

Elise M. Owen

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PROFESSIONAL EXPERIENCE

Standards Executive/Environmental Protection Specialist GS-0028-15
United States Environmental Protection Agency
1200 Pennsylvania Ave NW, Washington, DC 20460

2015 – Present
40 hours per week

The mission of the United States Environmental Protection Agency (EPA) is to protect human health and the environment. EPA undertakes various activities to accomplish this mission, including developing and enforcing regulations, giving grants, studying environmental issues and sponsoring partnerships

IMPLEMENTING NTTAA AND OMB A-119: Serves as EPA's Standards Executive, responsible for EPA's implementation of the *Office and Management and Budget Circular A-119: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities* (OMB A-119). Advises EPA Offices on matters relating to implementation of the National Technology Transfer and Advancement Act (NTTAA) and OMB A-119; develops EPA's annual NTTAA reporting. Under the NTTAA and OMB A-119, federal agencies are required to report annually: (1) A summary of the agency's activities undertaken to carry out the provisions of OMBA-119; and (2) The agency's use of Government-Unique Standards in lieu of Voluntary Consensus Standards (VCS), along with an explanation for the reasons for such usage.

PROGRAM DEVELOPMENT: Established new ways to organize EPA resources to facilitate efficient coordination across the agency, and to support implementation of the NTTAA and OMB A-119. This includes establishing an internal NTTAA Community of Practice consisting of over 150 working-level EPA staff who are involved in the development and/or use of private sector standards and conformity assessment activities. Established an internal process for EPA staff participation in private sector standards development activities, consistent with the NTTAA, OMB A-119 and other federal laws, regulations and policies.

TECHNICAL AND POLICY BRIEFINGS: Develops, reviews and edits briefing papers, reports, and policy papers on complex technical and policy topics. Staffs Assistant Administrator and other senior leadership participation in meetings with private sector stakeholders. Prepares and delivers briefings and formal presentations to senior leadership and staff within EPA, as well as to private sector organizations.

OUTREACH AND COLLABORATION WITHIN EPA: Conducted outreach to over 50 Division Directors across EPA to discuss their priorities, objectives and concerns as they relate to the NTTAA and OMB A-119. Developed a set of EPA-wide goals for the implementation of the NTTAA and OMB A-119 based on this outreach.

OUTREACH AND COLLABORATION WITH PRIVATE SECTOR: Builds networks and collaboration between EPA and the U.S. standards system. The U.S. standards system is led by the private sector and consists of 3.5 million technical professionals, representing 125,000 companies as well as academia, government, non-governmental organizations (NGOs) and other interests. These technical professionals work through over 250 standards bodies to develop over 100,000 private sector standards used in the U.S. market place.

INTERAGENCY RELATIONSHIPS: Represents EPA on the Interagency Committee on Standards Policy (ICSP). The ICSP provides a forum for coordination on policies related to Federal participation and use of standards and conformity assessment consistent with the NTTAA and OMB A-119. The ICSP advises heads of Federal agencies in matters relating to the implementation of OMB A-119 and reports to the Secretary of Commerce through the Director of the National Institute of Standards and Technology (NIST).

**Associate Vice President
Advanced Medical Technology Association**
701 Pennsylvania Ave NW, Suite 800, Washington, DC 20004

2013-2015
40 hours per week

The Advanced Medical Technology Association (AdvaMed) leads efforts to advance medical technology to achieve healthier lives and economies. AdvaMed represents 80% of medical technology firms in the U.S. and acts as the common voice for companies producing medical devices, diagnostic products, and health information systems. Advocate on a global basis for the highest ethical standards, timely patient access to safe and effective products, and economic policies that reward value creation.

IMPLEMENTING NTTAA AND OMB A-119: Organized and delivered training and information exchange programs in the People's Republic of China and Taiwan to advance government use of voluntary consensus standards and conformity assessment procedures as the basis for regulation.

STANDARDS DEVELOPMENT: Led a 15-month initiative to develop a standard for ethical business practices to be adopted by medical device companies operating in China. Coordinated feedback from 30+ heads of business in China, as well as from 50+ subject matter experts, gaining their support for the project, defending specific approaches, facilitating negotiation to resolve stakeholder disagreement, and delivering presentations to inform internal and external audiences of the initiative.

SUPPORTING DOCUMENTS FOR REGULATORY DEVELOPMENT PROCESS: Led industry advocacy in response to a major overhaul to China's medical device regulatory system. This overarching regulation brought sweeping top-to-bottom changes resulting in new/revised requirements, policies and regulations that impact nearly every aspect of product review and approval. I brought together U.S. and foreign Subject Matter Experts to develop and provide policy papers, comparative analysis of U.S./international standards and regulations, and other supporting documents to support the regulatory development process and to encourage alignment with global standards and best practices.

TECHNICAL AND POLICY BRIEFINGS: Developed, reviewed and edited briefing papers, reports, and policy papers on complex technical and policy topics. Staffed CEO's participation Asia Pacific Economic Cooperation (APEC), preparing materials for meetings with senior government leaders (e.g. President of Vietnam, Korean Trade Minister, U.S. Trade Representative, etc.) and for events with industry leaders, technical experts, and public interest groups. Prepared and delivered briefings and formal presentations to Board of Directors (company CEO's), government leaders, technical experts, representatives of regulatory agencies and internal audiences.

MEDIA INTERACTION: Frequently cited as Subject Matter Expert (SME) on technical and regulatory issues trade issues in mainstream news and trade publications. Regularly cited in business and political publications like "Politico" and "Bloomberg" as well as trade publications.

TEAM BUILDING: Coalesced multiple industry associations and companies to work as a team and to align priorities. In December 2014 we gained meaningful commitments on shared priorities from the heads of two U.S. federal agencies and a Vice Premier in China.

**Director, International Development
American National Standards Institute**
1899 L Street NW, 11th Floor, Washington, DC 20036

2006-2013
40 hours per week

As coordinator of the U.S. standards and conformity assessment systems, ANSI supports implementation of the NTTAA and OMB A-119 accrediting hundreds of standards developing organizations and conformity assessment bodies. These standards and conformity assessment programs have been incorporated by reference into thousands of federal government programs, including EPA regulations programs such as Energy Star and Water Sense, federal regulations and government purchasing.

BROAD STAKEHOLDER ENGAGEMENT: Advanced priority policies and programs by engaging and coordinating ANSI's membership: U.S. government agencies (EPA and more than 35 other federal, state and local government agencies), standards

development organizations, conformity assessment bodies, industry, academia, consumer, health and environmental organizations. Negotiated with these disparate interest groups to reach consensus on key policies and to gain support for new projects, policies and initiatives.

OUTREACH AND COLLABORATION: Performed outreach to external groups (government, industry groups, NGOs) in the U.S. and internationally to promote new programs, policies and initiatives and to explain (and, if needed, defend) U.S. approaches for standardization and conformity assessment.

PROGRAM DEVELOPMENT: Built up international development program, identifying and finding solutions for resource implementation issues. Devised annual program plan and ensured resources were maximized for short and long-term effect. Maintained communication with ANSI members to ensure proposed program elements reflected member priorities and added value to the efforts of the broader U.S. standards and conformity assessment.

BUDGET & FUNDING: Planned and executed the International Development Program's budget, as well as the budgets of numerous government grants and private sector consulting contracts. Managed the program budget, which included departmental Profit & Loss (P&L). Managed/projected revenue streams from multiple projects and ensuring that government grants, contract and cooperative agreements were carried out in accordance with U.S. government policies.

IMPLEMENTING NTTAA AND OMB A-119: Developed and delivered training programs, written papers and oral presentations on the NTTAA and OMB A-119 to foreign governments across five continents. Implemented a grant from the National Institute for Standards and Technology (NIST) to establish a multilingual website (www.standardsportal.org) to promote global harmonization and implementation of the principles of NTTAA and OMB A-119. This project was carried out in partnership with the governments of China, India and Korea.

GOVERNMENT GRANTS AND CONTRACTS: Developed successful proposals for government grants, contracts and cooperative agreements ranging from \$5k to \$5million. Applied project management principles to ensure that projects were consistently delivered on time and on budget.

DEVELOPING VOLUNTARY CONSENSUS STANDARDS/CONFORMITY ASSESSMENT PROCEDURES: Working under grants from EPA and the United Nations Foundation, led an initiative to develop international standards and conformity assessment procedures for clean cookstoves. Gathered more than 50 global technical experts who unanimously signed on to an International Organization for Standardization (ISO) document outlining standards and testing procedures for clean cookstoves. This laid the foundation for ongoing international standardization work that continues today.

PROJECT MANAGEMENT: Built a project management capability within ANSI, creating business process documents, document management, financial tracking systems, and supporting staff in earning PMP certification. Developed project priorities, tracked project budgets and resource requirements, set short- and long-term goals, coordinated project activities with my internal program staff and external organizations, monitored project progress and evaluated outcomes. Conducted congressional outreach to raise awareness of these projects; obtaining a congressional letter of support from Representative Jim McDermott (Washington's 7th District).

PERSONNEL SUPERVISION: Led team of full-time employees, consultants and contractors. Supervised activities, provided recommendations for ratings, and tracked performance. Completed performance management tasks, including clearly communicating performance expectations throughout the appraisal period, holding employees accountable, making meaningful distinctions in performance and rewarding excellent performance, promoting employee development and training, and promptly addressing performance and conduct issues.

International Trade Specialist GS-1140-11

2004-2006

United States Department of Commerce, International Trade Administration

40 hours per week

1401 Constitution Ave. NW, Washington DC, DC 20230

The International Trade Administration (ITA) strengthens the competitiveness of U.S. industry, promotes trade and investment, and ensures fair trade through the rigorous enforcement of trade laws and agreements.

ISSUE PAPERS ON ENVIRONMENTAL POLICIES Conducted analysis and of foreign environmental regulations, comparing to domestic regulations, outlining impact on bilateral and multilateral trade agreements, and presenting recommendations to senior leadership. This included analysis of foreign environmental regulations such as China's new chemical notification requirements (similar to EPA's Toxic Substances Control Act (TSCA)) and Restriction of Hazardous Substances (RoHS) directives.

INTERNATIONAL TRADE SME: Served as specialist on international trade topics relating to standards, conformity assessment and regulatory coordination. Promoted the principles of the NTTAA and OMB A-119 as well as the U.S. Administrative Procedures Act.

INTERAGENCY RELATIONSHIPS: Built relationships across the federal government (including federal trade agencies, regulatory and government procurement agencies) through informal collaboration on key issues and through participation in interagency meetings such as the Interagency Committee on Standards Policy (ICSP) coordinated by NIST and the Trade Policy Subcommittee coordinated by the Office of the U.S. Trade Representative.

BRIEFINGS ON COMPLEX TOPICS: Synthesized complex technical and policy topics to develop succinct, impactful and actionable briefings, policy papers and reports for Commerce Secretary, staff-level government representatives, industry groups and other technical and non-technical audiences.

STANDARDS COORDINATION: Coordinated standards activities across the International Trade Administration, managing monthly meetings of offices throughout the agency to share information on standards, conformity assessment and regulatory issues that impact trade. Brought together more than 150 representatives of the U.S. and Chinese governments and industry to organize the U.S. – China Standards and Conformity Assessment Workshop in Beijing, China.

EDUCATION AND CERTIFICATIONS

Certification: Project Management Professional (PMP) Project Management Institute (PMI) (Newtown Square, PA)	2012
Master of Business Administration University of Hawai'i at Mānoa (Honolulu, HI) <i>Concurrently earned a Management Certificate from the Japan-America Institute of Management Sciences (JAIMS)</i>	2003
Bachelor of Liberal Arts Regents College (Albany, NY) <i>Regents College is now called Excelsior College.</i>	2000
Certification: Mandarin Chinese and Japanese - Defense Language Proficiency Test Defense Language Institute (Monterey, CA)	2000