Market Clearance
- Not Testing, Certification, Registration or Inspection
- Recommend Determination of Substantial Equivalence (or Not) to Legally Marketed Device
- Accreditation covers - Eligible Devices, Personnel Qualifications, Conflict of Interest and Procedures
- FDA Trains, Assesses and Audits for Continued Compliance
- We Conduct Internal Audits (not required)

UL

SLIDE 11

DELIVERING
Tomorrow's
SOLUTIONS
Today

Resources to Facilitate High Integrity Effective, Efficient Conformity Assessment Programs

- Conformity assessment program infrastructure and procedures
- Engineering and technical
- Laboratory facilities
- Experienced inspectors, assessors/auditors stationed in the field

UL

SLIDE 12



Testing and Certification Programs for Federal/State Agencies

Joseph Hazeltine

SLIDE 1

Agenda

- Overview of Activities
- Details on Specific Programs
- Certification Process
- Auditing/ Enforcement
- Fees
- Marks Used
- Conclusions/ Recommendations
- Contact Information

SLIDE 2

Wyle - Huntsville, AL Facility



- Founded 1962
- >200 people
- 125 acre secure site
- 220,000 ft² Facilities
- >40 chambers up to 30'x18'x18"
- Wide range of electrical power loads plus fault/surge conditions
- All other utilities including natural gas, telecom & computer networks
- Highly-integrated & self-sufficient
- On-site engineering & fab
- Wide-ranging foreign compliance capability

SLIDE 3

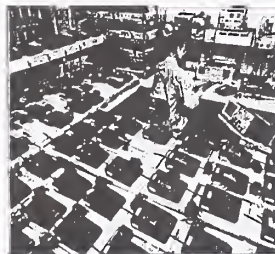
Overview of Wyle Certification Activities

- OSHA CAB for Safety (Low Voltage Directive)
- OSHA Nationally Recognized Testing Laboratory (NRTL)
- NIST CAB for EMC (EMC Directive)
- DOT Performance Oriented Packaging (POP)
- Verizon Independent Testing Laboratory (ITL)
- NASED Independent Testing Authority (ITA)
- FCC Listed Sites
- US Navy Shock Testing
- DoD Qualification Testing

SLIDE 4

OSHA NRTL Program

- Started in 1989
- Focus is workplace safety
- 18 NRTLs to date
- ~ 800 Standards covered
- Certification by standard
- ANSI/ UL/NFPA/ASTM
- Reciprocity ?
- Now permitted to participate in some standard revisions and development



SLIDE 5

NIST CAB for EMC

- Focus is workplace and household compatibility
- Started in 1999 via EU MRA
- Many CABs to date
- Certification by directives
- European Norm Standards
- Reciprocity?
- Some participation in standard revisions and development



SLIDE 6

DOT POP

- Focus is safety in container transporting hazardous goods
- Started in 1984
- Approx. 30 POP testing facilities
- UN Orange Book/ 49CFR/ICAO/IATA/IMDG Standards
- Reciprocity
- Administered by DOT Research & Special Programs Administration (RSPA)



SLIDE 7

Verizon ITL

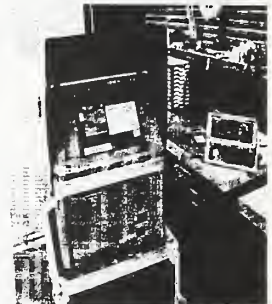
- Focus is workplace safety
- Started in 2001
- 5 ITLs to date
- Certification by vendor
- Bellcore/ Verizon
- No Reciprocity
- Not permitted to participate in standard revisions and/or development



SLIDE 8

NASED ITA

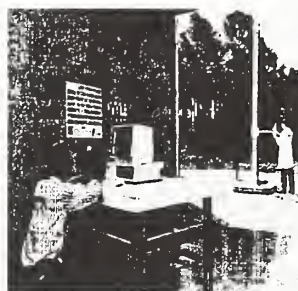
- Focus is electronic voting machines safety, reliability & performance
- Started in 1994
- 3 ITAs to-date
- FEC Guidelines
- Standard in revision process
- Issue NASED Control mark
- Includes Configuration Management



SLIDE 9

FCC Listed Facility

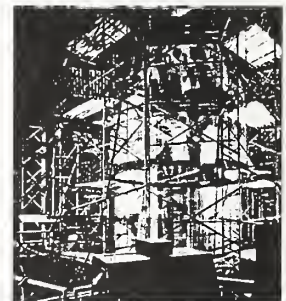
- Focus is workplace and home safety and EMC
- Started in 1975
- Hundreds of laboratories listed by FCC to date
- Certification by equipment category
- 47CFR series and ANSI Standards
- Permitted to participate in standard revisions and development



SLIDE 10

DoD Testing (Including US Navy Shock)

- Focus is military equipment operability & safety
- Wyle started in 1949
- Thousands of facilities
- Thousands of DoD Standards
- Navy Shock to Mil-Std 901 (Qualification based on machine size)
- Participation is available in all standard revisions and development
- DCMA Witnesses some testing



SLIDE 11

Certification Process

Certification	Process
OSHA NRTL	Audit + Proposal
OSHA CAB (Safety)	Proposal
NIST CAB (EMC)	Proposal
DOT POP	Site Visit
Verizon ITL	Proposal
NASED ITA	Audit + Proposal
FCC	Proposal
US NAVY	Proposal
DoD	DCMA

SLIDE 12

Certification Program Enforcement Activities

Certification	Auditing/Enforcement
OSHA NRTL	Annual Audit
OSHA CAB (Safety)	Accreditation
NIST CAB (EMC)	Accreditation
DOT POP	Bi-annual Audit
Verizon ITL	Quarterly Audits
NASED ITA	Quarterly Meetings
FCC	Accreditation + 3 yr Review
US NAVY	DCMA
DoD	DCMA

SLIDE 13

Certification Program Fees

Certification	Fees
OSHA NRTL	Cost of Audit
OSHA CAB (Safety)	None
NIST CAB (EMC)	None
DOT POP	Audit Fees
Verizon ITL	Annual Fee+ audits
NASED ITA	Initial Audit
FCC	None
US NAVY	None
DoD	None

SLIDE 14

Certification Marks

Certification	Marks
OSHA NRTL	NRTL Mark
OSHA CAB (Safety)	CE Mark
NIST CAB (EMC)	CE Mark
DOT POP	POP Mark
Verizon ITL	NRTL Mark
NASED ITA	NASED Mark
FCC	FCC Mark
US NAVY	None
DoD	None

SLIDE 15

Conclusion/Recommendations

- Must obtain reciprocity in international programs
- Involvement in standards development must be available to all participating organizations
- Cost of accreditations are growing- has become a barrier to entry in some markets
- Industry needs a common accreditation scheme with a common set of guidelines
- Need to have training available and forums where problems can be shared and resolved

SLIDE 16

Contacts

NRTL/FCC-Jim Dearman, ext. 218
 jdearman@hnt.wylelabs.com
Telecom-Don Smith, ext. 221
 desmith@hnt.wylelabs.com
DoD-Bob Porter, ext. 545
 rporter2@hnt.wylelabs.com
Div. Dir.-Joe Hazeltine, ext. 390
 hazeltin@hnt.wylelabs.com
GM-Keith Wilson, ext. 227
 kwilson@hnt.wylelabs.com

PO Box 077777
7800 Highway 20
Huntsville, AL 35807
Phone: (256) 837-4411
Fax: (256) 721-0144
www.wylelabs.com

SLIDE 17

Public/Private Partnerships: Factors for Success in Conformity Assessment

Gordon Bellen
NSF International
NIST Conformity Assessment Workshop
December 3, 2001

SLIDE 1

Today's Discussion

- Case Studies of third party conformity assessment(CA) programs at NSF.
- Review of four factors influencing success.

SLIDE 2

Verification of Claims

- Self certification.
- Third party conformity assessment (CA).
- Government regulation/oversight.

SLIDE 3

Conformity Assessment Decision Factors

- Risk severity – societal risk in the absence of verification.
- Response of market – confidence in verification.
- Reliability of verification – is the market properly informed.
- Resources – is the verification cost effective.

SLIDE 4

CA Continuum

- Photographic film – low risk, consumer verification.
- Food safety – high risk, consumer can't verify, government oversight.
- Airport security?

SLIDE 5

NSF Third Party Case Studies

- Success
 - Drinking Water Additives
 - Retail Food Service Equipment
 - Bottled Water
 - Environmental Technology Verification
- Less success
 - Shelf Stable Foods
 - Food Processing Equipment
 - Seafood Inspections

SLIDE 6

Success- Drinking Water Additives

- Chemicals and materials in contact with drinking water.
- Ingredient review.
- Product testing in water.
- Toxicology evaluation.
- Follow-up services.

SLIDE 7

Drinking Water Additives, cont.

- EPA advisory program.
- No EPA funding.
- Industry ambivalence.
- Strong State support.
- Strong utility support.
- Cost savings in reduced redundant reviews.

SLIDE 8

Success - Retail Food Service Equipment

- Commercial restaurant and institutional food preparation and storage.
- Design and construction.
- Food contact material content.
- Some performance.
- Follow-up services.

SLIDE 9

Retail Food Service Equipment, cont.

- FDA support.
- Strong local health department support.
- Strong industry support.
- Cost savings in reduced reviews.

SLIDE 10

Success – Bottled Water

- FDA plus IBWA requirements.
- Sanitary inspection.
- Source water testing.
- Product water testing.
- Containers and closures.

SLIDE 11

Bottled Water, cont.

- Industry driven.
- Regulatory awareness.
- Service in over 60 countries.
- Two levels of service.
- Industry risk management.

SLIDE 12

Success – Environmental Technology Verification (ETV)

- Drinking water treatment technologies – arsenic, cryptosporidium.
- Source water protection technologies – decentralized waste, infrastructure, ballast water.
- Wet weather flows – storm water treatment.
- One time verification.

SLIDE 13

ETV, cont.

- EPA support – improve commercialization and use through verification of performance.
- EPA funding reduced over time.
- Semi-finalist – Harvard/Ford Foundation innovations in government.
- Move towards CA program.

SLIDE 14

Less Success – Shelf Stable Foods

- Pies, pastries, etc.
- Product chemistry – water activity, pH.
- Microbiological challenge.
- Follow-up services.

SLIDE 15

Shelf Stable Foods, cont.

- Initial FDA support.
- NSF standard produced.
- State support.
- Industry resistance.
- No agreement on risk/reward issues.

SLIDE 16

Less Success – Food Processing Equipment

- Meat and poultry processing.
- Design and construction.
- Cleanable.
- Follow-up services.
- Replacing USDA program.

SLIDE 17

Food Processing Equipment, cont.

- Initial USDA support.
- NSF/international standard produced.
- USDA now competing.

SLIDE 18

Seafood Inspection

- Non regulatory program.
- Issues similar to food processing.

SLIDE 19

Conclusion

- Better collaboration between third parties, government and industry needed.
- Education on standards and conformity assessment needed in government.
- Analyze the four “Rs”: Risk, Response, Reliability and Resources.

SLIDE 20

Testing, Calibration, and Certification

NCSLI Perspective Conformity Assessment Workshop December 3, 2001

Georgia L. Harris
NCSLI V.P. Publications
(NIST, Office of Weights & Measures)

1

SLIDE 1

NCSLI Involvement

- WHY?
- Primary focus: Laboratory Accreditation
 - Policy on Laboratory Accreditation, Registration, and Certification
 - Standards Writing & Adoption & Resources
 - Participation with NACLA, ILAC, NMIs (incl. NIST)
 - Collaboration
- Secondary focus: Certification for product evaluation (barriers to trade)

2

SLIDE 2

Policy

- NCSLI International Position Statement published April 2001 NCSLI Newsletter
 - clarifies terminology related to Laboratory Accreditation, Registration, Certification, and Third Party
 - focus on accreditation and *competence*

3

SLIDE 3

Standards Writing and Adoption & Resources

- ANSI/NCSLI Z 540, Standards Writing Committee
- U.S. National Standards:
- Publications & Training

4

SLIDE 4

Participation

- Representation on NACLA Board
- Sponsorship of NACLA (Patron Member)
- Stakeholder member in ILAC
- Annual meetings with NMI management (NIST, CENAM, NRC)

5

SLIDE 5

Collaboration

- Requested NIST establish a laboratory accreditation program for "calibration laboratories" in NVLAP
- Includes government representatives on writing committees to encourage adoption of standards when published:
 - Adoption of Z 540-1-1994 in NVLAP & OWM laboratory criteria at NIST
 - Adoption of Z 540-1-1994 by DOD, DOE, etc for calibration laboratories
 - E.g., DOE adoption of ISO/IEC 17025
 - FAA contacted Airline Industry Committee - regarding Z 540-1 applicability to FAA regulations

6

SLIDE 6

Collaboration

- Met with Jim Turner, House Majority Counsel to Committee on Science, Commerce, Technology July 27, 2001
 - laboratory accreditation issues; lack of uniformity in acceptance of accreditation by Federal agencies, effectiveness of NCSLI in representing interests of members
 - possible proposal to OMB



7

SLIDE 7

Suggestions

- Government agencies should recognize competence of laboratories accredited to international quality standards
 - versus additional audits and requirements
 - compare ISO/IEC 17025 and NRC 10 CFR 50, find out if there are gaps, then address the gaps by 17025 updates
 - environmental, chemical, biological
- Collaboration among Federal & accredited labs to provide traceable calibration services



8

SLIDE 8

Conformity Assessment Options Federal Communications Commission

William S. Hurst
Office Engineering and Technology
December 3, 2001

3 December 2001

Federal Communications Commission

Slide 1

SLIDE 1

Equipment Authorization Program

- The FCC currently has three equipment approval programs
 - ↓ Verification
 - ↓ Declaration of Conformity (DoC)
 - ↓ Certification
- The product approval requirement is specified in the rule part under which equipment operates
- All three programs involve the use of the private sector to varying degrees

3 December 2001

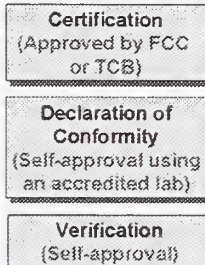
Federal Communications Commission

Slide 2

SLIDE 2

Equipment Authorization Program

The type of approval
is specified in the rules
for the particular
type of device



3 December 2001

Federal Communications Commission

Slide 3

SLIDE 3

FCC Authorization Requirements

Verification	DoC	Certification
Most ISM equipment	Cable Sys Term. Device	Cable Sys Term Device
TV & FM receivers	PC's & peripherals	PC's & peripherals ²
All other digital devices	Most receivers	Most receivers
Pt-to-Pt Microwave	TV Interface Devices	TV Interface Devices
Broadcast transmitters	Consumer ISM eqmt.	Consumer ISM eqmt.
Aux. Broadcast Xmters	Telephone Equipment ¹	Telephone Equipment ²
INMARSAT equipment		Most transmitters
406 MHz ELT		Scanning Receivers
CATV Relay Xmters		

(1) TTE does not require the use of an accredited lab.
(2) A TCB may certify this equipment

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Federal Communications Commission

Slide 4

SLIDE 4

Why Use the Private Sector?

- Speed at which technology is changing and shorter product life cycles require faster product approvals
- The private sector has the technical expertise and ability to certify equipment.
- Increase the resources performing conformity assessment
- Efficiencies in designing and approving product in the same geographic location
- Reduce uncertainty and delay in obtaining certification

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Federal Communications Commission

Slide 5

SLIDE 5

Objectives

- To meet the Commission's Mission:
 - ↓ "The FCC's mission is to encourage competition in communications and to promote and support access for every American to existing and advanced telecommunications services."
- ET Docket 98-68 provided for:
 - ↓ Private Certification Bodies known as Telecommunication Certification Bodies (TCBs); and
 - ↓ Permit the certification of equipment by private organizations outside of the United States through Mutual Recognition Agreements (MRAs)

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Federal Communications Commission

Slide 6

SLIDE 6

What Is a TCB?



- A Telecommunication Certification Body is a Certification Body that has been accredited to ISO/IEC Guide 65 by a recognized Accrediting Organization and designated by the FCC to approve equipment subject to certification.
- A TCB is not a test laboratory, nor should it function in that capacity.
- As a TCB, it has certain rights and responsibilities.
- Foreign entities may become a TCB in accordance with the terms of a government-to-government Mutual Recognition Agreement/Arrangement.

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Federal Communications Commission

Slide 7

SLIDE 7

New Rules for TCBs



- FCC GEN Docket 98-68
- Establishes procedures for designating a Telecommunications Certification Body (TCB)
 - ↓ Manufacturers have the option to choose a TCB or the FCC to obtain approval of a product subject to certification
 - ↓ NIST identified as the accrediting organization Authority for US Conformity Assessment Bodies (CABs)
 - ↓ A TCB must be accredited to ISO Guides 25 & 65

3 December 2001

Federal Communications Commission

Slide 8

SLIDE 8

TCB Scope of Responsibility



- A TCB (see § 2.962 (e) and Public Notice, DA 99-1640)
 - ↓ Is empowered to certify products in accordance with the FCC rules
 - ↓ Must provide fair and equitable treatment
 - ↓ Must accept test data from any source, subject to subcontracting clause in ISO Guide 65 and shall not unnecessarily repeat tests
 - ↓ May assess fees for processing applications
 - ↓ May rescind grant within 30 days

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Federal Communications Commission

Slide 9

SLIDE 9

TCB Limitations



- A TCB cannot (see §2.962(e)(5))
 - ↓ Waive the rules
 - ↓ Take enforcement actions (refer to FCC)
 - ↓ Certify a unique product for which there are no Rules
 - ↓ Revoke a grant after 30 days
 - ↓ Authorize transfer of control of a grantee

All TCB actions are subject to
FCC review

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Slide 10

SLIDE 10

TCB Implementation



- TCB Training Course - December 1999
- Accreditation and designation of TCBs - January - May 2000
- Designation of first group of TCBs - June 2000
- European Union designates first foreign TCBs - January 2001
- Total of 30 operational TCBs in the United States and Europe - October 2001

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Slide 11

SLIDE 11

Application Filing Trends



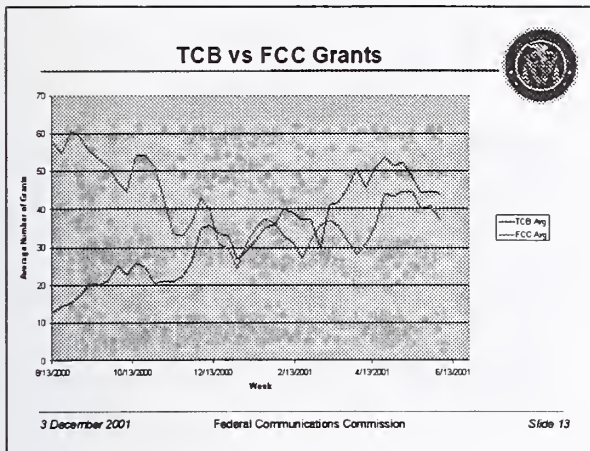
- Since June 2000, the TCBs have granted over 2300 certifications
- The number of applications granted by TCBs have been steadily increasing since June of last year.
- One year since the program started the number of grants issued by TCBs exceeds the number of grants issued by the FCC.
- TCBs are granting approximately 75% of the total number of grants issued.

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Slide 12

SLIDE 12



SLIDE 13

Thank You

William S. Hurst
Federal Communications Commission
Office of Engineering and Technology
Tel: (202) 418-7266
Fax: (202) 418-1944
whurst@fcc.gov

3 December 2001 Federal Communications Commission Slide 14

SLIDE 14

Model Building Codes Status and Support Infrastructure

NIST Workshop on Conformity
Assessment for a Changing
Government

December 3, 2001

Si Farvardin, Program Manager



SLIDE 1

Goal

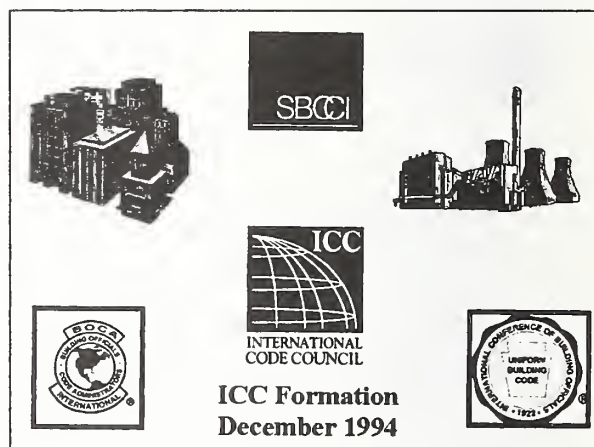
A better understanding of the
International Code Council's
model building codes and
efforts of the National
Evaluation Service related to
conformity assessment of
innovative building products
with respect to those codes

SLIDE 2

U.S. Situation Codes and Standards

- Numerous voluntary and public sector standards developers
- Three developers of model codes
 - developed a single and coordinated family of model building codes
 - are consolidating as the International Code Council
- Federal, state, and local government adoption and implementation of voluntary sector standards and model codes
- Increased national uniformity through adoption of the ICC International Codes

SLIDE 3



SLIDE 4

Development of Codes and Standards

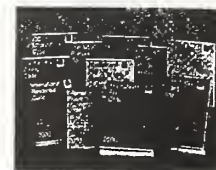
- ICC code development process
 - Any person, corporation or entity can participate
 - Regulatory-based consensus
 - Predictable agenda, no surprises
 - Two cycles every three years
 - Two hearings per cycle
- Proposed revisions to the process
 - Full consensus-based voting
- Full Consolidation - January 2003



SLIDE 5

Support Infrastructure for the ICC Codes

- Education and Training
- Certification Programs for Personnel
- Plan Review
- Code Interpretations
- Automated Products
- Technical Handbooks



SLIDE 6

Determining Compliance with the ICC Codes

- Specific prescriptive provisions - simple plan review and construction inspection
- Specific provisions that rely on reference standards and other criteria not easily field verified - testing and certification by third parties
- Few if any specific provisions - verification of equivalency with other materials and methods already accepted through **EVALUATION and ASSESSMENT**

SLIDE 7

The Need for Technology Evaluation and Assessment

- Adopted codes and standards criteria tend to lag behind new technology development and deployment
- It is difficult to easily determine if new technologies meet minimum building code requirements; especially if they are not mentioned in the code
 - Each code official would need to expend time and resources to determine how they were going to evaluate code compliance on the basis of equivalent performance
 - Each code official would then need to conduct an independent assessment based on the evaluation method they developed



National Evaluation Service, Inc.

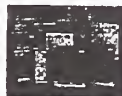
SLIDE 8

The Key to Technology Evaluation and Assessment

- Alternative Materials, Design and Methods of Construction (Chapter 1 of the model building codes)
 - The code is not intended to prevent anything not specifically prescribed by the code when such alternative has been approved by the code official
 - The code official can approve an alternative when it is found what is proposed is equivalent to that prescribed by the code



National Evaluation Service, Inc.



SLIDE 9

The Purpose of Technology Evaluation and Assessment

- Provide a defensible basis for code compliance and safety assurance
- Save time and money for the technology proponent and users of the technology
- Make the code official's job easier
- Facilitate technology acceptance and associated benefits
- Improve uniformity of code interpretation and application



National Evaluation Service, Inc.

SLIDE 10

National Evaluation Reports

- Provide basis for compliance with the International Codes and 3 Model Codes:
 - 2000 International Building Code
 - 1999 Standard Building Code
 - 1997 Uniform Building Code
 - 1999 BOCA National Building Code
- Relationship to the ICC:
 - Cooperative relationship and co-location
 - ICC Logo appears on all new reports



SLIDE 11

National Evaluation Reports

- NES evaluation reports provide:
 - Identification of the technology
 - Scope of evaluation
 - Technology description and relevant installation details
 - Information on labeling
 - List of testing and other documentation
 - Conditions of acceptance and use



National Evaluation Service, Inc.

SLIDE 12

The Evaluation Process

- Addresses evaluation and assessment in a way that would satisfy the majority of code official's "approval" authority
- Eliminates time and effort associated with each state or local agency designing an evaluation method and then performing the evaluation
- A benchmark for all parties to rely on and upon which uniformity can be realized

National Evaluation Service, Inc.



SLIDE 13

What Does this Mean for Federal Agencies?

Savings in manpower and money

- Codes exist upon which Federal construction requirements can be based
- A support infrastructure for those codes exists that readily applies to and can be used by Federal agencies
- Evaluation and assessment of new building technology is ongoing and available to Federal agencies

National Evaluation Service, Inc.



SLIDE 14

CONTACTING the ICC or the NES

International Code Council
National Evaluation Service
5203 Leesburg Pike, Suite 600
Falls Church, VA 22041

703-931-4533 (ICC)

703-931-2187 (NES)

www.intlcode.org

www.nateval.org



SLIDE 15

Suppliers Declaration of Conformity: Pros, Cons, and Enforcement



Use of a Supplier's Declaration of Conformity for Product Certification

Presenter:

Tim Jeffries

Director, Administrative Council for Terminal Attachments (ACTA) &
Technology Development
Alliance for Telecommunications Industry Solutions



SLIDE 1

Supplier's Declaration of Conformity

- Supplier's Declaration of Conformity (SDoC) continue to be debated
- Varying options among:
 - ☐ Regulators
 - ☐ Providers of Service
 - ☐ Manufacturers
- Pros & Cons are transposable
- Enforcement is critical

SLIDE 2

Arguments for SDoC

- Reduce complexity & cost
- Faster time to market
- Manufacturers have a vested interest
- Marketability of brand name
- Internal technical expertise, facilities, & test equipment
- Internationally recognized (ISO/IEC Guide 22)
- Precedence set with product verification

SLIDE 3

Arguments against SDoC

- Competitive disadvantage
- Increase product testing
- Manufacturers have a vested interest
- Loss of neutrality
- Lack of accountability
- Poorly-equipped
- Incorrect interpretation of criteria
- Prone to abuse

SLIDE 4

SDoC Enforcement

- Accountability is essential
 - ☐ Identify party responsible
 - ☐ Ensure traceability
 - ☐ Detailed evidence of compliance
- Mechanisms and procedures
 - ☐ Proactive (Audits, product monitoring)
 - ☐ Reactive (Industry & public complaints)
- Enforcement of compliance
 - ☐ Must be ready to act

SLIDE 5

SDoC in Part 68

- Responsible Party must be located in the USA
- Responsible Party must:
 - ☐ Submit a copy to ACTA
 - ☐ Include a copy in package
 - ☐ Post on website
- SDoC must include:
 - ☐ Identification of Responsible Party
 - ☐ Statement of compliance
 - ☐ Date & place of issue
 - ☐ Signature, name, and function of declarer

SLIDE 6

ACTA & Part 68 Information

Internet:

www.part68.org

Email:

ACTA@atis.org

ACTA

c/o ATIS

1200 G Street, N.W., Suite 500

Washington, DC 20005

Phone: +1.202.628.6380

SLIDE 7

Supplier's Declaration of Conformity

**Consumer Product Safety
Commission**

**By
Eric Stone**

SLIDE 1

CPSC Authority

- **Rulemaking authority under**
 - Consumer Product Safety Act (CPSA)
 - Federal Hazardous Substances Act (FHSA)
 - Flammable Fabrics Act (FFA)
 - Poison Prevention Packaging Act

SLIDE 2

Common Elements

- **Authority to set standards**
- **Preference for performance requirements**
- **Rigorous cost-benefit analysis**
- **Deferral to voluntary standards where they adequately address the risk of injury.**

SLIDE 3

Common Enforcement Schemes

- **Import surveillance**
 - Seizure or denial of entry
 - U.S. Customs penalties
- **Seizure (U.S. District Court)**
- **Injunction (U.S. District Court)**
- **Civil penalties for "knowing" violations**
- **Criminal penalties**

SLIDE 4

CPSA

- **CPSA adds a Certification provision (15 U.S.C. § 2063)**
- **Manufacturer issues certificate**
 - must accompany product
 - based on a reasonable test program
 - include name of manufacturer or private labeler on certificate
 - date and place of manufacture
- **Commission may require tests**

SLIDE 5

Example: Child Resistant Cigarette Lighters 16 CFR Part 1210

- **Child testing in U.S.**
- **Submit report 30 days before import including**
 - Child test results
 - Lighter specifications
 - Where lighters manufactured
 - Prototype of product

SLIDE 6

Lighters Continued

- **Must maintain testing records**
 - child resistance
 - production
 - keep for 3 years
- **Make available within limited time**
 - CR tests in U.S.--48 hours
 - Production tests w/in 7 days

SLIDE 7

Flammable Fabrics Act 15 U.S.C. § 1197

- **Guaranty Provisions**
 - continuing guaranty on file
 - guaranty for product
- **Protect customers**
- **Backed by reasonable and representative tests**
- **Example: clothing flammability standard (16 CFR 1610)**

SLIDE 8

Clothing Standard

- **Must be issued by U.S. firm**
- **Must keep records for 3 years**
- **Must produce records upon demand or assumption made that the guaranty is false**
- **Criminal penalties for false guaranty as well as penalties for any violations of standards.**

SLIDE 9

**Supplier's Declaration of Conformity
and the Motor Vehicle Safety Act**
Conformity Assessment for a Changing
Government

Rebecca B. MacPherson, Esq.
National Highway Traffic Safety
Administration (NHTSA)
December 3, 2001

SLIDE 1

Federal Motor Vehicle Safety Act
(49 U.S.C. 30101, et seq.)

- Regulation of motor vehicles is effected through compliance with Federal Motor Vehicle Safety Standards (FMVSS)
- FMVSS must be practicable, objective, and meet the need for motor vehicle safety;
- Regulations creating or amending a FMVSS are subject to extensive public notice and comment procedures under the Administrative Procedure Act.

SLIDE 2

**Prohibition on Manufacturing, Selling, and
Importing Noncomplying Motor Vehicles
and Equipment (49 U.S.C. 30112)**

An individual (including commercial businesses) may not

- manufacture for sale,
 - sell,
 - introduce or deliver for introduction in interstate commerce,
 - or import into the United States,
- any motor vehicle (including trailers) or motor vehicle equipment manufactured on or after the date an applicable FMVSS takes effect unless the vehicle or equipment complies with the standard and is certified as complying with the standard.

SLIDE 3

Certification Requirements
(49 U.S.C. 30115; 49 CFR 567)

- U.S. employs a system of manufacturer self-certification.
- U.S. Government does not conduct testing for manufacturers or certify that a vehicle or piece of motor vehicle equipment meets all applicable FMVSS.
- Either a vehicle manufacturer or a registered importer can certify that a vehicle complies with all applicable FMVSS.

SLIDE 4

Certification Requirements (cont)

- All manufacturer certifications must be based on a good faith belief that the certification is not false or misleading in any material respect. This good faith requirement for self-certification forces manufacturers to satisfy themselves that their vehicles comply with all applicable safety standards prior to first retail sale.
- If a vehicle complies with all applicable FMVSS in effect on the date of manufacture, a certification label may be applied to the vehicle.
- All vehicles must have a certification label that is permanently affixed to the vehicle.

SLIDE 5

Manufacturer Reporting Requirements
(49 CFR 573)

- Noncompliance information report – Must be submitted to NHTSA within 5 working days of either an agency or manufacturer determination that there is a non-compliance.
- Quarterly reports – Must be submitted to NHTSA on a quarterly basis for six consecutive quarters beginning with the quarter when the recall campaign was initiated
- Lists of purchasers, owners, lessors and lessees – Must be maintained by the manufacturer in a form suitable for inspection by NHTSA.
- Notices, bulletins, and other communications – must be submitted to NHTSA.

SLIDE 6

Manufacturer Notification Requirements (49 CFR 577)

- When a manufacturer determines a vehicle fails to conform to an applicable safety standard, it must provide notification in the time and manner required by 49 CFR 577.7.
- Manufacturer may not include a disclaimer in the notification letter.
- If, based on the quarterly reports, NHTSA determines a follow-up notification is necessary, it may order the manufacturer to send a follow-up letter.

SLIDE 7

Vehicle Recalls

- All noncomplying motor vehicles or motor vehicle equipment must be recalled.
- A recall consists of two parts, notification of the noncompliance to the vehicle owner and a remedy of the defect or noncompliance.
- Majority of recalls are based on a determination by the manufacturer that a vehicle or piece of equipment does not comply with an applicable FMVSS.

SLIDE 8

Ways to Remedy a Noncompliance

- Manufacturer of a noncomplying vehicle must remedy the noncompliance at no cost to the vehicle owner unless the vehicle was purchased at least 10 years before the agency determines there is a non-compliance or the manufacturer notified NHTSA that the vehicle is noncompliant.
- The manufacturer may remedy the noncompliance by repairing the vehicle, replacing the vehicle with an identical or reasonably equivalent vehicle, or by refunding the purchase price, minus a reasonable allowance for depreciation.


SLIDE 9

Enforcement (49 U.S.C. 30165; 49 CFR 578)

- Civil penalties for failure to comply or failure to attach a certification label to a vehicle that requires such a label may be assessed for up to \$5,000 per violation, with a maximum penalty for a related series of violations of \$15 million.
- NHTSA may decrease the amount of penalty after considering the size of the affected business and the gravity of the violation.

SLIDE 10

Registration


 ISO 9001 Program Office

NASA Headquarters (HQ) ISO 9001 Registration Overview

Scott M. Holliday
Director
ISO 9001 Program Office (Code JI)
NASA HQ

December 3, 2001 1 of 5

SLIDE 1


 ISO 9001 Program Office

Background - Key Milestones

- November 1996 - NASA Administrator directs all NASA Centers **AND** HQ to be certified to ISO 9001 NLT 9/30/99
- October 1997 - NASA HQ senior management decides to register the work of NASA's Strategic Enterprises (SE) to ISO 9001, but all efforts flounder until May 1998; involves 5 offices
- May 1998 - ISO 9001 Program Office established to lead the day-to-day effort required to achieve and maintain registration
 - Plan is developed utilizing a core staff, and matrixed team of SE representatives and key "functional" staff
 - Plan calls for May, 1999 registration of SE scope
- May 1999 - NASA HQ SE's are successfully registered to ISO 9001
- June 1999 - NASA HQ senior management decides to broaden the scope of registration to all HQ offices (23 total)
- May 2000 - All offices at NASA HQ are successfully registered

December 3, 2001 2 of 5

SLIDE 2


 ISO 9001 Program Office

Why ISO 9001?

- Administrator decision, i.e., top-down direction
- "Say what you do, do what you say and prove it" was appealing and promised much needed discipline and accountability
- Expansion of NASA international partnerships, especially with Space Station - registration viewed as a tool to improve our performance and build customer and stakeholder confidence
- Widely accepted in industry
- Fully deploy recent strategic and program/project management initiatives
- Establish one Quality Management System (QMS) for HQ parts of key Agency processes
- Provide a measure of continuity and stability to HQ employees after downsizing from ~ 2,500 to 950.

December 3, 2001 3 of 5

SLIDE 3


 ISO 9001 Program Office

Benefits

- 1st question is always "what did you save?" Answer - can't tell because: 1) after downsizing from 2,500 to 950 our focus was not to cut costs, therefore didn't focus on it; 2) no baseline, i.e., we don't account for costs by process, and don't measure cost of processes now, but know we're more effective and efficient
- Reengineering - impossible to implement a QMS that conforms to ISO 9001 without undertaking some to great amount of reengineering; all key processes are much "better" than previously
- Reduced rework - minimize variability of quality of products and services through consistency and better understanding of processes
- Better control of and understanding of documentation and records results in better products and services and traceability
- Improved communication and understanding of organizational goals at all levels, and how employees fit in - focused training
- Enhanced discipline in taking corrective action by addressing root causes and verifying effectiveness vice putting band-aids on symptoms

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SLIDE 4

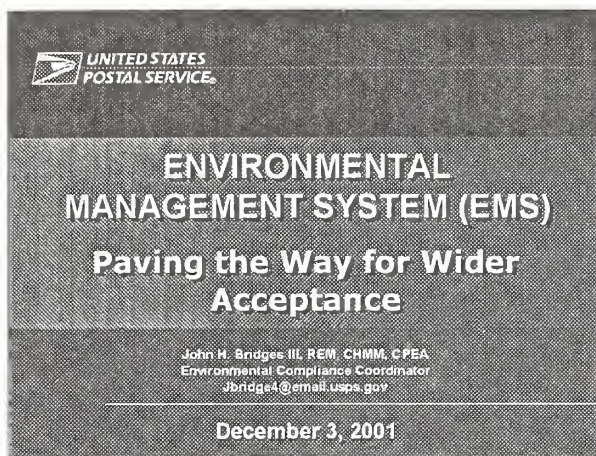
 ISO 9001 Program Office

Lessons learned

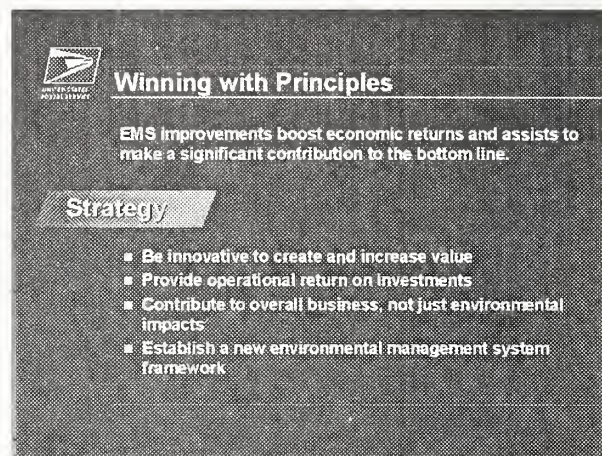
- Was it worth it? **ABSOLUTELY**
- Would we do it again? Not sure. In many cases, especially for a federal agency HQ, this is a dramatic change to the modus operandi requiring a serious commitment by top management (as opposed to trying to check the box), and lots of hard work.
- Don't focus so much on what needs to be done that you lose sight of the fact that the hardest part is not doing "the work," It's managing the change.
- See the big picture or risk suboptimizing
- Determine early on your reasons for doing, set measurable goals, take baseline measurements, and monitor
- Plan well - ambitious but achievable milestones keeping in mind:
 - being too ambitious can result in cutting some corners,
 - the work fits the time, and
 - "idle hands are the devil's workshop," i.e., it gives the "saboteurs" more time to plan and execute their strategy

December 3, 2001 5 of 5

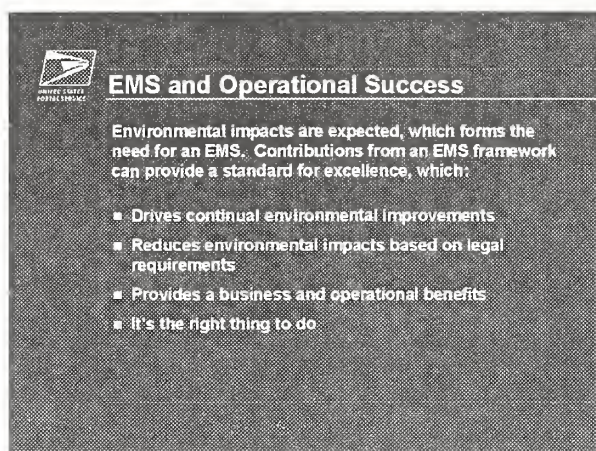
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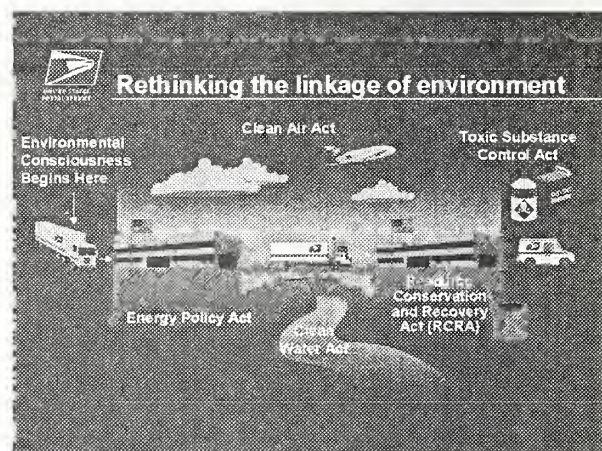
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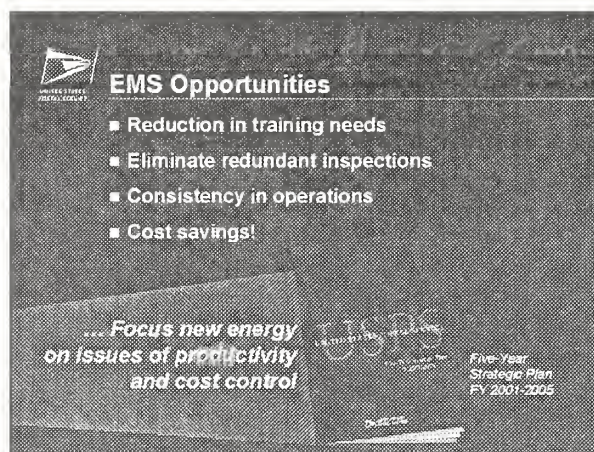
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SLIDE 3



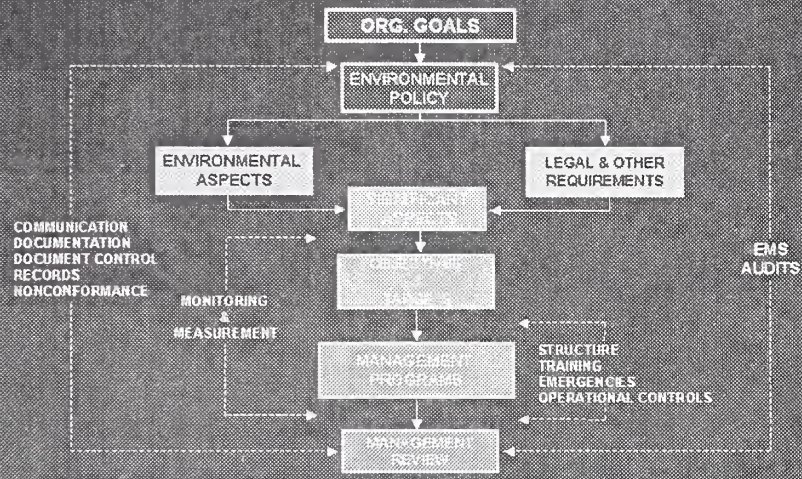
SLIDE 4



SLIDE 5



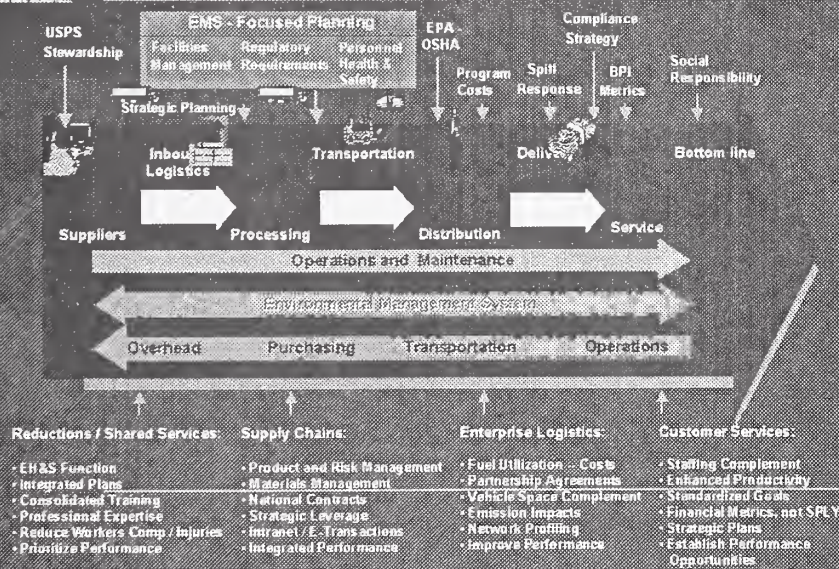
Adopt an Integrated Approach




SLIDE 6



Framework incorporation at all levels

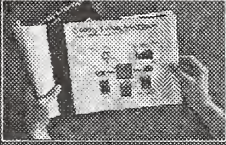


SLIDE 7


 **Lessons Learned**

Benefits

- **Environmental Management System**
 - Key processes are linked and measurable
 - Participation is critical to success
 - Shared responsibility
 - Reduction in waste streams, disposal costs and labor
 - Working towards a common goal

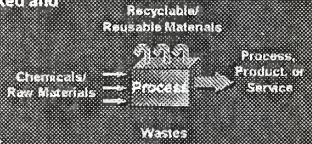


SLIDE 8


 **Managing our EMS through Stewardship**

Reflections

- **Contributions**
 - Key processes are linked and measurable
 - Participation is critical to success
 - \$200,000 cost avoidance
 - LQG to CESQG Status
 - 43 noncompliance findings to 3 minor after EMS



SLIDE 9

 **Summary**

By continuing to build on our successes and plan for the future, we will realize a "triple" bottom line that benefits:

- **Our environment**
- **Our Postal business**
- **Our customers and communities**

SLIDE 10

Mary McKiel
Director, EPA Standards Program
Environmental Protection Agency
(Presentation Material Not Available)



PART THREE

NATIONAL COOPERATION FOR LABORATORY ACCREDITATION (NACLA)

What is NACLA and What Can It Do For Your Agency?

NACLA Organization

National Cooperation for Laboratory Accreditation (NACLA)

What is NACLA and what can it do for your Agency

Don Heirman
President

December 3, 2001

NIST Workshop

SLIDE 1

NACLA purpose

Purpose of NACLA Recognition

- Offers recognition to laboratory accreditation bodies (ABs)
- Recognition creates mechanism for establishing confidence in equivalency of the operation of laboratory accreditation programs
- Following successful completion of evaluation procedure, ABs invited to sign Mutual Recognition Arrangement
- Laboratories accredited by signatory ABs considered to have demonstrated equivalent competence

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SLIDE 2

NACLA/NIST MOU

NACLA signs MOU in July 2000 which gave NACLA responsibility to recognize

Accrediting Bodies

NIST Workshop

SLIDE 3

NACLA Operation

- NACLA:
 - Coordinates and recognizes laboratory accreditation activities in the US
 - Planning to apply for national coordinating body in International Laboratory Accreditation Cooperation (ILAC) to represent US positions on ILAC accreditation matters.
 - Monitoring and emulating where applicable similar procedures for recognition used by ILAC, European Cooperation for Accreditation (EA), and Inter-American Accreditation Cooperation (IAAC), etc.
 - Is NOT another accrediting body

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SLIDE 4

NACLA Process

- NACLA recognizes competent accreditors by the following:
 - Recognition based on international quality standards (Guide 58 and Standard 17025 (Guide 25))
 - Mutual recognition arrangement among NACLA-recognized accrediting bodies

which leads to:

- Enhanced specifier choice
- Government recognition where needed

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SLIDE 5

NACLA--Government

- NACLA interfaces with regulators and government agencies:
 - Government agencies requested to agree on harmonizing common accrediting requirements and practices
 - May require special procedures, but the goal is to apply them consistently

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SLIDE 6

NACLA National Cooperation for Laboratory Accreditation

NIST Use of NACLA

- NACLA News--
- In October 2000, NIST designated 23 accredited testing labs to participate in the operational phase of the EMC sectoral annex of the US-EU MRA
- NIST established the competence of both A2LA and NVLAP (who accredited the 23 labs) on the basis of their NACLA recognition and thus designated these labs which they accredited
- Subsequent NIST designations have been made on the same basis

NIST Workshop

SLIDE 7

NACLA National Cooperation for Laboratory Accreditation

NIST Use of NACLA

- NACLA News-2000
- NIST is also relying on NACLA recognition as basis for designating test labs for Phase I of the APEC Telecommunication Equipment MRA
- Burden on NIST staff to verify technical competence of testing Taiwanese, Singapore, and Canadian testing labs designated by NIST has been significantly reduced by the NACLA recognition process!

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SLIDE 8

NACLA National Cooperation for Laboratory Accreditation

NIST NACLA citations

- NACLA News
- NIST published in August 2000 the final Guidance on Federal Conformity Assessment Activities in the Federal Register
- Section 287.4 (Responsibilities of Federal Agencies) directs agencies to identify appropriate private sector CA practices.
- Section 287.4g directs agencies to participate in efforts to improve government and private sector CA activities and makes specific reference to NACLA.

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SLIDE 9

NACLA National Cooperation for Laboratory Accreditation

NACLA This Year

NACLA 2001 activity:

- * Bilateral agreement signed with Standards Council of Canada
- * North American Calibration Committee MOU formed with Mexico, Canada and US (NACLA)
- * Stakeholder member of International Laboratory Accreditation Cooperation (ILAC) --recognition follows that of ILAC
- * Participating in ILAC Laboratory Liaison Committee
- * Considering formal linkage with the Inter-America Accreditation Cooperation

NIST Workshop

SLIDE 10

NACLA National Cooperation for Laboratory Accreditation

NACLA AB Action

NACLA 2001 activity:

- * Presently 8 Accrediting Bodies in queue
- * Department of Energy requires NACLA recognition of ABs used for DOE calibration labs which are accredited

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SLIDE 11

NACLA National Cooperation for Laboratory Accreditation

NACLA Business Plan

Though much has been accomplished, there are immediate concerns:

- Meet client needs
- Grow the membership
- Obtain financial independence as a 501(c)(6) not-for-profit organization

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SLIDE 12

In summary, NIST-recognition will help achieve
NACLA (and its customer's) goals:

* worldwide (as well as specific sector)
recognition of accreditations

* one test/calibration done once accepted
worldwide and sectorily

VISIT OUR WEBSITE: www.nacla.net

NIST Workshop

SLIDE 13

NIST-NACLA MOU

Mary Saunders
Director
Office of Standards Services

Workshop on Conformity Assessment for a
Changing Government
December 3, 2001

SLIDE 1

Outline

- NIST-NACLA Approach
- Purpose
- NIST's Mandate
- NACLA Responsibilities
- NIST Responsibilities
- Progress to Date
- Summary

SLIDE 2

NIST-NACLA Approach

Work together to develop and maintain a
system in the U.S. that will

- recognize laboratory accreditation bodies to accredit testing and calibration laboratories to meet the procurement and other requirements of the public and private sectors
- promote the use of such accreditation bodies
- recognize laboratory accreditation bodies to accredit testing and calibration laboratories to carry out specific activities under government-to-government trade agreements

SLIDE 3

Purpose

- Eliminate unnecessary duplication and complexity in laboratory accreditation requirements
- Support government-to-government trade agreements
- Improve communications within and between the public and private sectors on laboratory accreditation requirements and practices

SLIDE 4

NIST's Mandate

NIST's mandate under the National Technology Transfer and Advancement Act (NTTAA) of 1995 and OMB Circular A-119 is to

- coordinate Federal, State, and local conformity assessment activities with those of the private-sector to eliminate unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures
- rely on the private sector as much as possible

SLIDE 5

NACLA Responsibilities

- Recognize laboratory accreditation bodies as being generally competent
- Encourage the private sector to specify the use NACLA-recognized laboratory accreditation bodies
- Encourage laboratory accreditation bodies to seek NACLA recognition
- Assess the competence of laboratory accreditation bodies to accredit laboratories to meet the specific technical requirements of selected trade agreements

SLIDE 6

NIST Responsibilities

- Verify conformance of NACLA recognition of laboratory accreditation bodies to the MOU
- Encourage government at all levels to use NACLA-recognized accreditation bodies, taking into account agency-unique requirements
- Encourage laboratory accreditation bodies to seek NACLA recognition
- Designate testing and calibration laboratories accredited by NACLA-recognized accreditation bodies as Conformity Assessment Bodies under selected trade agreements

SLIDE 7

Progress to Date

- NIST has designated two NACLA-recognized accreditation bodies as competent to accredit testing laboratories to EU and APEC economy standards and regulatory requirements - supporting trade agreements
- NIST designations based on these accreditations:
 - 28 CABS under US-EU EMC sectoral annex
 - 11 CABS under US-EU telecom sectoral annex
 - APEC: Canada-20, Chinese Taipei-75, Singapore-6

SLIDE 8

Progress to Date


- The Interagency Committee on Standards Policy has formed a working group on conformity assessment
 - to advise ICSP on effective means of coordinating agency laboratory accreditation activities with those of the private sector
 - recommend practical ways to eliminate unnecessary duplication and complexity in development and promulgation of laboratory accreditation requirements at the federal level
 - Use of the NACLA recognition process is a primary focus

SLIDE 9

Summary

- The NIST-NACLA MOU will
 - help eliminate unnecessary duplication and complexity in laboratory accreditation requirements in the U.S.
 - help NIST meet its obligations under the NTTAA and OMB Circular A-119
 - help NIST meet its obligations as a designating authority under selected trade agreements
 - *all while relying on the private sector to the maximum extent possible*
- The MOU has the full support of NIST management

SLIDE 10




Use of Commercial Calibration Labs. In the DOE Nuclear Weapons Complex


Richard B. Pettit
Primary Standards Laboratory
Sandia National Laboratories
Albuquerque, New Mexico

Conformity Assessment for a Changing Government
December 3, 2001

Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company, for the United States Department of Energy under contract DE-AC04-94AL95000




SLIDE 1



OUTLINE

1. Describe Current Review/Approval Process
2. Requirements for Using Accredited Commercial Calibration Labs.
3. Develop Confidence in NACLA
4. Benefits



SLIDE 2




DOE/AL Nuclear Weapons Complex

- Eight Laboratories Throughout the U.S.
- Primary Standards Laboratory (Sandia)
 - Ensure all facilities follow same calibration program standard
 - Certify Reference Standards
 - Develop Needed Measurement Techniques
- Quality Standard: ANSI/NCSL Z540-1 1994
 - Transition to new ISO/IEC 17025 1999




SLIDE 3




Current DOE Review and Approval Process

- Identify DOE Technical Requirements
- Complete Technical Survey by Metrology Staff
- Include Proficiency Testing
- Approve for Specific Scope
- Periodically Report all Approved Calibration Labs. to Sandia
- DOE Process Essentially Identical to Accreditation Process




SLIDE 4



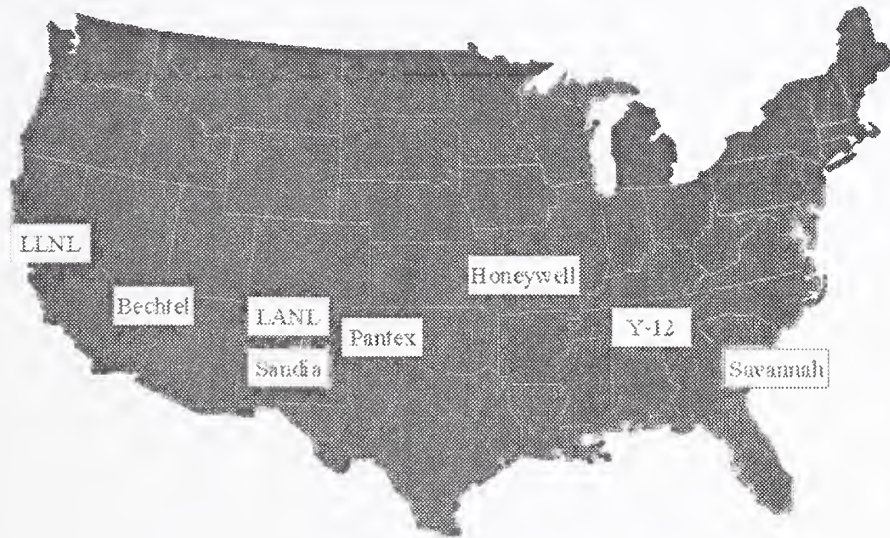
New DOE Approval Process

- Identify DOE Technical Requirements
- If Commercial Lab. is Accredited, Accept Without Oversight IF:
 - Accreditation Body is Recognized by NACLA
 - Scope of Accreditation Covers Tech. Requirements
- Reserve Right for Technical Survey IF:
 - Calibrations are State-of-the-Art; or
 - Support Critical DOE Requirement
- If all Technical Requirements NOT Covered:
 - Limit Technical Survey to only those areas



SLIDE 5

Participating DOE Laboratories



SLIDE 6

Confidence in NACLA

- Participate in Process
 - Member of NACLA Board of Directors
 - Team Member during NACLA Assessment of Accreditation Body
 - Member of NACLA Working Committees
 - Proficiency Test
 - Quality Committee
 - Seven DOE Labs. Members of NACLA
 - Become NACLA Team Member as "Observer"



SLIDE 7

Benefits of New Process

- DOE Technical Survey Time/Cost
 - 2-3 Days of Technical Staff Time
 - \$5-10K Each Survey
 - Currently 40 Commercial Calibration Labs.
- Commercial Calibration Labs. Reduce External Surveys
- Accreditation Recognized Internationally
- Uniformity of Quality & Technical Requirements



SLIDE 8

Closing Remarks

Closing Remarks

Belinda Collins

Deputy Director, Technology Services, NIST

It is now my pleasure to conclude today's meeting. During the first seven sessions, we heard an in-depth review of the National Technology Transfer and Advancement Act and what it means for Federal Agencies. We also learned about the Conformity Assessment Guidance that NIST issued in 2000, as well as some opportunities for Federal Agencies to collaborate more on conformity assessment requirements. The results of these efforts will enable us to meet the NTTAA responsibilities assigned to Federal Agencies; namely, to reduce redundancy and duplication while ensuring conformance to a standard or regulation.

The four panel sessions gave us a flavor of the complexity of the U.S. conformity assessment system and how it got that way. We heard about the wide variety of approaches used by the government, used by the private sector for itself, and used by the private sector to support the government, in many combinations. Throughout the discussions, speakers stressed the importance of having confidence in the process, that the results must be believable, and that a system should be in place to ensure that results will be reliable from one time to the next.

We heard quite a bit about certification of both products and systems. We also received a very good introduction to what we have called self-certification—since that's the term that the U.S. Congress uses. We learned about the power of recall, and about the underpinnings for the whole process of manufacturer's self declaration of conformity (SDOC), or "self-certification." We also received excellent information about testing and inspection, and descriptions of good case studies on the federal use of both quality management systems and environmental management systems. Speakers provided excellent examples that showed how the government could actually save money and improve its processes at the same time.

The last session summarized activities in the field of laboratory accreditation. The speakers emphasized that working together to build and maintain a national infrastructure, such as that provided by the National Cooperation for Laboratory Accreditation (NACLA), will result in the saving of time and money for a Federal Agency, and reduce the burdens of redundant evaluations on laboratories.

Many of the speakers offered specific recommendations, such as the need to coordinate Federal conformity assessment activities; the importance of reciprocity and acceptance of certifications, accreditations, and even data at times; the need for common accreditation schemes; the importance of training; and the need for better collaboration among third parties, government, and industry. The various talks about NACLA were a good example of how that process might work. Speakers also stressed the importance of education regarding standards and conformity assessment for Government agencies and for their collaborators in the private sector. They also reiterated the need for government to recognize the competence of laboratories accredited to international standards and the need for continued cooperation.

All the talks provided a very good flavor of the NTTAA and the importance of using consensus standards developed by the private sector. Time and time again, speakers mentioned the importance of using the international standards for laboratory accreditation, quality system management, and environmental system management. These exemplify the use of private sector standards, as urged by the NTTAA, to support conformity assessment processes.

Today's discussions referred to the possibility of using new building technology through agreements on conformity assessment. We were challenged by the fascinating discussion of some of the pros and cons of SDOC, and the importance of voluntary industry efforts to meet Federal requirements for conformity assessment.

I actually noted so many ideas that I could continue listing them for another hour, but I won't bore you with any more. NIST was challenged to return to these topics later, and review the lessons we learned to define opportunities for the ICSP to coordinate Federal efforts in conformity assessment. As a result of today's session, we now have a really good idea of the complexity of the system. One challenge is to reduce this complexity by starting to share more information, then look for opportunities to collaborate at the Federal level, and perhaps with the state and local level. Meeting the challenges for collaboration will be a major ICSP activity during 2002. I encourage all of you, Federal agencies in particular, to consider ideas from the private sector as well.

ClosingRemarks

Belinda Collins

(continued)

Mary Saunders mentioned the subcommittee on conformity assessment of the ICSP, which she chairs. I'd like to drum up membership in that while I have the microphone. Only by active participation from, and cooperation by, Federal agencies can we ensure that the processes for conformity assessment are as effective as they can be to meet the needs of the United States.

In summary, I thank all the speakers who gave their valuable time to come and talk to us today. I'd also like to thank the audience for staying to the bitter end.

Finally, I want to acknowledge and thank one particular person, Mary Jo DiBernardo, who played a major role in organizing the agenda, identifying and scheduling speakers, and then making sure that they understood the purpose of the program and submitted their talks on time. I'd also like to recognize Mary Saunders, Kevin McIntyre, Walter Light, and all the other OSS staff who worked so hard to make this workshop a success.

Thank you all very much.

Appendices

I. BIOGRAPHIES

GORDON E. BELLEN

Mr. Bellen is Vice President of Federal Programs at NSF International. In his current position he is responsible for government relations at the federal level and management of several Government sponsored environmental technology projects.

Mr. Bellen is a lifetime honorary member of the American Chemical Society's (ACS) Division of Environmental Chemistry. He Chaired the Division for two years (94-95) and has received its Distinguished Service Award. He also was chosen to Chair the Society's Committee on Environmental Improvement (91-93). Mr. Bellen was also Chair of the Environmental Labeling Delegation for the ISO 14000 series of standards.

Mr. Bellen has a B.S. in Chemistry and M.S. in Water Resources Science from the University of Michigan. He is an Adjunct Faculty Member at the University of Michigan School of Public Health.

Mr. Bellen is a retired Army officer with 23 years of service in Army aviation including active duty and the National Guard.

ROBERTA E. BREDEN

Roberta Breden is Director, Technical Regulatory Affairs, for the Telecommunications Industry Association (TIA). She is responsible for the Fiber Optics and User Premises Equipment Divisions, and coordinates the activities of these Divisions and their Sections in matters of regulatory and technical issues of concern to Association members. In addition, she is the Association's lead for conformity assessment issues.

Ms. Breden also represents the Association in many international regulatory, standards, and consumer issues. She participates on the American National Standards Institute Executive Standards Council, Consumer Interest Council, and the Board Committee on Conformity Assessment. At the end of 2000, she was appointed as a member of the United States National Committee/International Electrotechnical Commission (USNC/IEC) Council after its internal reorganization that year. Ms. Breden is also a member of the International Electrotechnical Commission (IEC) Sector Board 4 and participates the IEC World Wide System for Certification and Testing of Electrical Equipment (IECEE). She has participated as a member of the International Organization for Standardization Consumer Policy Committee (ISO COPOLCO) Working Group on a joint agreement between ISO and IEC on consumer participation in voluntary industry standards development.

On the constantly changing regulatory front, Ms. Breden was one of the telecommunications industry representatives working with the FCC on the streamlining and eventual privatization of the Part 68 consumer premises equipment (CPE) registration process and the regulatory transition of terminal attachment in the United States. She now represents TIA as one of the sponsors of the recently formed Administrative Council for Terminal Attachments (ACTA), the organization created to adopt technical criteria and to act as the clearing-house, publishing technical criteria for terminal equipment developed by ANSI-accredited standards development organizations; and to establish and maintain a registration database of equipment approved as compliant with the technical criteria.

Ms. Breden reports directly to Grant Seiffert, TIA's Vice President, External Affairs and Global Policy. Before joining TIA in 1994, Ms. Breden was a Systems Engineer and Task Leader with Titan Systems for tasks in support of the Federal Emergency Management Agency. She was actively involved in analyzing a variety of wireless telecommunications products and systems. From 1972 to 1992, Ms. Breden held various positions, both technical and administrative, with the United States Marine Corps. She retired in 1992 as a Captain, with prior enlisted experience.

Ms. Breden holds a Bachelor of Science degree in Electrical Engineering from Purdue University and a Master of Science in Systems Management from the University of Southern California.

MAUREEN BREITENBERG

Ms. Breitenberg is a senior economist with NIST and holds a B.S. in Mathematics and an M.B.A. in operations research from the University of Maryland. Her prior employment experience includes positions with the General Accounting Office and the Food and Drug Administration and the Indian Health Service within the Department of Health and Human Services (HHS).

She is currently responsible for providing technical advice and assistance on standards, conformity assessment and other trade-related matters to other government agencies, foreign government bodies, and private industry. She is the author of a number of reports on subjects related to standardization and conformity assessment. Her publications include two widely distributed reports on the ISO 9000 Standards Series; primers on U.S. standardization, certification, conformity assessment, and laboratory accreditation activities; and directories of European regional and international/regional standards related organizations, U.S. private sector and government certification programs, and federal government laboratory accreditation/designation programs.

Ms. Breitenberg is a winner of the Department of Commerce Bronze Medal and Vice President Gore's National Performance Review award.

JOHN H. BRIDGES III

John H. Bridges III is an Environmental Compliance Coordinator for the U.S. Postal Service and has responsibility for furthering postal manager's efforts to achieve environmental excellence as an integral part of overall business excellence. In addition, he has recently assumed responsibility for corporate positioning of USPS Environmental Management System efforts. He joined the Postal Service in 1996, after retiring from the U.S. Marine Corps. Over the past 25 years, he has held professional and leadership positions in environmental, health and safety (EHS) planning, operational integration, and sustainable development. John served for three years on the President's Council on Sustainable Development, Environmental Management Task Force, as well as the American Society for Testing and Materials (ASTM) E-50 Committee on Environmental Assessments. Most recently, Mr. Bridges was appointed to the American Society of Safety Engineers (ASSE) Z490 Committee developing Standard Guidelines for Safety, Health, and Environmental Training.

Mr. Bridges serves on the Chairman's Advisory Group for the U.S. Technical Advisory Group of ISO 14000, as well as a technical advisor on ISO 14001 for Environmental Management Systems. He holds a BS in Occupational Safety, is a graduate of the Marine Corps Command and Staff College and the Corporate Environmental Leadership Program from Yale University. In 1999, he received the Environmental Manager of the Year Award, by the National Association for Environmental Management and the Outstanding Service Award 2000 from the National Registry of Environmental Professionals. Most recently, his EMS facilitation was recognized as one of the 2001 White House Closing the Circle Awards winners.

KAREN H. BROWN

Karen H. Brown is the National Institute of Standards and Technology's Acting Director and Deputy Director. As a non-regulatory agency of the U.S. Department of Commerce's Technology Administration, NIST's mission is to strengthen the U.S. economy and improve the quality of life by working with industry to develop and apply technology, measurements, and standards through a portfolio of four major programs: the NIST Laboratories, the Baldrige National Quality Program, the Manufacturing Extension Partnership, and the Advanced Technology Program. Brown oversees an \$800M annual operating budget and 3,300 on-site staff complemented by 2,000 manufacturing and business specialists serving smaller manufacturers around the country. Brown came to NIST as deputy director in January 1999. Previously she was a Distinguished Engineer at IBM Microelectronics in Hopewell Junction, N.Y. Brown also served (on assignment from IBM) as director of lithography for SEMATECH from 1994-1998. Brown's 22-year career at IBM concentrated on solving problems in semiconductor lithography and microelectronics. She has a proven track record in management, having successfully met the challenges of moving ideas from the laboratory into manufacturing. Brown also has a keen awareness of the impact of national and international standards on U.S. industry and the economy, having held a variety of standards leadership positions in Semiconductor Equipment and Materials International and helping to bring a semiconductor fabrication line on-board in France.

A native of Schenectady, N.Y., Brown holds a B.A. in chemistry and in history, and a Ph.D. in chemistry from the University of Rochester.

BELINDA L. COLLINS

Belinda L. Collins is the Acting Deputy Director of the NIST Technology Services, which provides U.S. industry, government, and the public with measurements, standards, and knowledge resources and services from NIST that promote innovation, increase competitiveness, and facilitate trade. It also provides policy support for standards and conformity assessment activities for Federal agencies. Dr. Collins chairs the federal Interagency Committee on Standards Policy (ICSP), serves on the ANSI Board of Directors, representing the NIST Director, and is the immediate past chair of the International Laboratory Accreditation Cooperation (ILAC) and a past chair of the National Cooperation for Laboratory Accreditation (NACLA).

Dr. Collins received her M.A. and Ph.D. in experimental psychology (visual psychophysics) from the University of Virginia, and her B.A. in experimental psychology from Mary Washington College. While at NIST, she has served in several different positions, including research psychologist, Leader of the Lighting Group, Program Analyst in the Office of the NIST Director, Director of the Office of Standards Services, and now Acting Deputy Director, Technology Services. Dr. Collins has authored numerous technical publications and has been active in both domestic and international standardization, chairing several different technical committees.

Dr. Collins is a Fellow of the Illumination Engineering Society of North America (IESNA) and served as its Vice President for Education (1995-1997). Dr. Collins received the NIST Bronze Medal in 1984, a Meritorious Service Award from the American National Standards Institute, along with a Public Service Award from ACIL in 1997, the NACLA Lifetime Achievement award and the NIST Edward Bennett Rosa Award in 2000, and the Department of Commerce Silver Medal in 2001.

JOSEPH R. DUNBECK

Joseph R. Dunbeck is the first Chief Executive Officer of the Registrar Accreditation Board (RAB) in Milwaukee, WI. As CEO, Dunbeck directs the not-for-profit organization's ISO 9000 quality management systems and ISO 14000 environmental management systems programs for auditors, course providers, and registrars.

RAB, through a joint agreement with ANSI, manages the National Accreditation Program for accrediting registrars and course providers for Quality Management Systems (QMS) and Environmental Management Systems (EMS). RAB directly operates the QMS and EMS auditor certification program.

Before joining RAB in 1995, Dunbeck served as president of EKCO Housewares, Inc., Ingrid Housewares, Inc., and Bruning Paint Company. He began his career in sales and marketing positions for Kaiser Aluminum & Chemical Corporation, Maremont Corporation, and Cragar Industries.

Dunbeck holds a B. A. degree in economics from Lawrence University in Appleton, WI and an M.B.A. in marketing from Northwestern University in Evanston, IL.

SI FARVARDIN

Mr. Farvardin is Program Manager for the National Evaluation Service, Inc. He holds a Bachelor of Science Degree in Civil Engineering from the University of Louisville, and an Engineering Intern Certification (EIT). He has over 16 years of experience in building codes and standards, building inspections, design review, and materials and methods in building construction. His current technical work involves managing National Evaluation Service review and approval of emerging building technologies/products for industry manufactures. He manages the multi-year contract with the United States Department of Housing and Urban Development (HUD) for their Technical Suitability of Products Program (TSPP) as well. In the past, he served as a local building official in Anne Arundel County, Maryland, and Fairfax County, Virginia, as well as Project Engineer for the National Conference of States on Building Codes and Standards.

GORDON GILLERMAN

Mr. Gillerman works with government agencies and trade associations on domestic and global safety, conformity assessment and trade issues in Underwriters Laboratories' Washington, DC Office.

His experience includes: interfaces with elected officials, government agencies such as USTR, DOC, OSHA, FDA, FCC and CPSC, as well as trade associations concerning issues related to health, safety, protection of property, conformity assessment and trade.

Mr. Gillerman's technical expertise includes medical equipment, information technology equipment and power supplies. He has certified products to U.S., Canadian, European and other international standards and is an FDA 510(k) third party reviewer. He is a member of the IEC 62A, WG 18 for fire and thermal hazards in electromedical equipment and a central reviewer for IEC 60601 CB Scheme reports. He is also an expert on EU Directives for Medical Devices, Safety of Low Voltage Equipment, Machinery, and EMC.

He has conducted presentations on safety, conformity assessment and trade issues for domestic and foreign government and industry groups and has developed and conducted two-day open and in-house seminars on harmonized safety standards for electromedical equipment, IEC 60601 and information technology including telecommunications equipment. These seminars continue to be the primary source of training for regulatory compliance in both industries and their regulators.

He holds a BSEET from Bradley University in Illinois.

GEORGIA HARRIS

Georgia Harris is a Physical Scientist with the NIST Office of Weights and Measures (OWM). As manager of the OWM Laboratory Metrology Program, Georgia is responsible for the NIST recognition of the State weights and measures laboratories and the ongoing training and evaluation of metrologists in 55 laboratories. She coordinates numerous activities, such as round robins, regional measurement assurance groups, and the development and updating of technical handbooks with cooperative and voluntary efforts of State and industry metrologists through NIST working groups.

She has been active in NCSL functions since 1985 when she first attended a Twin Cities section meeting (St. Paul, MN). She has given presentations at both local and national meetings. She served as the Section Coordinator for the Twin Cities Section of NCSL in 1988 and 1989. Since 1991, she has functioned as liaison to the NCSL Board of Directors for the National Conference on Weights and Measures. She was a VP on the NCSL Board of Directors for the Eastern Division and the Measurement Science and Technology from 1994 through 1997. In 2001, she returned to the Board of Directors for NCSLI as the VP for Publications. She has spoken at numerous NCSL sectional and national meetings.

JOSEPH HAZELTINE

Joseph Hazeltine, PE, is a Senior Division Director at Wyle Laboratories Huntsville, Alabama test facility. He has been with Wyle Laboratories for over 20 years after serving in the U.S. Navy's Nuclear Submarine Force. Mr. Hazeltine has extensive testing experience and is in charge of all conformity assessment activities in the laboratory. Mr. Hazeltine graduated from Marquette University with a BSEE degree and Florida Institute of Technology with a MBA degree. He is a registered professional engineer and a member of many professional and engineering organizations.

DONALD N. HEIRMAN

Donald Heirman is President of Don HEIRMAN Consultants, a training and educational EMC consultation corporation. Previously he was with Bell Laboratories for over 30 years in many EMC roles including Manager of Lucent Technologies (Bell Labs) Global Product Compliance Laboratory where he was in charge of the Corporation's major EMC and regulatory test facility. He chairs, or is a principal contributor to, national and international EMC standards organizations including ANSI ASC C63 and the International Special Committee on Radio Interference (CISPR) that develop new emission and immunity instrumentation specifications and measurement techniques. Mr. Heirman is a Fellow of the IEEE, a member of its EMC Society Board of Directors (and its Vice President for Standards), chairs the Society's Electromagnetic Compatibility Measurement Committee, and has authored and presented internationally numerous papers, tutorials, and seminars/workshops on EMC subjects. He is also the chair of the IEEE Standards Association Standards Board and is President of the National Cooperation for Laboratory Accreditation (NACLA). He chairs the American National Standards Institute Accredited Standards Committee C63, Subcommittee One on EMC Techniques and Developments, which prepares guidelines or standards for EMC measurements, test site qualifications, antenna calibrations, automated measurements, and emission and immunity limit setting. Mr. Heirman is a technical expert for CISPR Subcommittees A (Radio Interference Measurements and Statistical Techniques) and I (Information Technology, Multimedia, and Receiver Equipment). He is also the Subcommittee A chairman and chairman of its Working Group 1 responsible for CISPR 16 Part 1 on EMC measurement instrumentation. He is also group manager for electromagnetics for the U.S. National Committee Executive Committee (now called the Technical Management Committee) for the IEC (International Electrotechnical Commission) responsible for facilitating the CISPR and TC77 (immunity) U.S. participation and Chair of its Coordinating Committee on EMC. Mr. Heirman is also an adjunct professor/senior research scientist at the University of Oklahoma and is the Associate Director for Wireless EMC at the University's Center for the Study of Wireless EMC. He is a retired Commander in the U.S. Navy Reserves and he is listed in multiple Who's Who publications.

SCOTT HOLLIDAY

Scott has worked for the National Aeronautics and Space Administration (NASA) Headquarters in Washington, DC since November 1991. He is currently the Director of the ISO 9001 Program Office. Over the past 3 years Scott led the day-to-day implementation of a Quality Management System (QMS) that conforms to the ISO 9001 quality standard at NASA Headquarters, to include third party certification of Headquarters compliance. Headquarters was initially certified to the ISO 9001 standard for Strategic Enterprise Management in May 1999. The certification was then expanded to all Headquarters offices in May 2000. For his efforts Scott was awarded the Aero-Space Technology Enterprise Award and NASA Headquarters Exceptional Performance Award. In October 2000, Scott's role was expanded to provide NASA-wide functional leadership for ISO 9001-based QMS's.

In his previous position with NASA Headquarters, Scott worked as a senior engineer responsible for leading NASA-wide facilities maintenance and management efforts. Major functions included leading NASA-wide benchmarking efforts, leading the NASA-wide conversion to Reliability Centered Maintenance; leading the effort to convert cost reimbursement, level of effort facilities maintenance contracts to fixed price performance based contracts; and providing strategic insight as a member of NASA's Strategic Management Working Group, responsible for coordinating all NASA-wide strategic management efforts. For his efforts, Scott received NASA's Outstanding Leadership Medal in June 1998, the Office of Safety and Mission Assurance's NASA-wide QASAR Award in October 1997, and two NASA Group Achievement Awards for the NASA Strategic Management Handbook and National Facilities Study in 1997 and 1994 respectively. Scott also accepted one of the Association for Facilities Engineering's highest awards for international Facilities Management Excellence (FAME) in October 1997 for his efforts as leader of the NASA-wide Corporate Maintenance Leadership Team.

Scott began his career in 1983 with the Navy in Philadelphia providing consulting services related to Public Works management to Navy bases in a 24 state area. His duties also included teaching various adult education classes. From 1989 until joining NASA in 1991, Scott worked for Naval Facilities Engineering Command (NAVFAC) Headquarters in Alexandria, VA where he was the Navy-wide Program Manager for Facility Support Contracts and facilities operations and maintenance outsourcing. His duties also included teaching advanced contract management. He was promoted to the Industrial Engineering Branch Head at NAVFAC Headquarters in May 1990 where he was responsible for Navy-wide facilities maintenance and management policy and programs.

Scott received a Bachelor of Science in Industrial and Management Systems Engineering from Pennsylvania State University in 1983. He currently resides in Lorton, Virginia with his wife Elizabeth and 2 daughters, Michaela and Caitlin.

WILLIAM S. HURST

William (Bill) Hurst is an Electrical Engineer for the Policy and Rules Division, Office of Engineering and Technology of the Federal Communications Commission, where he represents the FCC on national and international committees. He is responsible for the FCC's implementation of Mutual Recognition Agreements (MRAs) and coordinates with other government agencies and groups concerned with equipment authorization policy and rules.

Mr. Hurst spent 25 years in the private sector where he managed a telecommunications, EMC and product safety testing laboratory and certification body. He has authored and presented numerous papers and has actively participated in many industry organizations with regards to telecommunications, laboratory accreditation, EMC standards, and equipment authorization.

Mr. Hurst has been involved in Mutual Recognition Agreement (MRA) negotiations between the United States Government and the European Union, Asian Pacific Economic Cooperation (APEC) and the Inter-American Telecommunication Commission (CITEL).

TIM JEFFRIES

Mr. Tim Jeffries is the Director of the Administrative Council of Terminal Attachments, or ACTA, the newly formed industry council for FCC Part 68 certification, and Technology Development for the Alliance for Telecommunications Industry Solution (ATIS).

As the director of ACTA, Tim's primary responsibility is to carry out the directives of the Council, including the management of its activities and oversight of all Secretariat duties. Tim also provides ongoing support, guidance, and advice to the Council in the development, implementation, and achievement of its strategic objectives.

Tim joined ATIS' management staff after serving the Cellular Telecommunications & Internet Association (CTIA) as its Director of Certification Programs. At CTIA, Tim was responsible for all aspects of the wireless industry's product certification program; including its redesign to streamline the industry's product testing and approval processes.

The Alliance for Telecommunications Industry Solutions (ATIS) is a member company organization that is the leader for standards and operating procedures for the telecommunications industry. More than 1,500 experts from over 400 telecommunications companies participate in ATIS' 19 committees, forums, and Incubator Solutions programs.

RICHARD F. KAYSER

Dr. Kayser received a Sc.B. in physical chemistry from Brown University in June 1973 and a Ph.D. in physical chemistry from Rice University in May 1976. He moved to the National Bureau of Standards (now the National Institute of Standards and Technology) in May 1976 as a National Science Foundation Postdoctoral Fellow and joined the Thermophysics Division as a permanent staff member one year later.

Over the next ten years, Dr. Kayser performed research on a wide variety of theoretical and experimental topics, ranging from phase transitions to wetting phenomena. During that time, he published approximately 40 papers in the peer-reviewed archival literature.

Dr. Kayser became Chief of the Thermophysics Division in May 1989 and Chief of the Physical and Chemical Properties Division in May 1996. In these positions, he was responsible for NIST's programs on the thermophysical and thermochemical properties of gases, liquids, and solids; the rates and mechanisms of chemical reactions in the gas and liquid phases; process separations and low-temperature refrigeration, heat transfer, and flow; and pressure, vacuum, and low-flow-rate measurements and standards, including the U.S. national standards in those areas.

Dr. Kayser assumed the position of Director of Technology Services in August 1999. Among its activities, Technology Services supports the NIST Measurement and Standards Laboratories in the provision of calibrations, Standard Reference Materials, and Standard Reference Data; promotes accuracy and uniformity throughout the States in weights and measures; conducts the National Voluntary Laboratory Accreditation Program; and facilitates trade by promoting the efficient development and use of U.S. standards and technology and by reducing technical barriers to trade.

REBECCA B. MACPHERSON

A graduate of Tulane University School of Law, Ms. MacPherson has worked at the National Highway Traffic Safety Administration (NHTSA) as a rulemaking attorney for five years. She had previously worked as a litigation attorney for the U.S. Maritime Administration. During her tenure at NHTSA, Ms. MacPherson has worked on regulations addressing a variety of safety-related issues.

These projects include a new, comprehensive regulation on advanced air bags, regulations creating exemptions from the statutory prohibition against making mandated motor vehicle safety equipment inoperative, and certification of vehicles manufactured in two or more stages. Ms. MacPherson has also worked in the international sphere, assisting in the development of a U.N. agreement on the development of global technical regulations and representing NHTSA before governmental and private entities from Korea, Japan, China, and Mexico.

KEVIN L. MCINTYRE

Mr. McIntyre is a Senior Standards Specialist in NIST's Office of Standards Services. He is responsible for furthering NIST's progress in implementing Public Law 104-113, the National Technology Transfer and Advancement Act of 1995. Mr. McIntyre also serves as Secretary to the Interagency Committee on Standards Policy.

Prior to joining NIST in 1993, Mr. McIntyre worked in private industry in several capacities including manufacturing engineering, engineering management and new business development. While at NIST, Mr. McIntyre worked in the Manufacturing Extension Partnership Program, serving as a Regional Account Manager and Group Leader before joining the Office of Standards Services in June 2000. Mr. McIntyre holds a B.Sc. in Mechanical Engineering from the University of Maryland and an MBA from George Washington University. In 1996, Mr. McIntyre was awarded the Department of Commerce Bronze Medal Award for Superior Federal Service.

MARY C. MCKIEL

Dr. McKiel began her Federal career in 1976 as an analytical chemist at the *National Archives and Records Service* (now an independent Administration). There, she developed chemical methods for restoring and preserving textual and non-textual materials. As a member of the U.S. Group to ISO Technical Committee (6) on Paper, she participated in developing international standards for archival quality paper.

From 1982 to 1993, Mary served in several capacities at the *Federal Supply Service of the General Services Administration*: Chief of Engineering and Standards Policy, Director of Quality Standards, and Director of Environmental Planning. At GSA, among other achievements Mary instituted and managed quality control and assurance programs for the Service, and developed and published GSA's first "green" catalog. She earned several Outstanding Service awards and medals while at GSA.

In 1993, she joined the *Environmental Protection Agency* in the Office of Prevention, Pesticides and Toxic Substances. With the approval of EPA's Administrator, she initiated and managed the EPA's first cross-office program for voluntary standards. As Director of the EPA Standards Network, she coordinated Agency use of non-government standards and managed EPA's participation in the U.S. Technical Advisory Group (TAG) for the development of the ISO 14000 standards for Environmental Management. She was elected Vice Chair of the U.S. TAG and continues to serve in that capacity.

In 1998, Mary was appointed by to the position of EPA Standards Executive. As such, her role is Agency-wide in responsibility and includes implementing the National Technology Transfer and Advancement Act and OMB Circular A-119 throughout EPA. She heads up the Agency's Standards Program and represents the Agency on the Interagency Committee for Standards Policy. Mary represents EPA standards policies in national, regional and international standards-related fora, the International Organization for Standardization (ISO), the Pacific Area Standards Congress (PASC) and the South American Congress for Norms and Technical Standards (COPANT). She has earned the 1998 EPA Administrator's Silver Medal for Excellence in Service, as well as Silver and Bronze Agency medals from 1996 to the present.

Mary currently serves as a Vice Chair on the Board of Directors of the American National Standards Institute (ANSI) and is immediate past Chair of ANSI's Government Member Council. She has served on the Board of Directors for the International Policy Institute in Washington and represented the U.S. in international environmental discussions involving standards through the United Nations Environmental Program (UNEP) and the United Nations Committee on Trade and Development (UNCTAD) as well as in the Organization for Economic Cooperation and Development (OECD).

Mary has numerous publications on standards and standards in regulations and regularly makes national and international presentations on standards-related topics.

RICHARD (DICK) B. PETTIT

After gaining his Ph.D. in Applied Physics from Cornell University in 1971, Dick joined Sandia National Laboratories as a Member of the Technical Staff. Initial assignments involved developing optical measurement techniques and optical coatings for solar collectors, including black chrome solar absorbers, light-weight flexible mirror materials, and antireflection coatings for glazings. Since 1986 he has been a manager in the Sandia Primary Standards Laboratory overseeing electrical metrology in AC, DC, and Microwave disciplines.

Dr. Pettit's expertise includes:

- Metrology management systems and quality operations
- Calibration uncertainties
- Optical properties of solar absorbers, mirrors, and glazings
- Ellipsometry and multilayer thin film optical properties
- Thermal radiative properties of metals and coatings
- Transmission Electron Microscopy
- Enhanced superconductivity of thin films

He was a recipient of the Department of Energy (DOE) Solar Thermal Program Award in Technical Excellence in 1982; and he has been an American Society for Quality (ASQ) Certified Quality Engineer since 1992. Among several professional societies and various honors, Dick serves as Vice President of Measurement Science and Technology for NCSL International (NCSLI); and he was the DOE representative to the National Cooperation for Laboratory Accreditation (NACLA). He is also a member of the American Association for the Advancement of Science (AAAS) and the American Physical Society (APS).

Dick has been involved with the NCSLI for the past 13 years; he was Chairman of the Intrinsic/Derived Standards Committee for over 8 years and led the development of the recently published "Catalogue of Intrinsic/Derived

Standards.” He has organized several topical sessions and presented material on metrology issues at the annual NCSLI Symposium and Workshop, and he was the Technical Program Chair for the 2001 NCSLI Conference.

Dick’s outside interests include bicycling, camping, gardening, and traveling. He and his wife, Ellen, have been involved with hosting and assisting foreign exchange students over the past 10 years.

MARY H. SAUNDERS

Mary H. Saunders is the Director of NIST’s Office of Standards Services, which provides policy support for standards and conformity assessment activities for federal agencies. OSS administers programs in Laboratory Accreditation, Technical Standards Activities, Global Standards and Information, as well as the implementation of the National Technology Transfer and Advancement Act of 1995.

Ms. Saunders joined NIST in July 1993, having served for four years as Director of the Internal Market Staff of the Commerce Department’s Office of European Community Affairs, where she developed a program to track developments in Europe in the areas of product safety standards, testing and certification and accreditation requirements, and ISO 9000 registration and accreditation. While at NIST, she has served in several different positions, including Chief of the Global Standards and Information Program and Program Analyst in the Office of the NIST Director. Ms. Saunders received the NIST Bronze Medal in 1995 and the Department of Commerce Silver Medal in 1999. She continues to be active in both domestic and international standardization.

ERIC L. STONE

Mr. Stone is Director of the Legal Division of the Office of Compliance at the Consumer Product Safety Commission. Since 1977, Mr. Stone has served as a trial attorney at the Commission litigating administrative and federal court cases. Mr. Stone also wrote the Commission’s reporting regulations under section 15 of the Consumer Product Safety Act and the Child Safety Protection Act.

Mr. Stone graduated from the Washington College of Law (American University), Washington, D.C. in 1976 and received his BA from Franklin & Marshall College, Lancaster, PA in 1974. Mr. Stone has taught courses in consumer law, product liability, and government regulation at the University of Maryland and has authored several articles and a book about the Commission’s laws. (Consumer Product Safety Primer: An Industry Guide to the Regulatory System with Samuel Goldblatt, LRP Publications (1998))

JAMES K. WALTERS

Jim Walters is the Director, International Standards, at the Air-Conditioning and Refrigeration Institute (ARI), Arlington, Va. ARI is a trade association whose members manufacture about 90% of the central air-conditioning and refrigeration equipment sold in North America and account for about 80% of \$6 billion in exports per year. ARI administers the Secretariat of several ISO committees.

Prior to joining ARI’s staff in April 1999, Jim was Director and General Manager of a petroleum industry on-line information service in New York, which he sold to an international on-line information company.

Jim’s trade association and business experience includes managing an engineering standards and certification department and a \$20 million for-profit products and services group at the American Petroleum Institute. Jim’s background also includes government relations specializing in international trade issues. He is currently the Vice Chair of the Low Frequency Emissions Industry Coalition.

Jim was educated at the George Washington University, University of Virginia and the Stanford University Graduate School of Business.

Jim is a member of the Boards of Directors of the Standards Engineering Society and The Center for Global Standards Analysis, and is a member of ASTM, The American Society of Association Executives, several committees of the American National Standards Institute, and the Industry Advisory Committee of the Elliott School of International Affairs of the George Washington University. He is formerly Secretary of ASTM Committee D-2.

II. Final Participants List

Sherryl Acey
Entela, Inc
3033 Madison Ave., SE
Grand Rapids, MI 49548 USA
Telephone: 616/248-9608
Fax: 616/247-7527
Email: sacey@entela.com

David Alderman
NIST
100 Bureau Drive
Mail Stop 2140
Gaithersburg, MD 20899-2140 USA
Telephone: 301/975-4019
Fax: 301/926-2884
Email: david.alderman@nist.gov

Jim Allen
FHWA
400 Seventh Street, SW
Room 3416
Washington, DC 20590 USA
Telephone: 202/366-2211
Fax: 202/493-2027
Email: jim.allen@fhwa.dot.gov

Mel Altman
U.S. Food & Drug Administration
2094 Gaither Road
HFZ-80
Rockville, MD 20851 USA
Telephone: 301/594-4766
Fax: 301/827-0193
Email: mra@cdrh.fda.gov

Janet Anquez
U.S. Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20857 USA
Telephone: 301/827-0037
Fax: 301/480-0814
Email: CAnquez@oc.fda.gov

David Baker
U.S. Air Force Metrology & Calibration Program
813 Irving-Wick Drive
Heath, OH 43056 USA
Telephone: 740/788-5000
Fax: 740/788-5020
Email: david.baker@afmetcal.af.mil

Gordon Bellen
NSF International
789 Dixboro Road
Ann Arbor, MI 48105 USA
Telephone: 734/769-8010
Fax: 734/827-7181
Email: bellen@nsf.org

Reg Blake
BSI America, Inc.
12110 Sunset Hills Road
Suite 140
Reston, VA 20190 USA
Telephone: 703/464-1908
Fax: 703/437-9001
Email: reg.blake@bsiamericas.com

Roberta Breden
Telecommunications Industry Association
2500 Wilson Blvd.
Suite 300
Arlington, VA 22201 USA
Telephone: 703/907-7705
Fax: 703/907-7727
Email: rbreden@tia.eia.org

Maureen Breitenberg
NIST
100 Bureau Drive
Mail Stop 2100
Gaithersburg, MD 20899-2100 USA
Telephone: 301/975-4031
Fax: 301/963-2871
Email: maureen.breitenberg@nist.gov

Carroll Brickenkamp
NIST
100 Bureau Drive
Mail Stop 2140
Gaithersburg, MD 20899-2140 USA
Telephone: 301/975-4291
Fax: 301/926-2884
Email: carroll.brickenkamp@nist.gov

John Bridges
U.S. Postal Service
475 L'Enfant Plaza, SW
Room 1P830
Washington, DC 20260 USA
Telephone: 202/268-5595
Fax: 202/268-6016
Email: jbridget4@email.usps.gov

Milton Bush
The M Companies
3942 N. Upland Street
Arlington, VA 22207 USA
Telephone: 703/533-9539
Fax: 703/533-1612
Email: themcos@aol.com

Gum Ho Choe
NIST
100 Bureau Drive
Mail Stop 2100
Gaithersburg, MD 20899-2100 USA
Telephone: 301/975-2929
Fax: 301/963-2871
Email: choe@nist.gov

Alan Clune
AFMETCAL
813 Irving Wick Drive
Heath, OH 43056 USA
Telephone: 740/788-5051
Fax: 740/788-5021
Email: alan.clune@afmetcal.af.mil

Belinda Collins
NIST
100 Bureau Drive
Mail Stop 2000
Gaithersburg, MD 20899-2000 USA
Telephone: 301/975-6455
Fax: 301/975-2183
Email: belinda.collins@nist.gov

Dave Conover
National Evaluation Services, Inc.
5203 Leesburg Pike
Suite 600
Falls Church, VA 22041 USA
Telephone: 703/931-2187
Email: DConover@nateval.org

Stephen Cook
NIST
100 Bureau Drive
MS 2350
Gaithersburg, MD 20899-2350 USA
Telephone: 301/975-4003
Fax: 301/926-0647
Email: steven.cook@nist.gov

Ronald Cressman
U.S. Air Force
18 ALSAB Drive
Pataskala, OH 43062 USA
Telephone: 740/788-5030
Fax: 740/788-5036
Email: ron.cressman@afmetcal.af.mil

Zubin Dastoor
Air-Conditioning & Refrigeration Institute
4301 N. Fairfax Drive
Suite 425
Arlington, VA 22203 USA
Telephone: 703/524-8800
Fax: 703/524-9011
Email: zdastoor@ari.org

Tom Davis
NIST
100 Bureau Drive
Mail Stop 2140
Gaithersburg, MD 20899-2140 USA
Telephone: 301/975-6499
Fax: 301/926-2884
Email: thomas.davis@nist.gov

Christine DeVaux
NIST
100 Bureau Drive
Mail Stop 2100
Gaithersburg, MD 20899-2100 USA
Telephone: 301/975-4679
Fax: 301/963-2871
Email: christine.devaux@nist.gov

Mary Jo DiBernardo
NIST
100 Bureau Drive
Mail Stop 2100
Gaithersburg, MD 20899-2100 USA
Telephone: 301/975-5503
Fax: 301/963-2871
Email: maryjo.dibernardo@nist.gov

Andrew Dilworth
DOC/ITA/MAC/TCC
14th & Constitution Ave.
HCHB Room 3043
Washington, DC 20230 USA
Telephone: 202/482-8212
Fax: 202/501-0674
Email: andrew_dilworth@ita.doc.gov

Steve Doty
NIST
100 Bureau Drive
Mail Stop 2140
Gaithersburg, MD 20899-2140 USA
Telephone: 301/975-4857
Fax: 301/926-2884
Email: stephen.doty@nist.gov

Joseph Dunbeck
Registrar Accreditation Board
600 N. Plankinton Ave.
Suite 300
Milwaukee, WI 53203 USA
Telephone: 414/272-3937
Fax: 414/765-8661
Email: jdunbeck@rabnet.com

Catherine Ecalard
Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20857 USA
Telephone: 301/827-6615
Fax: 301/480-0814
Email: cecalard@oc.fda.gov

Si Farvardin
National Evaluation Service, Inc.
5203 Leesburg Pike
Suite 600
Falls Church, VA 22041 USA
Telephone: 703/931-2187
Fax: 703/931-6505
Email: sfarvardin@nateval.org

Reinaldo Figueiredo
ANSI
1819 L Street
Washington, DC 20036 USA
Telephone: 202/331-3611
Email: reinoldobf@aol.com

Mike Foran
U.S. Air Force Metrology & Calibration Program
813 Irving-Wick Drive
Heath, OH 43056 USA
Telephone: 740/788-5060
Email: Michael.Foran@afmetcal.af.mil

Leonard Frier
MET Laboratories
914 W. Patapsco Ave.
Baltimore, MD 21230 USA
Telephone: 410/354-3300
Fax: 410/354-3313
Email: lfrier@metlabs.com

Brian Gilda
U.S. Coast Guard
2100 Second Street, SW
G-MSE-4
Washington, DC 20593 USA
Telephone: 202/267-0147
Fax: 202/267-1069
Email: bgilda@comdt.uscg.mil

Gordon Gillerman
Underwriters Laboratories
1850 M Street, NW
Suite 1000
Washington, DC 20036 USA
Telephone: 202/296-7840
Fax: 202/872-1576
Email: gillermang@aol.com

Cecil Gittens
Eastman Kodak Co.
24 Woodside Drive
Rochester, NY 14624 USA
Telephone: 716/726-2290
Email: cecil.gittens@kodak.com

Allen Groh
Ericsson
740 E. Campbell Rd.
Richardson, TX 75081 USA
Telephone: 972/583-0902
Fax: 972/583-1809
Email: allen.groh@ericsson.com

Fred Grunder
American Industrial Hygiene Assoc.
2700 Prosperity Ave.
Suite 250
Fairfax, VA 22031 USA
Telephone: 703/849-8888
Fax: 703/207-8558
Email: fgrunder@aiha.org

Sandra Hale
NIST
100 Bureau Drive
MS 2100
Gaithersburg, MD 20899-2100 USA
Telephone: 301/975-3609
Email: sandra.hale@nist.gov

Denise Hanchulak
AAMVA
4301 Wilson Blvd.
Suite 400
Arlington, VA 22203 USA
Telephone: 703/908-5767
Fax: 703/908-2868
Email: dhanchulak@aamva.org

Jeanne Hankins
U.S. EPA
MD-75A
Res. Triangle Pk., NC 27711 USA
Telephone: 919/541-1120
Fax: 919/541-4261
Email: hankins.jeanne@epa.gov

Georgia Harris
NIST
100 Bureau Drive
MS 2350
Gaithersburg, MD 20899-2350 USA
Telephone: 301/975-4014
Email: g.harris@nist.gov

Joseph Hazeltine
Wyle Laboratories, Inc.
7800 Highway 20 West
Huntsville, AL 35806 USA
Telephone: 256/837-4411
Fax: 256/721-0144
Email: hazeltin@wylelabs.com

Donald Heirman
Lucent Technologies
143 Jumping Brook Road
Lincroft, NJ 07738 USA
Telephone: 732/741-7723
Fax: 732/530-5695
Email: d.heirman@worldnet.att.net

Scott Holliday
NASA HQ
300 E Street, SW
Code JJ, Rm. 7N80
Washington, DC 20546 USA
Telephone: 202/358-1096
Fax: 202/358-3944
Email: sholida@hq.nasa.gov

Jeffrey Horlick
NIST
100 Bureau Drive
Mail Stop 2140
Gaithersburg, MD 20899-2140 USA
Telephone: 301/975-4020
Fax: 301/926-2884
Email: jeffrey.horlick@nist.gov

Susan Hoyler
Telecommunications Industry Assoc.
2500 Wilson Blvd.
Arlington, VA 22201 USA
Telephone: 703/907-7704
Fax: 703/907-7728
Email: shoyler@tia.eia.org

William Hurst
Federal Communications Commission
445 12th Street, SW
Room 7-C257
Washington, DC 20554 USA
Telephone: 202/418-7266
Fax: 202/418-1944
Email: whurst@fcc.gov

Mary Hyer
The Marley Organization, Inc.
412 Main Street
Suite 3
Ridgefield, CT 06877 USA
Telephone: 203/438-3801
Fax: 203/438-3801
Email: CHyer@TMOinc.com

Tim Jeffries
ATIS
1200 G Street, NW
Suite 500
Washington, DC 20005 USA
Telephone: 202/662-8669
Email: tjeffries@atis.org

Edward Kantor
U.S. EPA
P.O. Box 93478
Las Vegas, NV 89193 USA
Telephone: 702/798-2690
Fax: 702/798-2261
Email: kantor.edward@epa.gov

Rich Kayser
NIST
100 Bureau Drive
Mail Stop 2000
Gaithersburg, MD 20899-2000 USA
Telephone: 301/975-4500
Fax: 301/975-2183
Email: richard.kayser@nist.gov

Larry Knab
NIST
100 Bureau Drive
Mail Stop 2140
Gaithersburg, MD 20899-2140 USA
Telephone: 301/975-6712
Fax: 301/926-2884
Email: lawrence.knab@nist.gov

Diane Lay
NIST
100 Bureau Drive
Mail Stop 2160
Gaithersburg, MD 20899-2160 USA
Telephone: 301/975-5634
Fax: 301/926-1559
Email: diane.lay@nist.gov

Walter Leight
NIST
100 Bureau Drive
Mail Stop 2100
Gaithersburg, MD 20899-2100 USA
Telephone: 301/975-4000
Fax: 301/963-2871
Email: walter.leight@nist.gov

Alvin Logan
FAA
800 Independence Ave., SW
AAS-100, Rm 61B
Washington, DC 20591 USA
Telephone: 202/267-8743
Fax: 202/267-5383
Email: alvin.logan@faa.gov

Carmina Londono
NIST
100 Bureau Drive
Mail Stop 2100
Gaithersburg, MD 20899-2100 USA
Telephone: 301/975-2573
Email: carmina.londono@nist.gov

Emiliano Lopez
U.S. DOT
10 S. Howard
Baltimore, MD 21201 USA
Telephone: 410/215-8130
Email: emiliano.lopez@fhwa.dot.gov

John Lucas
Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20857 USA
Telephone: 301/827-0917
Fax: 301/480-0814
Email: jlucas@oc.fda.gov

Rebecca MacPherson
National Highway Traffic Safety Administration
400 Seventh St., SW
Room 5219
Washington, DC 20003 USA
Telephone: 202/366-2992
Fax: 202/366-3820
Email: rebecca.macpherson@nhtsa.dot.gov

Ileana Martinez
NIST
100 Bureau Drive
Mail Stop 2100
Gaithersburg, MD 20899-2100 USA
Telephone: 301/975-2766
Fax: 301/963-2871
Email: ileana.martinez@nist.gov

Kevin McIntyre
NIST
100 Bureau Drive
Mail Stop 2150
Gaithersburg, MD 20899-2150 USA
Telephone: 301/975-4907
Fax: 301/975-5414
Email: kevin.mcintyre@nist.gov

Mary McKiel
U.S. EPA
1200 Pennsylvania Ave., NW
MC 7101, Ariel Rios Bldg.
Washington, DC 20460 USA
Telephone: 202/260-3584
Fax: 202/260-6906
Email: mckiel.mary@epa.gov

Mike Moore
NIST
100 Bureau Drive
Mail Stop 2150
Gaithersburg, MD 20899-2150 USA
Telephone: 301/975-2007
Fax: 301/975-5414
Email: mike.moore@nist.gov

Sherrey Nicolas
OSHA
200 Constitution Ave., NW
N3655
Washington, DC 20210 USA
Telephone: 202/693-2110
Fax: 202/693-1644
Email: sherrey.nicolas@osha.gov

Joseph O'Neil
NACLA
P.O. Box 4045
Gaithersburg, MD 20885 USA
Telephone: 301/975-6472
Fax: 301/963-2871
Email: secretariat@nacla.net

Kevin Oditt
U.S. Coast Guard
2100 Second Street, SW
G-MSE-4
Washington, DC 20593 USA
Telephone: 202/267-0169
Fax: 202/267-1069
Email: koditt@comdt.uscg.mil

Manny Olds
U.S. Government Printing Office
732 North Capitol Street, NW
Washington, DC 20401 USA
Telephone: 202/512-0767
Fax: 202/512-1314
Email: rbaker@gpo.gov

JoAnne Overman
NIST
100 Bureau Drive
Mail Stop 2160
Gaithersburg, MD 20899-2160 USA
Telephone: 301/975-4037
Fax: 301/926-1559
Email: joanne.overman@nist.gov

Libby Parker
NIST
100 Bureau Drive
Mail Stop 2100
Gaithersburg, MD 20899-2100 USA
Telephone: 301/975-3089
Fax: 301/963-2871
Email: libby.parker@nist.gov

Bernard Pasquet
OSHA
200 Constitution Ave., NW
N3655
Washington, DC 20210 USA
Telephone: 202/693-2110
Fax: 202/693-1644
Email: bernard.pasquet@osha.gov

Richard Pettit
Sandia National Laboratories
Mail Stop 0665
Albuquerque, NM 87185 USA
Telephone: 505/844-6242
Fax: 505/844-4372
Email: rbpetti@sandia.gov

Jerry Pittenger
Battelle
505 King Avenue
Columbus, OH 43201 USA
Telephone: 614/424-5189
Fax: 614/458-5189
Email: pittengj@battelle.org

C.P. (Chuck) Ramani
ICBO Evaluation Services, Inc.
5360 Workman Mill Road
Whittier, CA 90601 USA
Telephone: 562/699-0541
Fax: 562/692-2845
Email: ramani@icbo.org

Douglas Read
SAE International
1300 I Street, NW
Washington, DC 20005 USA
Telephone: 202/962-8691
Fax: 202/962-8692
Email: douglasr@sae.org

Hazel Richmond
NIST
100 Bureau Drive
Mail Stop 2140
Gaithersburg, MD 20899-2140 USA
Telephone: 301/975-3024
Fax: 301/926-2884
Email: hazel.richmond@nist.gov

Anita Ricketts
IEEE
445 Hoes Lane
Piscataway, NJ 08854 USA
Telephone: 732/562-3847
Fax: 732/562-1571
Email: a.ricketts@ieee.org

Ann Rollins
Information Technology Industry Council
1250 Eye Street, NW
Suite 200
Washington, DC 20005 USA
Telephone: 202/626-5735
Email: arollins@itc.org

Nathan Root
AAMVAnet
4301 Wilson Blvd.
Suite 400
Arlington, VA 22203 USA
Telephone: 703/908-5843
Fax: 703/908-2868

James Rountree
NIST
100 Bureau Drive
Mail Stop 2160
Gaithersburg, MD 20899-2160 USA
Telephone: 301/975-4035
Fax: 301/975-1559
Email: james.rountree@nist.gov

Sid Sanders
Timco Engineering, Inc.
849 N.W. State Road 45
Newberry, FL 32669 USA
Telephone: 352/472-5500
Fax: 352/472-2030
Email: info@timcoengr.com

Mary Saunders
NIST
100 Bureau Drive
Mail Stop 2100
Gaithersburg, MD 20899-2100 USA
Telephone: 301/975-2396
Fax: 301/963-2871
Email: mary.saunders@nist.gov

Michael Schagrin
U.S. DOT
400 7th Street, SW
Room 3416
Washington, DC 20590 USA
Telephone: 202/366-2180
Fax: 202/493-2027
Email: mike.schagrin@fhwa.dot.gov

Andy Schoka
Mitretek Systems
600 Maryland Ave., SW
Suite 755
Washington, DC 20024 USA
Telephone: 202/488-5702
Email: schoka@mitretek.org

Jane Schweiker
Schweiker & Associates
4853 Cordell Avenue
Suite 1515
Bethesda, MD 20814 USA
Telephone: 301/656-9599
Email: jschweiker@erols.com

Dennis Smith
Tyco Electronics
P.O. Box 3608
Harrisburg, PA 17105 USA
Telephone: 717/810-4667
Fax: 717/810-3400
Email: desmith@tycoelectronics.com

Joan Sterling
ITS
1233 S Street, NW
Suite A
Washington, DC 20009 USA
Telephone: 202/265-3378
Fax: 202/265-0687
Email: js@etlsemko.com

Eric Stone
U.S. Consumer Product Safety Commission
4340 East West Highway
Room 613 E
Bethesda, MD 20207 USA
Telephone: 301/504-0626
Fax: 301/504-0359
Email: estone@cpsc.gov

Diane Thompson
Thompson Consulting
7028 Roslyn Avenue
Derwood, MD 20855 USA
Telephone: 240/632-2660
Email: dianet2001@msn.com

Ambler Thompson
NIST
100 Bureau Drive
Mail Stop 2150
Gaithersburg, MD 20899-2150 USA
Telephone: 301/975-5414
Email: ambler@nist.gov

James Thurston
Information Technology Industry Council
1250 Eye Street, NW
Suite 200
Washington, DC 20005 USA
Telephone: 202/626-5721
Fax: 202/638-4922
Email: jthurston@itic.org

Ellen Trager
NIST
100 Bureau Drive
Mail Stop 2160
Gaithersburg, MD 20899-2160 USA
Telephone: 301/975-4038
Fax: 301/926-1559
Email: ellen.trager@nist.gov

Brenda Umberger
NIST
100 Bureau Drive, Mail Stop 2160
Gaithersburg, MD 20899-2160 USA
Telephone: 301/975-4036
Fax: 301/926-1559
Email: brenda.umberger@nist.gov

Peter Unger
A2LA
5301 Buckeystown Pike, Suite 350
Frederick, MD 21704 USA
Telephone: 301/644-3212
Fax: 301/662-2974
Email: punger@a2la.org

James Walters
Air-Conditioning & Refrigeration Institute
4301 N. Fairfax Drive, Suite 425
Arlington, VA 22203 USA
Telephone: 703/524-8800

Jeris White
Mitrotek Systems
600 Maryland Avenue
Washington, DC 20024 USA
Telephone: 202/488-5712
Fax: 202/863-2988
Email: jeris.white@mitrotek.org

Vanda White
NIST
100 Bureau Drive, Mail Stop 2140
Gaithersburg, MD 20899-2140 USA
Telephone: 301/975-3592
Fax: 301/926-2884
Email: vanda.white@nist.gov

Trudie Williams
U.S. DoD
8725 John J. Kingman Road, Suite 4235
Fort Belvoir, VA 22060 USA
Telephone: 703/767-6875
Fax: 703/767-6876
Email: trudie_williams@hq.dla.mil

George Willingmyre
GTW Associates
1012 Parrs Ridge Drive
Spencerville, MD 20868 USA
Telephone: 301/421-4138
Fax: 301/421-0977
Email: gtw@gtwassociates.com

Kathleen Winn
Kathleen Winn & Associates
213 A Street, NE
Washington, DC 20002 USA
Telephone: 202/547-3363
Fax: 202/544-6144
Email: kjayewinn@aol.com

Leanne Wright
Standards Council of Canada
270 Albert Street
Ottawa, ON K1P 6N7 CANADA
Telephone: 613/238-3222
Fax: 613/569-7808
Email: lwright@scc.ca

Grant Zammit
U.S. DOT
61 Forsyth Street, Suite 17T26
Atlanta, GA 30303 USA
Telephone: 404/562-3575
Fax: 404/562-3700
Email: grant.zammit@fhwa.dot.gov

Eldar Zulfugarzade
NIST
100 Bureau Drive
Mail Stop 2100
Gaithersburg, MD 20899-2100 USA
Telephone: 301/975-4412
Fax: 301/963-2871
Email: eldar.zulfugarzade@nist.gov

III. Public Law 104-113

PUBLIC LAW 104-113—MAR. 7, 1996

110 STAT. 775

Public Law 104-113 104th Congress

An Act

To amend the Stevenson-Wydler Technology Innovation Act of 1980 with respect to inventions made under cooperative research and development agreements, and for other purposes.

Mar. 7, 1996
[H.R. 2196]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Technology Transfer and Advancement Act of 1995".

SEC. 2. FINDINGS.

The Congress finds the following:

(1) Bringing technology and industrial innovation to the marketplace is central to the economic, environmental, and social well-being of the people of the United States.

(2) The Federal Government can help United States business to speed the development of new products and processes by entering into cooperative research and development agreements which make available the assistance of Federal laboratories to the private sector, but the commercialization of technology and industrial innovation in the United States depends upon actions by business.

(3) The commercialization of technology and industrial innovation in the United States will be enhanced if companies, in return for reasonable compensation to the Federal Government, can more easily obtain exclusive licenses to inventions which develop as a result of cooperative research with scientists employed by Federal laboratories.

SEC. 3. USE OF FEDERAL TECHNOLOGY.

Subparagraph (B) of section 11(e)(7) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710(e)(7)(B)) is amended to read as follows:

"(B) A transfer shall be made by any Federal agency under subparagraph (A), for any fiscal year, only if the amount so transferred by that agency (as determined under such subparagraph) would exceed \$10,000."

SEC. 4. TITLE TO INTELLECTUAL PROPERTY ARISING FROM COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS.

Subsection (b) of section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a(b)) is amended to read as follows:

"(b) ENUMERATED AUTHORITY.—(1) Under an agreement entered into pursuant to subsection (a)(1), the laboratory may grant, or

National
Technology
Transfer and
Advancement Act
of 1995.
15 USC 3701
note.
15 USC 3701
note.

agree to grant in advance, to a collaborating party patent licenses or assignments, or options thereto, in any invention made in whole or in part by a laboratory employee under the agreement, for reasonable compensation when appropriate. The laboratory shall ensure, through such agreement, that the collaborating party has the option to choose an exclusive license for a pre-negotiated field of use for any such invention under the agreement or, if there is more than one collaborating party, that the collaborating parties are offered the option to hold licensing rights that collectively encompass the rights that would be held under such an exclusive license by one party. In consideration for the Government's contribution under the agreement, grants under this paragraph shall be subject to the following explicit conditions:

Confidential
information.

"(A) A nonexclusive, nontransferable, irrevocable, paid-up license from the collaborating party to the laboratory to practice the invention or have the invention practiced throughout the world by or on behalf of the Government. In the exercise of such license, the Government shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of section 552(b)(4) of title 5, United States Code, or which would be considered as such if it had been obtained from a non-Federal party.

"(B) If a laboratory assigns title or grants an exclusive license to such an invention, the Government shall retain the right—

"(i) to require the collaborating party to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive license to use the invention in the applicant's licensed field of use, on terms that are reasonable under the circumstances; or

"(ii) if the collaborating party fails to grant such a license, to grant the license itself.

"(C) The Government may exercise its right retained under subparagraph (B) only in exceptional circumstances and only if the Government determines that—

"(i) the action is necessary to meet health or safety needs that are not reasonably satisfied by the collaborating party;

"(ii) the action is necessary to meet requirements for public use specified by Federal regulations, and such requirements are not reasonably satisfied by the collaborating party; or

"(iii) the collaborating party has failed to comply with an agreement containing provisions described in subsection (c)(4)(B).

This determination is subject to administrative appeal and judicial review under section 203(2) of title 35, United States Code.

"(2) Under agreements entered into pursuant to subsection (a)(1), the laboratory shall ensure that a collaborating party may retain title to any invention made solely by its employee in exchange for normally granting the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government for research or other Government purposes.

"(3) Under an agreement entered into pursuant to subsection (a)(1), a laboratory may—

"(A) accept, retain, and use funds, personnel, services, and property from a collaborating party and provide personnel, services, and property to a collaborating party;

"(B) use funds received from a collaborating party in accordance with subparagraph (A) to hire personnel to carry out the agreement who will not be subject to full-time-equivalent restrictions of the agency;

"(C) to the extent consistent with any applicable agency requirements or standards of conduct, permit an employee or former employee of the laboratory to participate in an effort to commercialize an invention made by the employee or former employee while in the employment or service of the Government; and

"(D) waive, subject to reservation by the Government of a nonexclusive, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government, in advance, in whole or in part, any right of ownership which the Federal Government may have to any subject invention made under the agreement by a collaborating party or employee of a collaborating party.

"(4) A collaborating party in an exclusive license in any invention made under an agreement entered into pursuant to subsection (a)(1) shall have the right of enforcement under chapter 29 of title 35, United States Code.

"(5) A Government-owned, contractor-operated laboratory that enters into a cooperative research and development agreement pursuant to subsection (a)(1) may use or obligate royalties or other income accruing to the laboratory under such agreement with respect to any invention only—

"(A) for payments to inventors;

"(B) for purposes described in clauses (i), (ii), (iii), and (iv) of section 14(a)(1)(B); and

"(C) for scientific research and development consistent with the research and development missions and objectives of the laboratory."

SEC. 5. DISTRIBUTION OF INCOME FROM INTELLECTUAL PROPERTY RECEIVED BY FEDERAL LABORATORIES.

Royalties.

Section 14 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710c) is amended—

(1) by amending subsection (a)(1) to read as follows:

"(1) Except as provided in paragraphs (2) and (4), any royalties or other payments received by a Federal agency from the licensing and assignment of inventions under agreements entered into by Federal laboratories under section 12, and from the licensing of inventions of Federal laboratories under section 207 of title 35, United States Code, or under any other provision of law, shall be retained by the laboratory which produced the invention and shall be disposed of as follows:

"(A)(i) The head of the agency or laboratory, or such individual's designee, shall pay each year the first \$2,000, and thereafter at least 15 percent, of the royalties or other payments to the inventor or coinventors.

"(ii) An agency or laboratory may provide appropriate incentives, from royalties, or other payments, to laboratory

employees who are not an inventor of such inventions but who substantially increased the technical value of such inventions.

"(iii) The agency or laboratory shall retain the royalties and other payments received from an invention until the agency or laboratory makes payments to employees of a laboratory under clause (i) or (ii).

"(B) The balance of the royalties or other payments shall be transferred by the agency to its laboratories, with the majority share of the royalties or other payments from any invention going to the laboratory where the invention occurred. The royalties or other payments so transferred to any laboratory may be used or obligated by that laboratory during the fiscal year in which they are received or during the succeeding fiscal year—

"(i) to reward scientific, engineering, and technical employees of the laboratory, including developers of sensitive or classified technology, regardless of whether the technology has commercial applications;

"(ii) to further scientific exchange among the laboratories of the agency;

"(iii) for education and training of employees consistent with the research and development missions and objectives of the agency or laboratory, and for other activities that increase the potential for transfer of the technology of the laboratories of the agency;

"(iv) for payment of expenses incidental to the administration and licensing of intellectual property by the agency or laboratory with respect to inventions made at that laboratory, including the fees or other costs for the services of other agencies, persons, or organizations for intellectual property management and licensing services; or

"(v) for scientific research and development consistent with the research and development missions and objectives of the laboratory.

"(C) All royalties or other payments retained by the agency or laboratory after payments have been made pursuant to subparagraphs (A) and (B) that is unobligated and unexpended at the end of the second fiscal year succeeding the fiscal year in which the royalties and other payments were received shall be paid into the Treasury.";

(2) in subsection (a)(2)—

(A) by inserting "or other payments" after "royalties"; and

(B) by striking "for the purposes described in clauses (i) through (iv) of paragraph (1)(B) during that fiscal year or the succeeding fiscal year" and inserting in lieu thereof "under paragraph (1)(B)";

(3) in subsection (a)(3), by striking "\$100,000" both places it appears and inserting "\$150,000";

(4) in subsection (a)(4)—

(A) by striking "income" each place it appears and inserting in lieu thereof "payments";

(B) by striking "the payment of royalties to inventors" in the first sentence thereof and inserting in lieu thereof "payments to inventors";

(C) by striking "clause (i) of paragraph (1)(B)" and inserting in lieu thereof "clause (iv) of paragraph (1)(B)";

(D) by striking "payment of the royalties," in the second sentence thereof and inserting in lieu thereof "offsetting the payments to inventors,"; and

(E) by striking "clauses (i) through (iv) of"; and

(5) by amending paragraph (1) of subsection (b) to read as follows:

"(1) by a contractor, grantee, or participant, or an employee of a contractor, grantee, or participant, in an agreement or other arrangement with the agency, or".

SEC. 6. EMPLOYEE ACTIVITIES.

Section 15(a) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710d(a)) is amended—

(1) by striking "the right of ownership to an invention under this Act" and inserting in lieu thereof "ownership of or the right of ownership to an invention made by a Federal employee"; and

(2) by inserting "obtain or" after "the Government, to".

SEC. 7. AMENDMENT TO BAYH-DOLE ACT.

Section 210(e) of title 35, United States Code, is amended by striking ", as amended by the Federal Technology Transfer Act of 1986,".

SEC. 8. NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY ACT AMENDMENTS.

The National Institute of Standards and Technology Act (15 U.S.C. 271 et seq.) is amended—

(1) in section 10(a)—

(A) by striking "nine" and inserting in lieu thereof "15"; and

(B) by striking "five" and inserting in lieu thereof "10";

(2) in section 15—

(A) by striking "Pay Act of 1945; and" and inserting in lieu thereof "Pay Act of 1945;"; and

(B) by inserting "; and (h) the provision of transportation services for employees of the Institute between the facilities of the Institute and nearby public transportation, notwithstanding section 1344 of title 31, United States Code" after "interests of the Government"; and

(3) in section 19—

(A) by inserting ", subject to the availability of appropriations," after "post-doctoral fellowship program"; and

(B) by striking "nor more than forty" and inserting in lieu thereof "nor more than 60".

15 USC 278.

15 USC 278e.

15 USC 278g-2.

SEC. 9. RESEARCH EQUIPMENT.

Section 11(i) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710(i)) is amended by inserting "loan, lease, or" before "give".

SEC. 10. PERSONNEL.

15 USC 275 note.

The personnel management demonstration project established under section 10 of the National Bureau of Standards Authorization Act for Fiscal Year 1987 (15 U.S.C. 275 note) is extended indefinitely.

SEC. 11. FASTENER QUALITY ACT AMENDMENTS.

(a) SECTION 2 AMENDMENTS.—Section 2 of the Fastener Quality Act (15 U.S.C. 5401) is amended—

(1) by striking subsection (a)(4), and redesignating paragraphs (5) through (9) as paragraphs (4) through (8), respectively;

(2) in subsection (a)(7), as so redesignated by paragraph (1) of this subsection, by striking "by lot number"; and

(3) in subsection (b), by striking "used in critical applications" and inserting in lieu thereof "in commerce".

(b) SECTION 3 AMENDMENTS.—Section 3 of the Fastener Quality Act (15 U.S.C. 5402) is amended—

(1) in paragraph (1)(B) by striking "having a minimum tensile strength of 150,000 pounds per square inch";

(2) in paragraph (2), by inserting "consensus" after "or any other";

(3) in paragraph (5)—

(A) by inserting "or" after "standard or specification," in subparagraph (B);

(B) by striking "or" at the end of subparagraph (C);

(C) by striking subparagraph (D); and

(D) by inserting "or produced in accordance with ASTM F 432" after "307 Grade A";

(4) in paragraph (6) by striking "other person" and inserting in lieu thereof "government agency";

(5) in paragraph (8) by striking "Standard" and inserting in lieu thereof "Standards";

(6) by striking paragraph (11) and redesignating paragraphs (12) through (15) as paragraphs (11) through (14), respectively;

(7) in paragraph (13), as so redesignated by paragraph (6) of this subsection, by striking ", a government agency" and all that follows through "markings of any fastener" and inserting in lieu thereof "or a government agency"; and

(8) in paragraph (14), as so redesignated by paragraph (6) of this subsection, by inserting "for the purpose of achieving a uniform hardness" after "quenching and tempering".

(c) SECTION 4 REPEAL.—Section 4 of the Fastener Quality Act (15 U.S.C. 5403) is repealed.

(d) SECTION 5 AMENDMENTS.—Section 5 of the Fastener Quality Act (15 U.S.C. 5404) is amended—

(1) in subsection (a)(1)(B) and (2)(A)(i) by striking "subsections (b) and (c)" and inserting in lieu thereof "subsections (b), (c), and (d)";

(2) in subsection (c)(2) by striking "or, where applicable" and all that follows through "section 7(c)(1)";

(3) in subsection (c)(3) by striking ", such as the chemical, dimensional, physical, mechanical, and any other";

(4) in subsection (c)(4) by inserting "except as provided in subsection (d)," before "state whether"; and

(5) by adding at the end the following new subsection:

"(d) ALTERNATIVE PROCEDURE FOR CHEMICAL CHARACTERISTICS.—Notwithstanding the requirements of subsections (b) and (c), a manufacturer shall be deemed to have demonstrated, for purposes of subsection (a)(1), that the chemical characteristics of a lot conform to the standards and specifications to which the

manufacturer represents such lot has been manufactured if the following requirements are met:

"(1) The coil or heat number of metal from which such lot was fabricated has been inspected and tested with respect to its chemical characteristics by a laboratory accredited in accordance with the procedures and conditions specified by the Secretary under section 6.

"(2) Such laboratory has provided to the manufacturer, either directly or through the metal manufacturer, a written inspection and testing report, which shall be in a form prescribed by the Secretary by regulation, listing the chemical characteristics of such coil or heat number.

"(3) The report described in paragraph (2) indicates that the chemical characteristics of such coil or heat number conform to those required by the standards and specifications to which the manufacturer represents such lot has been manufactured.

"(4) The manufacturer demonstrates that such lot has been fabricated from the coil or heat number of metal to which the report described in paragraphs (2) and (3) relates.

In prescribing the form of report required by subsection (c), the Secretary shall provide for an alternative to the statement required by subsection (c)(4), insofar as such statement pertains to chemical characteristics, for cases in which a manufacturer elects to use the procedure permitted by this subsection."

(e) SECTION 6 AMENDMENT.—Section 6(a)(1) of the Fastener Quality Act (15 U.S.C. 5405(a)(1)) is amended by striking "Within 180 days after the date of enactment of this Act, the" and inserting in lieu thereof "The".

(f) SECTION 7 AMENDMENTS.—Section 7 of the Fastener Quality Act (15 U.S.C. 5406) is amended—

(1) by amending subsection (a) to read as follows:

"(a) DOMESTICALLY PRODUCED FASTENERS.—It shall be unlawful for a manufacturer to sell any shipment of fasteners covered by this Act which are manufactured in the United States unless the fasteners—

"(1) have been manufactured according to the requirements of the applicable standards and specifications and have been inspected and tested by a laboratory accredited in accordance with the procedures and conditions specified by the Secretary under section 6; and

"(2) an original laboratory testing report described in section 5(c) and a manufacturer's certificate of conformance are on file with the manufacturer, or under such custody as may be prescribed by the Secretary, and available for inspection.";

(2) in subsection (c)(2) by inserting "to the same" after "in the same manner and";

(3) in subsection (d)(1) by striking "certificate" and inserting in lieu thereof "test report"; and

(4) by striking subsections (e), (f), and (g) and inserting in lieu thereof the following:

"(e) COMMINGLING.—It shall be unlawful for any manufacturer, importer, or private label distributor to commingle like fasteners from different lots in the same container, except that such manufacturer, importer, or private label distributor may commingle like fasteners of the same type, grade, and dimension from not more than two tested and certified lots in the same container during repackaging and plating operations. Any container which contains

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Regulations.

fasteners from two lots shall be conspicuously marked with the lot identification numbers of both lots.

"(f) SUBSEQUENT PURCHASER.—If a person who purchases fasteners for any purpose so requests either prior to the sale or at the time of sale, the seller shall conspicuously mark the container of the fasteners with the lot number from which such fasteners were taken."

(g) SECTION 9 AMENDMENT.—Section 9 of the Fastener Quality Act (15 U.S.C. 5408) is amended by adding at the end the following new subsection:

"(d) ENFORCEMENT.—The Secretary may designate officers or employees of the Department of Commerce to conduct investigations pursuant to this Act. In conducting such investigations, those officers or employees may, to the extent necessary or appropriate to the enforcement of this Act, exercise such authorities as are conferred upon them by other laws of the United States, subject to policies and procedures approved by the Attorney General."

(h) SECTION 10 AMENDMENTS.—Section 10 of the Fastener Quality Act (15 U.S.C. 5409) is amended—

(1) in subsections (a) and (b), by striking "10 years" and inserting in lieu thereof "5 years"; and

(2) in subsection (b), by striking "any subsequent" and inserting in lieu thereof "the subsequent".

(i) SECTION 13 AMENDMENT.—Section 13 of the Fastener Quality Act (15 U.S.C. 5412) is amended by striking "within 180 days after the date of enactment of this Act".

(j) SECTION 14 REPEAL.—Section 14 of the Fastener Quality Act (15 U.S.C. 5413) is repealed.

SEC. 12. STANDARDS CONFORMITY.

(a) USE OF STANDARDS.—Section 2(b) of the National Institute of Standards and Technology Act (15 U.S.C. 272(b)) is amended—

(1) in paragraph (2), by striking ", including comparing standards" and all that follows through "Federal Government";

(2) by redesignating paragraphs (3) through (11) as paragraphs (4) through (12), respectively; and

(3) by inserting after paragraph (2) the following new paragraph:

"(3) to compare standards used in scientific investigations, engineering, manufacturing, commerce, industry, and educational institutions with the standards adopted or recognized by the Federal Government and to coordinate the use by Federal agencies of private sector standards, emphasizing where possible the use of standards developed by private, consensus organizations;"

(b) CONFORMITY ASSESSMENT ACTIVITIES.—Section 2(b) of the National Institute of Standards and Technology Act (15 U.S.C. 272(b)) is amended—

(1) by striking "and" at the end of paragraph (11), as so redesignated by subsection (a)(2) of this section;

(2) by striking the period at the end of paragraph (12), as so redesignated by subsection (a)(2) of this section, and inserting in lieu thereof "; and"; and

(3) by adding at the end the following new paragraph:

"(13) to coordinate Federal, State, and local technical standards activities and conformity assessment activities, with private sector technical standards activities and conformity assess-

ment activities, with the goal of eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures.”.

(c) TRANSMITTAL OF PLAN TO CONGRESS.—The National Institute of Standards and Technology shall, within 90 days after the date of enactment of this Act, transmit to the Congress a plan for implementing the amendments made by this section.

15 USC 272 note.

(d) UTILIZATION OF CONSENSUS TECHNICAL STANDARDS BY FEDERAL AGENCIES; REPORTS.—

15 USC 272 note.

(1) IN GENERAL.—Except as provided in paragraph (3) of this subsection, all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.

(2) CONSULTATION; PARTICIPATION.—In carrying out paragraph (1) of this subsection, Federal agencies and departments shall consult with voluntary, private sector, consensus standards bodies and shall, when such participation is in the public interest and is compatible with agency and departmental missions, authorities, priorities, and budget resources, participate with such bodies in the development of technical standards.

(3) EXCEPTION.—If compliance with paragraph (1) of this subsection is inconsistent with applicable law or otherwise impractical, a Federal agency or department may elect to use technical standards that are not developed or adopted by voluntary consensus standards bodies if the head of each such agency or department transmits to the Office of Management and Budget an explanation of the reasons for using such standards. Each year, beginning with fiscal year 1997, the Office of Management and Budget shall transmit to Congress and its committees a report summarizing all explanations received in the preceding year under this paragraph.

(4) DEFINITION OF TECHNICAL STANDARDS.—As used in this subsection, the term “technical standards” means performance-based or design-specific technical specifications and related management systems practices.

SEC. 13. SENSE OF CONGRESS.

It is the sense of the Congress that the Malcolm Baldrige National Quality Award program offers substantial benefits to

110 STAT. 784

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United States industry, and that all funds appropriated for such program should be spent in support of the goals of the program.

Approved March 7, 1996.

LEGISLATIVE HISTORY—H.R. 2196:

HOUSE REPORTS: No. 104-390 (Comm. on Science).

CONGRESSIONAL RECORD:

Vol. 141 (1995): Dec. 12, considered and passed House.

Vol. 142 (1996): Feb. 7, considered and passed Senate, amended.

Feb. 27, House concurred in Senate amendments.



IV. OMB Circular A-119 (Text Only)

OMB Home

February 10, 1998

CIRCULAR NO. A-119

Revised

MEMORANDUM FOR HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

SUBJECT:

Federal Participation in the Development and Use of Voluntary Consensus
Standards and in Conformity Assessment Activities

Revised OMB Circular A-119 establishes policies on Federal use and development of voluntary consensus standards and on conformity assessment activities. Pub. L. 104-113, the "National Technology Transfer and Advancement Act of 1995," codified existing policies in A-119, established reporting requirements, and authorized the National Institute of Standards and Technology to coordinate conformity assessment activities of the agencies. OMB is issuing this revision of the Circular in order to make the terminology of the Circular consistent with the National Technology Transfer and Advancement Act of 1995, to issue guidance to the agencies on making their reports to OMB, to direct the Secretary of Commerce to issue policy guidance for conformity assessment, and to make changes for clarity.

Franklin D. Raines

Circular No. A-119

Revised

(Accompanying Federal Register Materials – 2/10/98)

TO THE HEADS OF EXECUTIVE DEPARTMENTS AND ESTABLISHMENTS

SUBJECT: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities

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BACKGROUND

1. What Is The Purpose Of This Circular?

This Circular establishes policies to improve the internal management of the Executive Branch. Consistent with Section 12(d) of P.L. 104-113, the "National Technology Transfer and Advancement Act of 1995" (hereinafter "the Act"), this Circular directs agencies to use voluntary consensus standards in lieu of government-unique standards except where inconsistent with law or otherwise impractical. It also provides guidance for agencies participating in voluntary consensus standards bodies and describes procedures for satisfying the reporting requirements in the Act. The policies in this Circular are intended to reduce to a minimum the reliance by agencies on government-unique standards. These policies do not create the bases for discrimination in agency procurement or regulatory activities among standards developed in the private sector, whether or not they are developed by voluntary consensus standards bodies. Consistent with Section 12(b) of the Act, this Circular directs the Secretary of Commerce to issue guidance to the agencies in order to coordinate conformity assessment activities. This Circular replaces OMB Circular No. A-119, dated October 20, 1993.

2. What Are The Goals Of The Government In Using Voluntary Consensus Standards?

Many voluntary consensus standards are appropriate or adaptable for the Government's purposes. The use of such standards, whenever practicable and appropriate, is intended to achieve the following goals:

- a. Eliminate the cost to the Government of developing its own standards and decrease the cost of goods procured and the burden of complying with agency regulation.
- b. Provide incentives and opportunities to establish standards that serve national needs.
- c. Encourage long-term growth for U.S. enterprises and promote efficiency and economic competition through harmonization of standards.
- d. Further the policy of reliance upon the private sector to supply Government needs for goods and services.

WHAT DEFINITIONS OF STANDARDS

3. What Is A Standard?

a. The term “standard,” or “technical standard” as cited in the Act, includes all of the following:

(1) Common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods, and related management systems practices.

(2) The definition of terms; classification of components; delineation of procedures; specification of dimensions, materials, performance, designs, or operations; measurement of quality and quantity in describing materials, processes, products, systems, services, or practices; test methods and sampling procedures; or descriptions of fit and measurements of size or strength.

b. The term “standard” does not include the following:

(1) Professional standards of personal conduct.

(2) Institutional codes of ethics.

c. “Performance standard” is a standard as defined above that states requirements in terms of required results with criteria for verifying compliance but without stating the methods for achieving required results. A performance standard may define the functional requirements for the item, operational requirements, and/or interface and interchangeability characteristics. A performance standard may be viewed in juxtaposition to a prescriptive standard which may specify design requirements, such as materials to be used, how a requirement is to be achieved, or how an item is to be fabricated or constructed.

d. “Non-government standard” is a standard as defined above that is in the form of a standardization document developed by a private sector association, organization or technical society which plans, develops, establishes or coordinates standards, specifications, handbooks, or related documents.

4. What Are Voluntary, Consensus Standards?

a. For purposes of this policy, “voluntary consensus standards” are standards developed or adopted by voluntary consensus standards bodies, both domestic and international. These standards include provisions requiring that owners of relevant intellectual property have agreed to make that intellectual property available on a non-discriminatory, royalty-free or reasonable royalty basis to all interested parties. For purposes of this Circular, “technical standards that are developed or adopted by voluntary consensus standard bodies” is an equivalent term.

(1) "Voluntary consensus standards bodies" are domestic or international organizations which plan, develop, establish, or coordinate voluntary consensus standards using agreed-upon procedures. For purposes of this Circular, "voluntary, private sector, consensus standards bodies," as cited in Act, is an equivalent term. The Act and the Circular encourage the participation of federal representatives in these bodies to increase the likelihood that the standards they develop will meet both public and private sector needs. A voluntary consensus standards body is defined by the following attributes:

- (i) Openness.
- (ii) Balance of interest.
- (iii) Due process.
- (vi) An appeals process.
- (v) Consensus, which is defined as general agreement, but not necessarily unanimity, and includes a process for attempting to resolve objections by interested parties, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reasons why, and the consensus body members are given an opportunity to change their votes after reviewing the comments.

b. Other types of standards, which are distinct from voluntary consensus standards, are the following:

- (1) "Non-consensus standards," "Industry standards," "Company standards," or "de facto standards," which are developed in the private sector but not in the full consensus process.
- (2) "Government-unique standards," which are developed by the government for its own uses.
- (3) Standards mandated by law, such as those contained in the United States Pharmacopeia and the National Formulary, as referenced in 21 U.S.C. 351.

POLICY

5. Who Does This Policy Apply To?

This Circular applies to all agencies and agency employees who use standards and participate in voluntary consensus standards activities, domestic and international, except for activities carried out pursuant to treaties. "Agency" means any executive 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 insofar as they are subject to separate statutory requirements regarding the use of voluntary consensus standards. It does not include the legislative or judicial branches of the Federal Government.

6. What Is The Policy For Federal Use Of Standards?

All federal agencies must use voluntary consensus standards in lieu of government-unique standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical. In these circumstances, your agency must submit a report describing the reason(s) for its use of government-unique standards in lieu of voluntary consensus standards to the Office of Management and Budget (OMB) through the National Institute of Standards and Technology (NIST).

a. When must my agency use voluntary consensus standards?

Your agency must use voluntary consensus standards, both domestic and international, in its regulatory and procurement activities in lieu of government-unique standards, unless use of such standards would be inconsistent with applicable law or otherwise impractical. In all cases, your agency has the discretion to decline to use existing voluntary consensus standards if your agency determines that such standards are inconsistent with applicable law or otherwise impractical.

(1) “Use” means incorporation of a standard in whole, in part, or by reference for procurement purposes, and the inclusion of a standard in whole, in part, or by reference in regulation(s).

(2) “Impractical” includes circumstances in which such use would fail to serve the agency’s program needs; would be infeasible; would be inadequate, ineffectual, inefficient, or inconsistent with agency mission; or would impose more burdens, or would be less useful, than the use of another standard.

b. What must my agency do when such use is determined by my agency to be inconsistent with applicable law or otherwise impractical?

The head of your agency must transmit to the Office of Management and Budget (OMB), through the National Institute of Standards and Technology (NIST), an explanation of the reason(s) for using government-unique standards in lieu of voluntary consensus standards. For more information on reporting, see section 9.

c. How does this policy affect my agency’s regulatory authorities and responsibilities?

This policy does not preempt or restrict agencies’ authorities and responsibilities to make regulatory decisions authorized by statute. Such regulatory authorities and responsibilities include determining the level of acceptable risk; setting the level of protection; and balancing risk, cost, and availability of technology in establishing regulatory standards. However, to determine whether established regulatory limits or targets have been met, agencies should use voluntary consensus standards for test methods, sampling procedures, or protocols.

d. How does this policy affect my agency's procurement authority?

This policy does not preempt or restrict agencies' authorities and responsibilities to identify the capabilities that they need to obtain through procurements. Rather, this policy limits an agency's authority to pursue an identified capability through reliance on a government-unique standard when a voluntary consensus standard exists (see Section 6a).

e. What are the goals of agency use of voluntary consensus standards?

Agencies should recognize the positive contribution of standards development and related activities. When properly conducted, standards development can increase productivity and efficiency in Government and industry, expand opportunities for international trade, conserve resources, improve health and safety, and protect the environment.

f. What considerations should my agency make when it is considering using a standard?

When considering using a standard, your agency should take full account of the effect of using the standard on the economy, and of applicable federal laws and policies, including laws and regulations relating to antitrust, national security, small business, product safety, environment, metrication, technology development, and conflicts of interest. Your agency should also recognize that use of standards, if improperly conducted, can suppress free and fair competition; impede innovation and technical progress; exclude safer or less expensive products; or otherwise adversely affect trade, commerce, health, or safety. If your agency is proposing to incorporate a standard into a proposed or final rulemaking, your agency must comply with the "Principles of Regulation" (enumerated in Section 1(b)) and with the other analytical requirements of Executive Order 12866, "Regulatory Planning and Review."

g. Does this policy establish a preference between consensus and non-consensus standards that are developed in the private sector?

This policy does not establish a preference among standards developed in the private sector. Specifically, agencies that promulgate regulations referencing non-consensus standards developed in the private sector are not required to report on these actions, and agencies that procure products or services based on non-consensus standards are not required to report on such procurements. For example, this policy allows agencies to select a non-consensus standard developed in the private sector as a means of establishing testing methods in a regulation and to choose among commercial-off-the-shelf products, regardless of whether the underlying standards are developed by voluntary consensus standards bodies or not.

h. Does this policy establish a preference between domestic and international voluntary consensus standards?

This policy does not establish a preference between domestic and international voluntary consensus standards. However, in the interests of promoting trade and implementing the provisions of international treaty agreements, your agency should consider international standards in procurement and regulatory applications.

i. Should my agency give preference to performance standards?

In using voluntary consensus standards, your agency should give preference to performance standards when such standards may reasonably be used in lieu of prescriptive standards.

j. How should my agency reference voluntary consensus standards?

Your agency should reference voluntary consensus standards, along with sources of availability, in appropriate publications, regulatory orders, and related internal documents. In regulations, the reference must include the date of issuance. For all other uses, your agency must determine the most appropriate form of reference, which may exclude the date of issuance as long as users are elsewhere directed to the latest issue. If a voluntary standard is used and published in an agency document, your agency must observe and protect the rights of the copyright holder and any other similar obligations.

k. What if no voluntary consensus standard exists?

In cases where no voluntary consensus standards exist, an agency may use government-unique standards (in addition to other standards, see Section 6g) and is not required to file a report on its use of government-unique standards. As explained above (see Section 6a), an agency may use government-unique standards in lieu of voluntary consensus standards if the use of such standards would be inconsistent with applicable law or otherwise impractical; in such cases, the agency must file a report under Section 9a regarding its use of government-unique standards.

l. How may my agency identify voluntary consensus standards?

Your agency may identify voluntary consensus standards through databases of standards maintained by the National Institute of Standards and Technology (NIST), or by other organizations including voluntary consensus standards bodies, other federal agencies, or standards publishing companies.

7. What Is The Policy For Federal Participation In Voluntary Consensus Standards Bodies?

Agencies must consult with voluntary consensus standards bodies, both domestic and international, and must participate with such bodies in the development of voluntary consensus standards when consultation and participation is in the public interest and is compatible with their missions, authorities, priorities, and budget resources.

a. What are the purposes of agency participation?

Agency representatives should participate in voluntary consensus standards activities in order to accomplish the following purposes:

- (1) Eliminate the necessity for development or maintenance of separate Government-unique standards.
- (2) Further such national goals and objectives as increased use of the metric system of measurement; use of environmentally sound and energy efficient materials, products, systems, services, or practices; and improvement of public health and safety.

b. What are the general principles that apply to agency support?

Agency support provided to a voluntary consensus standards activity must be limited to that which clearly furthers agency and departmental missions, authorities, priorities, and is consistent with budget resources. Agency support must not be contingent upon the outcome of the standards activity. Normally, the total amount of federal support should be no greater than that of other participants in that activity, except when it is in the direct and predominant interest of the Government to develop or revise a standard, and its timely development or revision appears unlikely in the absence of such support.

c. What forms of support may my agency provide?

The form of agency support, may include the following:

- (1) Direct financial support; e.g., grants, memberships, and contracts.
- (2) Administrative support; e.g., travel costs, hosting of meetings, and secretarial functions.
- (3) Technical support; e.g., cooperative testing for standards evaluation and participation of agency personnel in the activities of voluntary consensus standards bodies.
- (4) Joint planning with voluntary consensus standards bodies to promote the identification and development of needed standards.
- (5) Participation of agency personnel.

d. Must agency participants be authorized?

Agency employees who, at Government expense, participate in standards activities of voluntary consensus standards bodies on behalf of the agency must do so as specifically authorized agency representatives. Agency support for, and participation by agency personnel in, voluntary consensus standards bodies must be in compliance with applicable laws and regulations. For example, agency support is subject to legal and budgetary authority and availability of funds. Similarly, participation by agency employees (whether or not on behalf of the agency) in the activities of voluntary consensus standards bodies is subject to the laws and regulations that apply to participation by federal employees in the activities of outside organizations. While we anticipate that participation in a committee that is developing a standard would generally not raise significant issues, participation as an officer, director, or trustee of an organization would raise more significant issues. An agency should involve its agency ethics officer, as appropriate, before authorizing support for or participation in a voluntary consensus standards body.

e. Does agency participation indicate endorsement of any decisions reached by voluntary consensus standards bodies?

Agency participation in voluntary consensus standards bodies does not necessarily connote agency agreement with, or endorsement of, decisions reached by such organizations.

f. Do agency representatives participate equally with other members?

Agency representatives serving as members of voluntary consensus standards bodies should participate actively and on an equal basis with other members, consistent with the procedures of those bodies, particularly in matters such as establishing priorities, developing procedures for preparing, reviewing, and approving standards, and developing or adopting new standards. Active participation includes full involvement in discussions and technical debates, registering of opinions and, if selected, serving as chairpersons or in other official capacities. Agency representatives may vote, in accordance with the procedures of the voluntary consensus standards body, at each stage of the standards development process unless prohibited from doing so by law or their agencies.

g. Are there any limitations on participation by agency representatives?

In order to maintain the independence of voluntary consensus standards bodies, agency representatives must refrain from involvement in the internal management of such organizations (e.g., selection of salaried officers and employees, establishment of staff salaries, and administrative policies). Agency representatives must not dominate such bodies, and in any case are bound by voluntary consensus standards bodies' rules and procedures, including those regarding domination of proceedings by any individual. Regardless, such agency employees must avoid the practice or the appearance of undue influence relating to their agency representation and activities in voluntary consensus standards bodies.

h. Are there any limits on the number of federal participants in voluntary consensus standards bodies?

The number of individual agency participants in a given voluntary standards activity should be kept to the minimum required for effective representation of the various program, technical, or other concerns of federal agencies.

i. Is there anything else agency representatives should know?

This Circular does not provide guidance concerning the internal operating procedures that may be applicable to voluntary consensus standards bodies because of their relationships to agencies under this Circular. Agencies should, however, carefully consider what laws or rules may apply in a particular instance because of these relationships. For example, these relationships may involve the Federal Advisory Committee Act, as amended (5 U.S.C. App. I), or a provision of an authorizing statute for a particular agency.

j. What if a voluntary consensus standards body is likely to develop an acceptable, needed standard in a timely fashion?

If a voluntary consensus standards body is in the process of developing or adopting a voluntary consensus standard that would likely be lawful and practical for an agency to use, and would likely be developed or adopted on a timely basis, an agency should not be developing its own government-unique standard and instead should be participating in the activities of the voluntary consensus standards body.

8. What Is The Policy On Conformity Assessment?

Section 12(b) of the Act requires NIST to coordinate Federal, State, and local standards activities and conformity assessment activities with private sector standards activities and conformity assessment activities, with the goal of eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures. To ensure effective coordination, the Secretary of Commerce must issue guidance to the agencies.

MANAGEMENT AND REPORTING OF STANDARDS USE

9. What Is My Agency Required to Report?

a. As required by the Act, your agency must report to NIST, no later than December 31 of each year, the decisions by your agency in the previous fiscal year to use government-unique standards in lieu of voluntary consensus standards. If no voluntary consensus standard exists, your agency does not need to report its use of government-unique standards. (In addition, an agency is not required to report on its use of other standards. See Section 6g.) Your agency must include an explanation of the reason(s) why use of such voluntary consensus standard would be inconsistent with applicable law or otherwise impractical, as described in Sections 11b(2), 12a(3), and 12b(2) of this Circular. Your agency must report in accordance with format instructions issued by NIST.

b. Your agency must report to NIST, no later than December 31 of each year, information on the nature and extent of agency participation in the development and use of voluntary consensus standards from the previous fiscal year. Your agency must report in accordance with format instructions issued by NIST. Such reporting must include the following:

- (1) The number of voluntary consensus standards bodies in which there is agency participation, as well as the number of agency employees participating.
- (2) The number of voluntary consensus standards the agency has used since the last report, based on the procedures set forth in sections 11 and 12 of this Circular.
- (3) Identification of voluntary consensus standards that have been substituted for government-unique standards as a result of an agency review under section 15b(7) of this Circular.
- (4) An evaluation of the effectiveness of this policy and recommendations for any changes.

c. No later than the following January 31, NIST must transmit to OMB a summary report of the information received.

10. How Does My Agency Manage And Report Its Development and Use Of Standards?

Your agency must establish a process to identify, manage, and review your agency's development and use of standards. At minimum, your agency must have the ability to (1) report to OMB through NIST on the agency's use of government-unique standards in lieu of voluntary consensus standards, along with an explanation of the reasons for such non-usage, as described in section 9a, and (2) report on your agency's participation in the development and use of voluntary consensus standards, as described in section 9b. This policy establishes two ways, category based reporting and transaction based reporting, for agencies to manage and report their use of standards. Your agency must report all uses of standards in one or both ways.

11. What Are The Procedures For Reporting My Agency's Use Of Standards In Regulations?

Your agency should use transaction based reporting if your agency issues regulations that use or reference standards. If your agency is issuing or revising a regulation that contains a standard, your agency must follow these procedures:

a. Publish a request for comment within the preamble of a Notice of Proposed Rulemaking (NPRM) or Interim Final Rule (IFR). Such request must provide the appropriate information, as follows:

(1) When your agency is proposing to use a voluntary consensus standard, provide a statement which identifies such standard.

(2) When your agency is proposing to use a government-unique standard in lieu of a voluntary consensus standard, provide a statement which identifies such standards and provides a preliminary explanation for the proposed use of a government-unique standard in lieu of a voluntary consensus standard.

(3) When your agency is proposing to use a government-unique standard, and no voluntary consensus standard has been identified, a statement to that effect and an invitation to identify any such standard and to explain why such standard should be used.

b. Publish a discussion in the preamble of a Final Rulemaking that restates the statement in the NPRM or IFR, acknowledges and summarizes any comments received and responds to them, and explains the agency's final decision. This discussion must provide the appropriate information, as follows:

(1) When a voluntary consensus standard is being used, provide a statement that identifies such standard and any alternative voluntary consensus standards which have been identified.

(2) When a government-unique standard is being used in lieu of a voluntary consensus standard, provide a statement that identifies the standards and explains why using the voluntary consensus standard would be inconsistent with applicable law or otherwise impractical. Such explanation must be transmitted in accordance with the requirements of Section 9a.

(3) When a government-unique standard is being used, and no voluntary consensus standard has been identified, provide a statement to that effect.

12. What Are The Procedures For Reporting My Agency's Use Of Standards In Procurements?

To identify, manage, and review the standards used in your agency's procurements, your agency must either report on a categorical basis or on a transaction basis.

a. How does my agency report the use of standards in procurements on a categorical basis?

Your agency must report on a category basis when your agency identifies, manages, and reviews the use of standards by group or category. Category based reporting is especially useful when your agency either conducts large procurements or large numbers of

procurements using government-unique standards, or is involved in long-term procurement contracts which require replacement parts based on government-unique standards. To report use of government-unique standards on a categorical basis, your agency must:

- (1) Maintain a centralized standards management system that identifies how your agency uses both government-unique and voluntary consensus standards.
- (2) Systematically review your agency's use of government-unique standards for conversion to voluntary consensus standards.
- (3) Maintain records on the groups or categories in which your agency uses government-unique standards in lieu of voluntary consensus standards, including an explanation of the reasons for such use, which must be transmitted according to Section 9a.
- (4) Enable potential offerors to suggest voluntary consensus standards that can replace government-unique standards.

b. How does my agency report the use of standards in procurements on a transaction basis?

Your agency should report on a transaction basis when your agency identifies, manages, and reviews the use of standards on a transaction basis rather than a category basis. Transaction based reporting is especially useful when your agency conducts procurement mostly through commercial products and services, but is occasionally involved in a procurement involving government-unique standards. To report use of government-unique standards on a transaction basis, your agency must follow the following procedures:

- (1) In each solicitation which references government-unique standards, the solicitation must:
 - (i) Identify such standards.
 - (ii) Provide potential offerors an opportunity to suggest alternative voluntary consensus standards that meet the agency's requirements.
- (2) If such suggestions are made and the agency decides to use government-unique standards in lieu of voluntary consensus standards, the agency must explain in its report to OMB as described in Section 9a why using such voluntary consensus standards is inconsistent with applicable law or otherwise impractical.

c. For those solicitations that are for commercial-off-the-shelf products (COTS), or for products or services that rely on voluntary consensus standards or non-consensus standards developed in the private sector, or for products that otherwise do not rely on government-unique standards, the requirements in this section do not apply.

AGENCY RESPONSIBILITIES

13. What Are The Responsibilities Of The Secretary Of Commerce?

The Secretary of Commerce:

- a. Coordinates and fosters executive branch implementation of this Circular and, as appropriate, provides administrative guidance to assist agencies in implementing this Circular including guidance on identifying voluntary consensus standards bodies and voluntary consensus standards.
- b. Sponsors and supports the Interagency Committee on Standards Policy (ICSP), chaired by the National Institute of Standards and Technology, which considers agency views and advises the Secretary and agency heads on the Circular.
- c. Reports to the Director of OMB concerning the implementation of the policy provisions of this Circular.
- d. Establishes procedures for agencies to use when developing directories described in Section 15b(5) and establish procedures to make these directories available to the public.
- e. Issues guidance to the agencies to improve coordination on conformity assessment in accordance with section 8.

14. What Are The Responsibilities Of The Heads Of Agencies?

The Heads of Agencies:

- a. Implement the policies of this Circular in accordance with procedures described.
- b. Ensure agency compliance with the policies of the Circular.
- c. In the case of an agency with significant interest in the use of standards, designate a senior level official as the Standards Executive who will be responsible for the agency's implementation of this Circular and who will represent the agency on the ICSP.
- d. Transmit the annual report prepared by the Agency Standards Executive as described in Sections 9 and 15b(6).

15. What Are The Responsibilities Of Agency Standards Executives?

An Agency Standards Executive:

- a. Promotes the following goals:

- (1) Effective use of agency resources and participation.
 - (2) The development of agency positions that are in the public interest and that do not conflict with each other.
 - (3) The development of agency positions that are consistent with administration policy.
 - (4) The development of agency technical and policy positions that are clearly defined and known in advance to all federal participants on a given committee.
- b. Coordinates his or her agency's participation in voluntary consensus standards bodies by:
- (1) Establishing procedures to ensure that agency representatives who participate in voluntary consensus standards bodies will, to the extent possible, ascertain the views of the agency on matters of paramount interest and will, at a minimum, express views that are not inconsistent or in conflict with established agency views.
 - (2) To the extent possible, ensuring that the agency's participation in voluntary consensus standards bodies is consistent with agency missions, authorities, priorities, and budget resources.
 - (3) Ensuring, when two or more agencies participate in a given voluntary consensus standards activity, that they coordinate their views on matters of paramount importance so as to present, whenever feasible, a single, unified position and, where not feasible, a mutual recognition of differences.
 - (4) Cooperating with the Secretary in carrying out his or her responsibilities under this Circular.
 - (5) Consulting with the Secretary, as necessary, in the development and issuance of internal agency procedures and guidance implementing this Circular, including the development and implementation of an agency-wide directory identifying agency employees participating in voluntary consensus standards bodies and the identification of voluntary consensus standards bodies.
 - (6) Preparing, as described in Section 9, a report on uses of government-unique standards in lieu of voluntary consensus standards and a report on the status of agency standards policy activities.
 - (7) Establishing a process for ongoing review of the agency's use of standards for purposes of updating such use.
 - (8) Coordinating with appropriate agency offices (e.g., budget and legal offices) to ensure that effective processes exist for the review of proposed agency support for, and participation in, voluntary consensus standards bodies, so that agency support and participation will comply with applicable laws and regulations.

SUPPLEMENTARY INFORMATION

16. When Will This Circular Be Reviewed?

This Circular will be reviewed for effectiveness by the OMB three years from the date of issuance.

17. What Is The Legal Effect Of This Circular?

Authority for this Circular is based on 31 U.S.C. 1111, which gives OMB broad authority to establish policies for the improved management of the Executive Branch. This Circular is intended to implement Section 12(d) of P.L. 104-113 and to establish policies that will improve the internal management of the Executive Branch. This Circular is not intended to create delay in the administrative process, provide new grounds for judicial review, or create new rights or benefits, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, or its officers or employees.

18. Do You Have Further Questions?

For information concerning this Circular, contact the Office of Management and Budget, Office of Information and Regulatory Affairs: Telephone 202/395-3785.

V. Conformity Assessment Guidance Document

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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 Airport, VOR RWY 14, Amdt 3
Gaithersburg, MD, Montgomery County Airport, NDB RWY 14, Amdt 1
Gaithersburg, MD, Montgomery County Airport, RNAV RWY 14, Orig
Gaithersburg, MD, Montgomery County Airport, 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 Airport, VOR-A, Amdt 4
Westminster, MD, Clearview Airport, 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 NTAA, 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 NTAA 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 NTAA. 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 NTAA'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 "supplier's 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 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



NIST Technical Publications

Periodical

Journal of Research of the National Institute of Standards and Technology—Reports NIST research and development in metrology and related fields of physical science, engineering, applied mathematics, statistics, biotechnology, and information technology. Papers cover a broad range of subjects, with major emphasis on measurement methodology and the basic technology underlying standardization. Also included from time to time are survey articles on topics closely related to the Institute's technical and scientific programs. Issued six times a year.

Nonperiodicals

Monographs—Major contributions to the technical literature on various subjects related to the Institute's scientific and technical activities.

Handbooks—Recommended codes of engineering and industrial practice (including safety codes) developed in cooperation with interested industries, professional organizations, and regulatory bodies.

Special Publications—Include proceedings of conferences sponsored by NIST, NIST annual reports, and other special publications appropriate to this grouping such as wall charts, pocket cards, and bibliographies.

National Standard Reference Data Series—Provides quantitative data on the physical and chemical properties of materials, compiled from the world's literature and critically evaluated. Developed under a worldwide program coordinated by NIST under the authority of the National Standard Data Act (Public Law 90-396). NOTE: The Journal of Physical and Chemical Reference Data (JPCRD) is published bimonthly for NIST by the American Institute of Physics (AIP). Subscription orders and renewals are available from AIP, P.O. Box 503284, St. Louis, MO 63150-3284.

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Technical Notes—Studies or reports which are complete in themselves but restrictive in their treatment of a subject. Analogous to monographs but not so comprehensive in scope or definitive in treatment of the subject area. Often serve as a vehicle for final reports of work performed at NIST under the sponsorship of other government agencies.

Voluntary Product Standards—Developed under procedures published by the Department of Commerce in Part 10, Title 15, of the Code of Federal Regulations. The standards establish nationally recognized requirements for products, and provide all concerned interests with a basis for common understanding of the characteristics of the products. NIST administers this program in support of the efforts of private-sector standardizing organizations.

Order the following NIST publications—FIPS and NISTIRs—from the National Technical Information Service, Springfield, VA 22161.

Federal Information Processing Standards Publications (FIPS PUB)—Publications in this series collectively constitute the Federal Information Processing Standards Register. The Register serves as the official source of information in the Federal Government regarding standards issued by NIST pursuant to the Federal Property and Administrative Services Act of 1949 as amended, Public Law 89-306 (79 Stat. 1127), and as implemented by Executive Order 11717 (38 FR 12315, dated May 11, 1973) and Part 6 of Title 15 CFR (Code of Federal Regulations).

NIST Interagency or Internal Reports (NISTIR)—The series includes interim or final reports on work performed by NIST for outside sponsors (both government and nongovernment). In general, initial distribution is handled by the sponsor; public distribution is handled by sales through the National Technical Information Service, Springfield, VA 22161, in hard copy, electronic media, or microfiche form. NISTIR's may also report results of NIST projects of transitory or limited interest, including those that will be published subsequently in more comprehensive form.

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