

**FDA STAFF MANUAL GUIDES, VOLUME IV - AGENCY PROGRAM
DIRECTIVES**

COMMON STANDARDS

DEVELOPMENT AND USE OF STANDARDS

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1. PURPOSE

This Staff Manual Guide (SMG) establishes Agency-wide policies and procedures related to standards management to assure a unified approach to standards within the U.S. Food and Drug Administration (FDA). This SMG:

- details the responsibilities of FDA employees for their participation in non-governmental organizations (NGOs), including voluntary consensus standards bodies and intergovernmental international standards organizations engaged in the development of standards related to FDA regulated products;
- describes procedures related to the establishment of a Standards Management Program (SMP) within FDA;
- describes the responsibilities of the Office of the Chief Scientist (OCS) in managing the SMP and the responsibilities of the FDA Standards Committee in providing cross-Agency policy direction to the SMP; and,
- details the procedures associated with executing these responsibilities.
- This Guide is based on and supplements the information provided by statute in the National Technology Transfer and Advancement Act (NTTAA; PL 104-113), by OMB directive (OMB A-119), by regulation (21 CFR 10.95, Participation in outside standard-setting activities) and the FDA Policy on Standards (“Policy regarding the development and use of standards with respect to international harmonization of regulatory requirements and guidelines”, 60 FR 53078 (Oct. 11, 1995)).

2. BACKGROUND

Congress passed the National Technology Transfer and Advancement Act (NTTAA) (PL104-113), codifying an Office of Management and Budget (OMB) directive (OMB Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities) that had previously been issued several times, dating back to the late 1970s. The NTTAA and OMB A119 establish federal government policies to improve the internal management of the Executive Branch by directing agencies to use voluntary consensus standards in lieu of government-unique standards except where inconsistent with law or otherwise impractical.

The policies of Circular A-119 are intended to: (1) encourage federal agencies to benefit from the expertise of the private sector; (2) promote federal agency participation in such bodies to ensure creation of standards that are useable by federal agencies; and (3) reduce reliance on government-unique standards where an existing voluntary standard would suffice.

The NTTAA gives the agencies discretion to use other standards, e.g. government-unique standards, in lieu of voluntary consensus standards where use of the latter would be “inconsistent with applicable law or otherwise impractical.” However, in such cases, the head of an agency or department must send to OMB, through the National Institute of Standards and Technology (NIST), “an explanation of the reasons for using such standards.” Rationales provided must be explicit and demonstrative of why a voluntary consensus standard is not used and can be based upon cost concerns, technology issues, performance standards, timing (need vs. availability), and policy matters among other factors.

The development and use of standards have been integral to the execution of the mission of FDA since its establishment. Standard-setting activities include matters such as the development of performance characteristics, testing methodology, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. FDA staff has historically participated in a range of standard setting activities outside the Agency. As noted in 21 CFR 10.95 (a), “FDA encourages employee participation in outside standard-setting activities that are in the public interest.”

FDA participates in the development of and uses standards developed by outside organizations in every Center and at every level in the organization. As the complexity of products for which FDA has jurisdiction increases, the interaction among Centers to manage the risks posed by these products must also increase. Information on “standards of performance” that FDA expects these products to achieve is of great importance to the regulated industry and

in improving conformity assessment. FDA is mindful of the considerable time, knowledge and experience necessary to develop a useful standard for these complex and evolving products. Likewise, the uniqueness and novelty of many products must allow for development of appropriate and flexible standards. It is, therefore, challenging to determine in which standards group[s] it is appropriate for FDA to participate, especially since competing standards organizations often exist.

Effective and meaningful participation in the organizations that develop standards for the products FDA regulates is critical. Encouraging these organizations to develop the standards FDA needs advances the interests of both the Agency and the industry. Information exchange to encourage coordination of technical discussions and information dissemination can enable more effective engagement with our stakeholders and develop efficiencies in the standards setting processes. In addition, FDA can take advantage of the management resources of standards-developing organizations (SDOs) to create standards, thereby better using limited FDA resources. FDA can exercise leadership in these SDOs to encourage development of the best possible standards and improve technical requirements. The Agency always has the option to augment voluntary consensus standards with additional recommendations through publication of Guidance.

3. POLICY

3.1 Implementing the previously mentioned legislation, regulation and policy statement, FDA adopts, by reference, either in their entirety or in part, standards developed through non-government organizations (NGOs) and intergovernmental international standards organizations in lieu of internally developed government-unique standards and guidance, when those standards represent the most appropriate standards for a specific purpose and are not in conflict with US statute or regulation.

3.2 FDA will preferentially use internationally harmonized standards – standards developed by organizations typically involving representatives from many countries - in their processes, when those standards represent the most appropriate standards for a specific purpose and are not in conflict with US statute or regulation.

3.3 Guidance documents published by FDA will, wherever appropriate, reference the standards, including test methods, practices, guides, and material specifications, developed through voluntary consensus processes with the regulated industry and other interested parties. Wherever appropriate, these standards will be adopted in lieu of methods developed solely within FDA.

3.4 Where appropriate, FDA encourages sponsors of product applications and manufacturers to cite appropriate voluntary consensus standards in support of their applications and manufacturing process documents. Where the use of voluntary consensus standards would be inconsistent with applicable law or otherwise impractical, citation of other non-government standards should be considered.

3.5 Where FDA decides to incorporate voluntary consensus or other non-government standards/guidelines into FDA regulations or guidance, it does so under FDA's rule on promulgation of regulations (21 CFR 10.40), other procedural regulations in 21 CFR, or under its good guidance practices regulations under 21 CFR 10.115. Unless promulgated by regulation, the use of these standards is voluntary by the industry or government.

3.6 For Medical Devices, as described in statute, FDA shall, by publication in the Federal Register, recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket submission requirement or other requirement under this Act to which such standard is applicable. (Federal Food, Drug, and Cosmetic Act Section 514(c) (1) (A) (21 U.S.C. 360d))

3.7 Engagement by an FDA employee as the liaison to activities of a standards development organization does not connote FDA agreement with, or endorsement of decisions reached or standards developed. The FDA employee remains obligated to represent and support Agency policy, practices, and priorities while engaged in these activities.

FDA supports this policy with increased staff training and encourages participation in non-government standards committees and intergovernmental international standards organizations when such is in the public interest, consistent with the Agency mission, and compatible with FDA priorities and available resources.

4. DEFINITIONS

4.1 Standard – For the purposes of this SMG, a standard is a document approved by a standards development organization (see 7.6) that provides for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method.

4.1.1 The term “standard” or “technical standard” as defined in OMB Circular No. A-119 and cited in the Act (PL 104-113), 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. (OMB Circular A-119)

4.1.2 The term "standard" does not include the following (OMB Circular A-119):

1. Professional standards of personal conduct.
2. Institutional codes of ethics.

4.1.3 **"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. (OMB Circular A-119)

4.1.4 **"Non-government standard"** is a standard as defined above that is developed by a private sector association, organization or technical society which plans, develops, establishes or coordinates standards, specifications, handbooks, or related documents. (OMB Circular A-119)

4.1.5 **Voluntary Consensus Standards** - For purposes of this Guide, "voluntary consensus standards" are standards as defined above 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 Guide, "technical standards" that are developed or adopted by voluntary consensus standard bodies is an equivalent term. (OMB Circular A-119)

4.1.6 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 United States government for its own uses.
3. Standards mandated by law, such as those contained in the United States Pharmacopeia, as referenced in 21 U.S.C. 351.
4. Standards adopted by treaty through such intergovernmental international standard-setting organizations such as Codex Alimentarius, World Organization for Animal Health (OIE), International Plant Protection Convention (IPPC), etc.

4.2 Voluntary consensus standards bodies - Domestic or international organizations that plan, develop, establish, or coordinate voluntary consensus standards using agreed-upon procedures. For purposes of this SMG, "voluntary, private sector, consensus standards bodies," as cited in National Technology Transfer and Advancement Act, is an equivalent term. The Act and OMB Circular A-119 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 World Trade Organization (WTO) to have the following attributes:

1. Due Process, whereby any person or entity with a direct and material interest has a right to participate by (i) expressing a position on the proposed Standard and its basis, (ii) having that position considered by the consensus body, and (iii) having the right to appeal.
2. Openness, whereby participation shall be open to all parties who are directly and materially affected by the Standard and elect to participate in the consensus process.
3. Balance and Lack of Dominance, whereby the consensus body invites the participation in the consensus process by representatives of directly and materially affected interest categories, and is not dominated by any single person or interest category.

4. Public Notice, whereby the proposed Standard (and any revision or reaffirmation thereof) shall be made available and publicly announced for review and comment by directly and materially affected parties.
5. Consideration of Views and Objections, whereby comments submitted by voting members of the consensus body and by any public review commenter must be evaluated, responded to and, if appropriate, incorporated into the draft Standard.
6. Consensus, whereby substantial agreement on the Standard has been reached by directly and materially affected interest categories. Consensus 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.

4.3 Voluntary Consensus Process - Standards development procedures (such as the ANSI Procedures for the Development and Coordination of American National Standards Essential Requirements: Due-process requirements for American National Standards) that provide for process characteristics as described in 4.2.

4.4 Recognition/Use/Adoption – These terms are often used as synonyms but have specific meaning when referring to particular portions of the Federal Food, Drug, and Cosmetic Act or FDA regulations.

4.4.1 Use – The general term used in this SMG to describe FDA’s citation of standards, either in whole or in part, in regulation or guidance, incorporation into policy statements, etc.

4.4.2 Recognition – Specific term derived from the medical device legislation, specifically FD&C Act 514(c), describing the process for FDA identification of standards that manufacturers of medical devices may cite to meet relevant requirements in the FD&C Act.

4.4.3 Adoption – Specific term used in certain FDA regulations and Guidance to address the standards developed for foods, cosmetics, etc.

4.5 Liaison – FDA staff members who participate in domestic and international, government and non-government, standards committee activities, as well as other professional committee programs relating to the FDA mission, including committees of organizations such as WHO, GHTF, OECD, Codex Alimentarius, ICH, PAHO, FAO, PIC/S, etc. A liaison may be

an FDA representative on a U.S. delegation to an international standard-setting body and thus serve with representatives from other federal agencies, as well as private sector groups. For the purposes of this SMG, the terms “liaison”, “expert”, and “delegate” are equivalent.

4.6 Standards Developing Organization (SDO) – An entity that develops or sponsors the development of voluntary standards for use or information by any person involved in the manufacture, distribution, sale, or use of products or services or the legal regulation of such products or services. This definition includes, but is not limited to voluntary consensus standards bodies, as defined in Section 4.2.

4.7 Committee - Any board, commission, council, conference, panel, task force, or other similar group or any subcommittee or other subgroup thereof.

4.8 Standards Committee - Any governmental or private sector group that exercises policy control over standards activities, or that administers one or more standards programs, or that develops or approves or promulgates standards. Examples are committees of the American National Standards Institute (ANSI), ASTM International (also known as the American Society for Testing and Materials), and of professional and scientific organizations such as the Institute for Electrical and Electronics Engineers (IEEE) or the American Society of Mechanical Engineers (ASME).

4.9 Professional Committee - Any committee concerned with the accomplishment of professional, technical, or scientific objectives other than the development of standards.

4.10 National (or Domestic) Standards Committee - Any governmental or private sector committee concerned primarily with standards that apply within the United States or with the development of positions to be put forth for consideration in international arenas on behalf of U.S. interests. Examples of the latter include U.S. Working Groups for the International Organization of Legal Metrology (OIML), the U.S. National Committee for the International Electrotechnical Commission (USNC/IEC) and Technical Advisory Groups (TAGs) for committees of the International Organization for Standardization (ISO).

4.11 International Standards Committee - Any standards committee sponsored by an international private sector or governmental (treaty or non-treaty) organization. Examples include committees of the International Organization for Standardization (ISO), the International Union of Pure and Applied Chemistry (IUPAC), Codex Alimentarius, ICH, VICH, etc.

5. RESPONSIBILITIES

5.1. Office of the Chief Scientist

The Office of the Chief Scientist (OCS) will maintain a Standards Management Program (SMP) for FDA. The SMP will develop and operate a unified standards system within FDA, including:

1. Development of procedures for the appointment of liaisons or delegates to standards developing organizations;
2. Coordination of standards development among Centers, including establishment of mechanisms to enable the Agency to speak with a consensus voice on standards issues;
3. Identification of current government-unique standards used by FDA;
4. Establishment of a Standards Information Management System (SIMS) on the FDA Information Retrieval System (FIRSt). The goals of the SIMS are to:
 - a. Provide a model standards management system for the internal use by the Centers;
 - b. Improve internal communication within the Agency; and,
 - c. Establish an Agency-wide standards record keeping system of Agency standards participation.
5. Coordination of a strategic planning mechanism to identify where new standards are needed to carry out FDA responsibilities, and to determine the best ways to develop those standards; as planning for standards occurs in different Agency components, (e.g., Centers, Data Council, Pharmaceutical Quality Council) OHSC will serve to coordinate these efforts.
6. Improved access to standards by FDA employees;
7. Participation in and assistance to the Centers in coordinating training for Agency participants in standards development committees to improve participation in technical discussions and increase awareness of underlying ethical considerations; and
8. Establish and maintain public files as required in 21 CFR 10.95

5.2. Office of International Programs

OCS will maintain coordination with the Office of International Programs (OIP) on international trade issues, e.g. Mutual Recognition Agreements (MRAs), global harmonization, etc., as described in the active Memorandum of Understanding between these Offices. See Appendix 1.

5.3. FDA Centers

FDA Centers will implement the Policy, as described in this SMG, in their regulatory activities. Each Center will establish procedures (e.g., Standard Operating Procedures and Policies (SOPP), Manual of Policy and Procedures (MAPP) for implementing relevant sections of the SMG that may include development of appropriate documents (e.g. Appointment of Liaisons, Records Management, etc.)).

5.4. FDA Standards Committee

To improve the internal coordination of FDA's participation in standards development organizations (SDOs), FDA establishes the FDA Standards Committee (FDASC). The purpose of the FDASC is to ensure effective participation by FDA in the development of domestic and international standards and to promote FDA adherence to uniform policies in the development and use of standards and in conformity assessment activities.

The FDASC will promote effective, consistent and appropriate standards and conformity assessment policies in furtherance of FDA domestic and international goals that are compatible with FDA priorities and available resources, and, to this end, will foster cooperative participation by FDA, U.S. industry, and other private organizations in standards activities. Determination of the appropriate standards to follow in various areas is handled by cross Agency groups with knowledge of Agency operations subject area and standards activities (e.g., Pharmaceutical Quality Council, Data Standards Council, etc.).

5.4.1. Functions

As appropriate, FDASC will obtain from the Centers and other Agency components their current information about standards, product testing, and related regulations, rules, policies, and activities:

- a. conducted within or established by FDA;
- b. conducted by private domestic and foreign national standards bodies and by regional and international private and

intergovernmental organizations engaged in such programs;
and,

- c. pertaining to the relationships among Centers of FDA, with industry, and the various national, regional, and international organizations engaged in such programs.

On the basis of such information and when appropriate with respect to the activities above, FDASC will make recommendations to the Commissioner to:

- a. strengthen coordination of standards-related and conformity assessment-related policies and activities across FDA;
- b. improve the efficiency within FDA of standardization efforts with the U.S. private sector, as well as with regional and international organizations, both private and governmental;
- c. promote standards-related policies within FDA consistent with statutory obligations in regard to interactions with non-federal government organizations;
- d. ensure effective representation of FDA at significant regional and international standards-related meetings and conferences;
- e. maintain directories of personnel participating in standards activities
- f. promote the use of internationally acceptable standards and related activities with a view to increasing trade and economic integration and development; and,
- g. encourage the development of Center strategic plans for managing and monitoring use of voluntary standards and participation in standards-related activities.

5.4.2. Membership

Together with the Office of Commissioner the following Centers/Offices constitute the membership of the FDASC:

Center for Biologics Evaluation and Research

Center for Drug Evaluation and Research

Center for Devices and Radiological Health

Center for Food Safety and Applied Nutrition

Center for Veterinary Medicine

National Center for Toxicological Research

Office of Critical Path Programs

Office of International Programs

Office of Policy and Planning

Office of Regulatory Affairs

Office of the Chief Scientist

The Director, OCS, will serve as the chair of the FDASC. The head of each member Center /Office will ensure representation by two officials who serve as the Center/Office representatives on the FDASC. Appointments to the FDASC will be for an indefinite term.

- a. Representatives must designate alternates to serve in their absence.
- b. Experts from organizations within the member Centers may be designated to serve on task groups established by the FDASC.
- c. Other OUs may become members of the FDASC upon application to or invitation by the Director, OCS, or Commissioner.

5.5. FDA Employees

In accordance with the NTTAA, OMB Circular A-119, 21 CFR 10.95, FDA policy and this SMG, FDA employees are encouraged to participate in domestic and international, government and non-government standards committee activities, as well as other professional committee programs relating to the FDA mission, whenever such participation is in the public interest, is compatible with FDA priorities and available resources, and the activity and resulting standards will not otherwise violate any applicable federal law, regulation, or international treaty to which the US adheres as a signatory or otherwise.

In accordance with Regulation 21 CFR 10.95 (d) (5), “the following minimum standards apply to an outside private standard-setting activity in which FDA employees participate:

1. The activity will be based upon consideration of sound scientific and technological information, will permit revision on the basis of new information, and will be designed to protect the public against unsafe, ineffective, or deceptive products or practices.
2. The activity and resulting standards will not be designed for the economic benefit of any company, group, or organization, will not be used for such antitrust violations as fixing prices or hindering competition, and will not involve establishment of certification of specific approval of individual products or services.
3. The group or organization responsible for the standard-setting activity must have a procedure by which an interested person will have an opportunity to provide information and views on the activity and standards involved, without the payment of fees, and the information and views will be considered. How this is accomplished, including whether the presentation will be in person or in writing, will be decided by the group or organization responsible for the activity”.

5.5.1. Types of SDOs

Because FDA is involved in many different types of SDOs, and because the standards developed by these organizations are intended to be utilized by FDA, this section describes the scope of FDA standards-related activities (see Appendix 2).

- a. Organizations with close daily cooperation with FDA including state cooperatives and standards development organizations (see Appendix 4).
- b. International organizations such as WHO, GHTF, OECD, Codex Alimentarius, PAHO, FAO, and ICH.
- c. Voluntary consensus SDOs such as ISO, IEEE, ASTM, HL7.
- d. Commodity groups where FDA does not fully participate in the development of commodity specific guidelines but provides technical expertise.

- e. Scientific/professional societies that develop “consensus” standards within the organizations' membership but do not necessarily comply with the attributes described in Section 4.2.

5.5.2. Types of SDO Activities

Standard-setting activities include the development of performance characteristics, testing methodology, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. (21 CFR 10.95 (a))

5.5.3. Appointment to Committees of International Organizations

To assure that the information shared as part of participation in standards development best represents the Agency and the Department of Health and Human Services (DHHS or the Department) and is consistent with the Agency's mission, the Department's international agenda, and the overall U.S. government objectives, FDA employees who communicate with, participate in, and respond to requests from major international organizations or about major international organizations' matters will conform to the Standard Operating Procedures for FDA Interactions with Major International Organizations. (Appendix 2)

5.5.4. Appointment as Part of an Employee's Official Duties

Appointments as a liaison/expert/delegate, etc. to committees as described in Section 5.5.6, are part of the employees' official duties and should be reflected in the employees' annual Performance Management Appraisal Program, Performance Contract, or equivalent document. Employees who participate in such activities as part of the official FDA duties have a fundamental obligation to know and act in conformity with established policies and program objectives of FDA, DHHS, and the Administration. As such, FDA employees are expected to represent the positions of the DHHS and the U.S. government (if there are specific HHS or USG positions), and not just the position of their respective organizational unit (FDA OU). FDA employees are expected to take steps to ensure that they are knowledgeable about positions of other FDA OUs and any cleared FDA or inter-agency U.S. government positions on the subject matter. FDA/OIP will assist travelers in this regard by working with the DHHS Office of Global Health Affairs (OGHA) to obtain information about other USG involvement in the specific issue. However, it is the traveler's responsibility to be appropriately prepared. Therefore, each Center will establish procedures for the formal appointment of liaisons and will, at

least annually, update the records of the Standards Management System (SMS) database. As noted previously, committee participation does not necessarily connote FDA agreement with, or endorsement of, the decisions reached by a committee or the standards developed by voluntary standards bodies.

5.5.5. Participation in a Committee as an “Independent Expert”

As noted above, it is FDA policy that when FDA employees - whether civil service or Commissioned Corps - participate in any activity as part of their assigned duties, they are doing so in their official capacity as a U.S. government representative and not in their personal capacity, even if the invitation for such participation implies or specifies that participation is in a “personal” or “expert” capacity.

Only in very rare circumstances will the Commissioner consider approving as an official duty assignment participation as an “independent expert”. If an FDA employee wishes to apply to provide her/his services as an expert/consultant in a personal capacity (i.e., not as part of her/his official duties), the employee must realize that the Standards of Ethical Conduct for Employees of the Executive Branch still apply. As such, the employee must have on file an approved HHS-Form 520 (Request for Approval of an Outside Activity). Additionally, if FDA determines that the subject matter of the consultation is too closely related to the employee’s current work, the activity will not be considered appropriate as an outside activity because of recusal obligations that could arise.

All HHS-Form 520’s that include a request to perform international work/consultation/etc. in a personal capacity as an “independent expert” must be approved by the employee’s Center/OC-Office director, as well as by the Commissioner and by OGHA. After signature by the appropriate Center Director/OC-Office Director, any such Form-520’s must be submitted to OIP for further submission to the Commissioner and OGHA.

When participation as an independent expert is permitted, employees must comply with the prior approval requirements and restrictions on use of their government title. The restrictions are as follows: If the employee’s FDA title is used in connection with the activity, there must be a disclaimer satisfactory to the agency, unless the FDA title is but one of several biographical details and the FDA title is given no more prominence than the other significant biographical details.

5.5.6. Appointment Procedures

For each proposed new or previously unreported committee assignment, the following steps are to be taken by the relevant FDA OU:

- a. Complete a Record of Committee Assignment (See Appendix 5), and submit original and two copies to the Division Director or higher official as appropriate and per OU procedure for approval.
- b. Following approval, a copy of the Record of Committee Assignment Form is to be sent to OCS to ensure the name and affiliation of the appointed liaison is included in the Directory of Staff Memberships on Outside Standards Committees. OCS will contact all Centers annually to maintain currency of this database.
- c. Complete and return any forms that may be required by the outside committee or parent organization.
- d. FDA OUs may establish additional procedures to insure internal communication and coordination.
- e. See 5.6.9 for approval procedures when participation as a secretariat function is requested.

5.5.7. Participation in a Policy-Making Body

An FDA staff member who is invited to serve, as an outside activity (i.e., not as an official FDA duty activity), on a board or other policy-making body of a professional or standards-developing organization must forward a Request for Approval of an Outside Activity through his/her management chain to the FDA Office of the Chief Scientist for approval by the FDA Office of the Commissioner. This request for FDA approval should include a recommendation as to the voting or non-voting status of the proposed participation.

5.5.8. Participation as a US Delegate or Leader of a US Delegation to Intergovernmental International Standard-Setting Organizations –

FDA employees may lead a U.S. delegation and serve as a leader of an international standards committee, and thus may have to coordinate views of other federal agencies, industry, and public groups. Appointment as a U.S. Delegate or Alternate Delegate follows the procedures for specific organizations. For example, appointment as a

U.S. Delegate or Alternate Delegate to a Codex Alimentarius committee is achieved by: (1) preparation of appropriate nomination letters by participating Center to forward through the Commissioner to the Chairperson of the US Codex Policy Steering Committee via the US Codex Office.

5.5.9. Approval Procedures for Acceptance of Standards Committee Secretariat Functions:

Occasionally, FDA employees, and consequently their OU, are asked to assume the role of a committee or task group secretariat. In addition to the requirements of Section 5.5.6. of this SMG, the following apply:

- a. FDA OUs may assume secretariat responsibilities for national and international standards committees and their subgroups and may serve as Administrators of U.S. Technical Advisory Groups that provide input to international standards committees. If acceptance of a secretariat is considered necessary and appropriate for accomplishment of FDA objectives, and if no reasonable sponsor or cosponsor is willing to accept responsibility for ensuring due process procedures, a FDA unit may take that responsibility only if approved by the Director of the appropriate FDA OU.
- b. Proposals for acceptance of standards committee secretariat functions are to be submitted to line management for the FDA OU Director's approval and to FDA OCS and FDA Ethics Staff for policy review.
- c. Following approval, a copy of the final correspondence establishing the secretariat is to be sent to OCS to ensure the information is included in the FDA Standards Management System.
- d. A FDA OU that accepts approved secretariat functions should not automatically assume final responsibility for ensuring that all appropriate due process procedures are followed in the course of standards development. The OU Director or designee should reach an agreement with the parent organization that indicates that the latter is responsible for ensuring that all appropriate procedures are followed.

5.5.10. Responsibilities of FDA Liaisons to Standards Developing Organization (SDO) Activities

The FDA employee should become familiar with the purpose, organization, structure and operating procedures of the SDO selected. Because it may be relevant to later FDA deliberations about the use of the standard or other document, the employee should determine if the committee is: (1) balanced; (2) follows agreed-on procedures (including transparency and due process); (3) maintains openness; and (4) operates by consensus. ANSI accreditation is one indication that these procedures have been followed. Participants in standards committees should review the purpose and scope of each particular activity, and should seek clarification of any ambiguities. Participants should also be aware that the use or abuse of standard procedures by participants in standards developing activities in order to restrict competition is improper and may violate various federal and state antitrust statutes; such violations are subject to civil and criminal prosecution. FDA liaisons should become familiar with the operational procedures and common practices of the standards setting organization that are relevant to their participation level. A list of ANSI-accredited SDOs is available from ANSI at <http://www.ansi.org/>. Many SDOs conduct meetings using procedures based on "Robert's Rules of Order". FDA liaisons should become familiar with common practices and the specific practices of the SDO to be effective. ANSI and several SDOs periodically offer a training course on effective participation as well as specific operating procedures.

The liaison should clearly articulate to the specific committee of the SDO the capacity in which they are participating (e.g., voting or not voting) and salient FDA standards policy information such as: 1) they represent FDA and may not express personal views; 2) participation does not constitute agreement on any standard developed, etc.

FDA liaisons should be familiar with FDA's positions on major policy issues and, if necessary, be prepared to articulate official positions. In most instances, FDA employees participate in aspects of standards development that are closely related to their technical expertise. Nevertheless, issues related to general governmental policy or sensitive issues may arise, particularly in higher-level committees. Employees participating as an official FDA duty should never express personal opinions on significant policy issues since they might be construed to be official FDA policy. When such issues arise, FDA employees should seek help and advice of management on policy and procedural matters.

FDA liaisons should keep OU management informed of significant developments, both technical and policy, that occur at committee meetings. In addition, certain “high-impact” issues should be brought to the attention of Center management and the OCS Director. An issue can be considered to have high impact if it meets any of the following criteria:

- The issue may be brought to the attention of the FDA Commissioner and/ or the Center Director by one or more outside groups, such as Congress, another Federal agency, a trade organization or standards developer, or a firm;
- More than one organizational unit would be affected by the standard and therefore, would require broad coordination across internal FDA OUs;
- It could entail anti-trust violations or even the concern of potential anti-trust violations;
- It generates a need for policy guidance regarding appropriate limits of FDA responsibility, whether technical or financial;
- It may result in significant outside criticism of FDA; or,
- It would have significant impact on the health, safety, or environmental conditions of U.S. citizens or U.S. international trade.

FDA employees, when they participate in standards-developing activities, will almost certainly be involved with representatives of the private sector, imposing numerous responsibilities, ethical obligations, and possible antitrust considerations. Federal employees are subject to constraints on conduct that may not apply to their private sector counterparts. These include limitations and restrictions on acceptance of gifts, meals, travel expenses, and the like. Any questions should be referred to the FDA Ethics Staff for a full explanation of all ethical rules pertaining to working with the private sector on standards activities.

The United States has obligations specified under the Trade Agreements Act of 1979 (1995 revision) and the World Trade Organization Agreements on Technical Barriers to Trade, Application of Sanitary and Phytosanitary Measures and other related agreements. Therefore, employees should be aware of international standards and standardization activities related to their national standards committee work. They should also be mindful, per this Standards Policy, to

promote the inclusion of U.S. technology, both existing and emerging, in national and international standards.

All participants should maintain a file of committee-related information, including the committee's by-laws, membership lists, minutes of meetings, final ballots, and relevant correspondence, as described in Center policy. The liaison, or Center, should retain this file in accordance with applicable provisions of the General Records Schedules issued by the National Archives and Records Administration and the FDA Records Control Schedule. (See <http://intranet.fda.gov/omp/records/retention.htm>)

Whenever appropriate, FDA employees can encourage the development and use of appropriate performance standards. Performance criteria in standards generally do not stand in the way of innovation, whereas prescriptive specifications tend to do so. However, prescriptive standards may sometimes be more appropriate, particularly for describing test methods or procedures. Nevertheless, employees should keep in mind that design specifications or reference to patented devices, materials or processes, may deter technical progress and may be prohibited by some SDOs.

FDA offers training on issues that affect participation by FDA employees in standards programs. Employees who represent FDA will take the training as specified by the FDASC and their Center.

- a. ANSI offers a number of helpful training programs, which are described at the ANSI website: <http://www.standardslearn.org>
- b. Many SDOs, such as ASTM (<http://www.astm.org>) also offer training courses for their committee members.
- c. OCS and OIP offer a short training program for new employees to familiarize them with the standards development process and the FDA procedures for participating in standards activities. Information on these courses can be obtained from OCS or OIP.

FDA OUs support staff travel to standards committee meetings in the same way that they support other official travel. The FDA OU will pay the participation fees and/or membership fee for the standards development activities of qualifying organizations. In the case of professional societies that also develop standards, FDA is unable to cover membership fees or dues unless they can be clearly differentiated from other activities of the organization. Each Center will establish procedures for implementing this paragraph of the SMG.

In addition, FDA OUs pay administrative service fees to ANSI when FDA staff becomes secretariats of committees of international organizations such as ISO and IEC, of which ANSI is the recognized U.S. member body. While the funds are provided by the appropriate OUs, OCS coordinates the payment of secretariat fees with both the OUs and ANSI.

6. REFERENCES

6.1 - "Policy regarding the development and use of standards with respect to International Harmonization of Regulatory Requirements and Guidelines" (60 FR53078, October 11, 1995). <http://www.fda.gov/oia/Harmonization.htm>

6.2 – General Redelegations of Authority - SMG 1410.21 (1)(f)(3) With respect to any matter delegated to the Associate Commissioner for Policy and Planning (ACPP) and the Assistant Commissioner for Policy (ACP) under this paragraph, the ACPP and the ACP are authorized to perform the function of the Commissioner under sections 10.40, 10.45, 10.50, 10.55, 10.60, 10.65, 10.80, 10.90, and 10.95 of 21 CFR and of the Deputy Commissioner under section 10.206(g) and (h) of 21 CFR. These officials may not further redelegate this authority. http://www.fda.gov/smg/1410_21.html

6.3 – National Technology Transfer and Advancement Act of 1995, PL 104-113, <http://ts.nist.gov/Standards/Conformity/pubs.cfm>

6.4 - Office of Management and Budget Circular A119 - Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, <http://ts.nist.gov/Standards/Conformity/pubs.cfm>

7. EFFECTIVE DATE

The effective date of this guide is May 22, 2007.

8. Document History -- SMG 9100.1, Development and Use of Standards

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	05/22/2007	N/a	OCS, HF 33	Secretary of Health and Human Services
Change	11/28/2007	Sec.Heading 6, 6.1	OISP, HF-3	Dr. Mac Lumpkin, Deputy Commissioner, Office of International and Special Programs

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Change	06/18/2012	OSHC to OCS	OC/OCS	Jesse Goodman, Chief Scientist, OC/OCS

SMG 9100.1 APPENDIX 1 – Development of “Standards” - Memorandum of Understanding between FDA's Office of International Programs (OIP) and Office of the Chief Scientist (OCS)

Whereas:

- As a public health agency charged with protecting and promoting the public health of the United States by assuring the safety, effectiveness, and quality of medical products and the safety and wholesomeness of food products, FDA develops, helps develop, adopts, and uses “standards” of many types at every level in the organization.
- As the complexity of and overlap between products over which we have jurisdiction increases, the interactions between product centers that manage the products on a day-to-day basis and between the product centers and the Office of the Commissioner must increase.
- The ongoing attempts to lower international trade barriers increase the international flow of FDA-regulated products and increase the importance of effective collaboration between FDA and both foreign government regulators and international organizations seeking to harmonize regulatory policies and requirements as much as possible in bilateral and multilateral fora. As a world leader in regulatory science and policy, FDA must have a visible, effective, and coordinated presence in these fora.
- When initiatives involve the development of standards, it is imperative that there be a clear understanding of the responsibilities within FDA for coordinating FDA participation in standards development both domestically and internationally and for assuring the most appropriate scientists within FDA are engaged in these initiatives. In addition to a strong and committed application of scientific expertise, FDA must contribute a visionary policy and cooperative strategy to standards development initiatives. To accomplish this, FDA must have well-coordinated policy staffs to direct and maintain FDA’s standards development efforts.
- We note that the National Technology Transfer and Advancement Act of 1995 guides U.S. Government participation in the development and use of standards. [P.L. 104-113, 110 Stat. 775, 783 (15 U.S.C. 272 note)].

Therefore, the Office of the Chief Scientist and the Office of International Programs within the Office of the Commissioner agree to the following.

- To establish needed visibility within the Office of the Commissioner and to improve coordination of efforts: (a) the Office of the Chief Scientist (OCS) will assume primary responsibility for coordinating domestic standards development and for assuring that appropriate scientific expertise from the Agency is engaged in both domestic and international standards development initiatives, and (b) the Office of International Programs (OIP)

SMG 9100.1 APPENDIX 1 – Development of “Standards” - Memorandum of Understanding between FDA's Office of International Programs (OIP) and Office of the Chief Scientist (OCS)

- will assume primary responsibility for coordinating international standards development initiatives (including coordination with that the Office of the Chief Scientist to ensure that appropriate scientific expertise from the Agency is engaged in the initiative), and (c) the Office of International Programs will assume primary responsibility for coordinating international policy issues relating to standards with respect to trade, treaties, and mutual recognition agreements.
- The offices will use both formal and informal coordinating mechanisms in order to coordinate these efforts.
 - The program centers will continue to provide the bulk of scientific expertise on standards committees and working groups within their areas of competence.
 - OCS will carry out the functions of the Standards Executive for the Department of Health and Human Services pursuant to Office of Management and Budget (OMB) Circular A-119. These duties include attendance at the Interagency Committee on Standards Policy (ICSP), which is responsible for implementing the NTTAA and preparation of the annual report to OMB on the use of standards.
 - OCS will maintain a liaison with the FDA Data Council. OCS will coordinate with OIP on FDA Data Council activities potentially affecting international standards.
 - ANSI is the principal organization for coordination of national standards activities and representation of U.S. standards policies to the international standards development organizations. FDA participates in ANSI deliberations through a large number of policy and standards development committees. For those committees dealing with primarily scientific issues for which technical expertise is paramount, program center offices with the requisite expertise should provide support with the guidance and coordination of OCS and OIP. OCS will participate in the several management councils and forums of ANSI, including the ANSI Government Member Forum, the ANSI Consumer Interest Forum, the ANSI National Policy Committee, and the ANSI Board of Directors (if appropriate). OIP will research the need for membership on the ANSI Health Informatics Committee, International Policy Committee (and related Regional Standing Committees) and the International Conformity Assessment Committee.
 - OIP will continue its oversight of the ISO Technical Committee (TC) 34 on Food Products and is exploring the possibility of the U.S. becoming a Participating Member on the ISO TC 217 on Cosmetics. The remainder of

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FDA involvement on the ISO Technical Committees will continue to reside primarily within the FDA program centers, mainly within CDRH.

- OIP will continue its role in overseeing and coordinating bilateral and multilateral international standards development/regulatory harmonization programs, including ICH, VICH, GHTF, CHIC, Codex, OECD, WHO, FAO, OIE.

Future

The FDA must take a strong role in promoting the visibility and use of standards applicable to FDA's public health mission. This MOU represents the first step in achieving these goals. We will work together to develop a long-term plan for implementing a greater focus on standards. In their various roles, OIP and OCS will continue to serve as a mechanism for coordinating, integrating and reporting on our progress. These offices should report regularly to their leadership and to the joint executive leadership of the Agency, including the program center directors, on the actions taken and the progress made in the realm of standards development.

Jesse Goodman, M.D., M.P.H.
Director, Chief Scientist
(for Office of Chief Scientist)

Mary Lou Valdez, M.S.M.
Associate Commissioner
(for Office of International Programs)

SMG 9100.1 APPENDIX 2 – Standard Operating Procedures: U.S. Food and Drug Administration - Interactions With Major International Organizations

GOAL: To assure appropriate U.S. Food and Drug Administration's (FDA or Agency) communication and interactions with major international organizations, including, but not limited to, the World Health Organization (WHO), the Pan American Health Organization (PAHO), and the Food and Agriculture Organization (FAO). More specific SOP's for certain other organizations (e.g., OECD, Codex Alimentarius) may be written to supplement the policies established in this document.

OBJECTIVE: Establish an agency-wide process for how FDA communicates with, participates in, and responds to requests from major international organizations or about major international organizations' matters, to assure information shared best represents the Agency and the Department of Health and Human Services (DHHS or the Department) and is consistent with the Agency's mission, the Department's international agenda, and the overall U.S. government objectives.

FDA and DHHS play a critical role in providing technical support and assistance to many major international organizations. It is imperative that the manner in which the Agency interacts with these major organizations or about these major organizations' matters assures that all information shared or provided represents an Agency/Department position, and that the Agency/Department's senior leadership is afforded the opportunity to consider all requests from these major organizations and matters pertaining to these major organizations.

DEFINITION: In this document, "office" refers generically only to FDA organizational components that are not located within one of the Centers, such as the Office of Regulatory Affairs, the Office of Policy and Planning, or the Office of Science, among others. It does not refer to organizational components designated as "offices" that are located within one of the Centers.

BACKGROUND: FDA receives many types of requests from these major organizations, including:

- A. Review or preparation of documents
- B. Speakers at organization sponsored workshops, conferences, or events
- C. Technical Assistance from an FDA expert designated as a Temporary Advisor or Expert Consultant
- D. FDA experts detailed to the organization for a specific period of time on a specific issue

Requests from these organizations may come into FDA from many channels, including:

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- A. Directly - through the Office of International Programs (OIP)
- B. Directly - through informal contacts around the Agency
- C. Directly - through Centers designated as "Collaborating Centers" CDRH: CC for Standardization of Protection Against Non-Ionizing Radiation
CDRH: CC for Training and General Tasks in Radiation Medicine (listed as "pending redesignation")
CFSAN: CC for Food Contamination Monitoring (listed as "pending re-designation") CBER: CC for Biological Standardization (listed as "pending re-designation") JIFSAN is a CC for Risk Assessment in Food Safety
- D. Indirectly, by posting general requests on their web site
- E. The Department
- F. Other US Government entities

RESPONSIBILITIES:

OIP is the Agency's primary coordinator and clearinghouse for all communications with these international organizations - with one exception noted below.

It is OIP's responsibility to work with the appropriate Center or Office to obtain input/clearance, if needed; interface, as appropriate with the Department; and provide the response back to the international organization. In general, responses should only be transmitted from Centers or Offices directly to the international organization in exceptional circumstances or when a specific transmittal procedure for a specific document or set of documents has been agreed in advance by OIP and the appropriate Center or Office.

In general, DHHS' Office of Global Health Affairs (OGHA) is the Department lead on all WHO matters. It will be OIP's responsibility to assure appropriate coordination with OGHA on all WHO issues and other issues with major international organizations, as appropriate and desired by OGHA.

Exception:

"WHO Collaborating Centers" - Interactions with WHO that are specific to these designated relationships will be the Collaborating Center's responsibility to manage, in terms of the scope of collaborative work to be accomplished.

Requests for expert consultants, technical experts, or temporary advisors must still be vetted through the Office of the Commissioner (OC) as indicated

SMG 9100.1 APPENDIX 2 – Standard Operating Procedures: U.S. Food and Drug Administration - Interactions With Major International Organizations

below, even if the consultancy is within the scope of the work defined through the collaborative work.

It will be the responsibility of the Collaborating Center to keep OIP apprised of ongoing activities through these relationships.

POLICIES:

1. All agreements that designate FDA components as "WHO Collaborating Centers" must be submitted through OIP for approval by the Commissioner (or his/her designee).
2. For all types of incoming requests: *(The timelines are contingent on the turnaround time requested by the international organization or the Department. These timelines assume a two-week response time.)*
 - a. Regardless of the channel through which a request covered by this SOP arrives at any FDA component, all incoming requests from major international organizations or about major international organizations' matters must be routed to the appropriate Center/Office's international point of contact and OIP's staff point of contact within *24 hours* of receipt. This includes both informal exploratory inquiries and formal invitations or requests. The Center/Office will prepare the proposed Center/Office response to a given request and provide the proposed response - cleared through the Center/Office Director -- to OIP for clearance through Office of the Commissioner (OC) and the Department, as appropriate. OIP will make available to all Center/Office international points of contact and on the FDA intranet a list of who the appropriate OIP points of contact are for these purposes.
 - b. In general, the Center/Office will have two *working days* to provide a proposed response to OIP.
 - c. In general, once OIP receives a proposed response from a Centers/Office, OIP will have five working days to obtain appropriate OC and DHHS review and/or clearances, finalize the response, communicate back to the Center/Office, and provide the response to WHO/FAO, through appropriate channels.
3. Review or Preparation of Documents
 - a. Upon receipt by OIP of a document for review or a request for preparation of a document from a major international organization, OIP will assure that the document is immediately distributed electronically to the appropriate Center(s)/Office(s). It will be the responsibility of the

SMG 9100.1 APPENDIX 2 – Standard Operating Procedures: U.S. Food and Drug Administration - Interactions With Major International Organizations

Center(s)/Office(s) to assure the document is distributed within their Center/Office for review by their appropriate Center/Office staff.

- b. Each Center/Office will provide OIP, within the time frames requested when the document/request is sent to the Center(s)/Office(s), one set of comments/proposed document that has been cleared by the Center/Office and represents the views of the Center/Office.
 - c. OIP will review the comments/documents submitted by each participating Center/Office, consolidate the comments, attempt to resolve any conflicting comments, prepare the final response, obtain appropriate OC and DHHS clearances, and transmit the comments/document to the major international organization via appropriate channels.
 - d. OIP will maintain files of the incoming document/request for document and FDA's final response.
 - e. Only responses that have gone through this process and received the clearances outlined in this SOP are considered to represent an official expression of FDA opinion or policy on the matter.
 - f. No FDA employee may submit responses to such requests without going through this process and obtaining the clearances outlined in this SOP, unless: (a) the response is requested directly of that person by the international organization specifically in his/her personal capacity, (b) the response specifically and clearly states that it is submitted in the submitter's personal capacity and does not represent FDA policy or opinion, (c) the submitter uses no non-public information, to which he/she may have access as an FDA employee, as a basis or background for their private capacity submission, and (d) the submitter has on file an approved outside activity form for performing such activity outside government time.
4. Speakers at International Organization Sponsored Workshops, Conferences, or Events; Technical Assistance from an FDA expert designated as a Temporary Advisor or Expert Consultant; or Requests for FDA experts to be detailed to an international organization for a specific period of time on a specific issue
- a. After receiving such requests, OIP will consult with the Principal Associate Commissioner, the Deputy Commissioner, and/or the Commissioner of Food and Drugs to first ascertain if the invitation/request is one that the Agency might want to accept. In addition, OIP will ascertain from the requester specific details on proposed financial support, if any, and expected time commitments

SMG 9100.1 APPENDIX 2 – Standard Operating Procedures: U.S. Food and Drug Administration - Interactions With Major International Organizations

required of the FDA representative(s) if the invitation were to be accepted.

- b. Once a decision has been made to seek further input on the invitation, OIP will send the invitation to the appropriate Center(s)/Office(s) for consideration of possible appropriate nominee(s) to be the FDA representative(s).
- c. The Center(s)/Office(s) will provide OIP with their recommended nomination(s). OIP will obtain final choice clearance from OC and DHHS (as appropriate) and notify the requesting organization of the Agency's decision.
- d. In the case of individuals serving as a Temporary Advisor, Expert Consultant, or providing Technical Assistance: Although the Agency has approved an individual's designation as a temporary advisor or designated expert through the general process outlined above, all future interactions with a major intentional organization regarding his/her participation in that capacity must be approved by her/his Center/Office leadership and cleared through OC via OIP.
- e. Only representatives that have gone through this process and received the clearances outlined in this SOP are considered to be official FDA representatives for these purposes.
- f. DHHS and FDA ethical/financial policies govern FDA official participation in such activities.
- g. No FDA employee may participate as an official FDA representative in response to such requests without going through the process and obtaining the clearances outlined in this SOP. An FDA employee may participate in such activities as a private citizen if. (a) the participation is requested directly of that person by the international organization specifically in his/her personal capacity, (b) the participant, specifically and clearly states that s/he is participating in his/her personal capacity and that the participant is does not represent FDA and is not necessarily expressing FDA policy or opinion, (c) the participant uses no non-public information, to which s/he may have access as an FDA employee, as a basis or background for his/her private capacity participation, (d) the participant is using no government funds or government time to participate, and (e) the participant has on file an approved outside activity form for performing such activity outside government time.

Concur Nonconcur

SMG 9100.1 APPENDIX 2 – Standard Operating Procedures: U.S. Food and Drug Administration - Interactions With Major International Organizations

Murray M. Lumpkin, M.D., Principal Associate Commissioner

Date

Concur Non-concur

Mark B. McClellan, M.D., Ph.D. Commissioner
Food and Drugs

Date

Final: MLumpkin 5/5/03 Final: MLumpkin 5/15/03

SMG 9100.1 APPENDIX 3 – Capacity of Representation - Official Versus Personal

*(The following is extracted from the Memorandum titled “**Updated Requirements for International Travel – IMPORTANT**” from the Acting Deputy Commissioner, International and Special Programs, dated 17 December 2004)*

It is HHS policy that when HHS/FDA employees - whether civil service or Commissioned Corps - represent HHS/FDA in any international activity, they are doing so in their official capacity as a U.S. government representative and not in their personal capacity, even if the invitation for such participation implied or specified that participation was in a “personal” capacity. As such, HHS/FDA employees are expected to represent the positions of the Department of Health and Human Services and the U.S. government (if there are specific HHS or USG positions), and not just the position of their respective organizational unit. HHS/FDA employees are expected to take steps to ensure that they are knowledgeable about positions of other HHS Operating Divisions, and any cleared, HHS or inter-agency U.S. government positions on the subject matter. OIP will assist travelers in this regard by working with OGHA to obtain information about other HHS/USG involvement in the specific issue. However, it is the traveler’s responsibility to be appropriately prepared.

Only in very rare circumstances will the Commissioner and HHS consider approving a HHS/FDA employee participating in such activities in his/her personal capacity. If an FDA employee wishes to apply to provide her/his services internationally as an expert/consultant in a personal capacity (i.e., not as part of her/his official duties), the employee must realize that the Standards of Ethical Conduct for Employees of the Executive Branch still apply. As such, the employee must have on file an approved HHS-Form 520 (Request for Approval of an Outside Activity). Additionally, if it is determined that the subject matter of the consultation is too closely related to the employee’s current HHS work, the activity will not be considered appropriate as an outside activity because of recusal obligations that could arise.

All HHS-Form 520’s that include a request to perform international work/consultation/etc. in a personal capacity must be approved by the employee’s Center/OC-Office director, as well as by the Commissioner, and by OGHA. After signature by the appropriate Center Director/OC-Office Director, any such Form-520’s must be submitted to OIP for further submission to the Commissioner and OGHA.

SMG 9100.1 APPENDIX 4 – Institutional Standards Developers Previously Approved by FDA Commissioner

These SDOs are exempt by regulation from paragraphs (d)(1) through (7) of 21 CFR 10.95 participation in outside standard-setting activities except that a list of the committees and other groups of these associations will be included in the public file on standard-setting activities. The names on this list have been amended to reflect changes in corporate names since the original list was published in 21 CFR 10.95

American Association of Food Hygiene Veterinarians (AAFHV)

American Public Health Association (APHA)

Association of American Feed Control Officials, Inc. (AAFCO)

Association of Food and Drug Officials (AFDO)

AOAC International (AOAC)

Association of State and Territorial Health Officials (ASTHO)

Conference for Food Protection (CFP)

Conference on State Health and Environmental Managers (COSHEM)

Conference of Radiation Control Program Directors (CRCPD)

International Association for Food Protection (IAFP)

Interstate Shellfish Sanitation Conference (ISSC)

National Association of Boards of Pharmacy (NABP)

National Association of State Departments of Agriculture (NASDA)

National Conference on Interstate Milk Shipments (NCIMS)

National Conference of Local Environmental Health Administrators (NCLEHA)

National Conference on Weights and Measures (NCWW)

National Environmental Health Association (NEHA)

National Society of Professional Sanitarians (NSPS)

SMG 9100.1 APPENDIX 5 – Record of Committee Assignment

DATE OF THIS RECORD

PURPOSE OF THIS RECORD

New assignment
Change of previously supplied information

NAME

Last
First

CONTACT INFORMATION

Organizational Code
Mailing address
FDA telephone number
E-mail address

COMMITTEE ASSIGNMENT

Complete name of Activity
Parent Committee (Organization, Committee number (if applicable))
Subcommittee
Other

DATE OF ASSIGNMENT

Expiration date (if any)

TYPE OF COMMITTEE

Intergovernmental
Voluntary standards (domestic)
Voluntary standards (international)
Commodity group
Scientific/professional group

POSITION ON COMMITTEE (all that apply)

Member/Delegate/Liaison
Alternate
Chair
Other officer

FDA OU APPROVALS

SMG 9100.1 APPENDIX 5 – Record of Committee Assignment

Name
Signature
Date

FDA APPROVALS (if required)

(Example, OIP approval for international activity)

SMG 9100.1 APPENDIX 6 – Glossary

Term	Definition
A119	OMB Circular A119 - Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities
AATB	American Association of Tissue Banks
ANS	American National Standard
ANSI	American National Standards Institute
ARC	American Red Cross
ASME	American Society of Mechanical Engineers
ASTM	ASTM International
BMD	FDA Bureau of Medical Devices
BRH	FDA Bureau of Radiological Health
CHIC	Cosmetics Harmonization and International Cooperation
Codex Alimentarius	CODEX Alimentarius Commission
FAO	Food and Agriculture Organization of the United Nations
FDAMA	Food and Drug Modernization Act of 1997
FIRSt	FDA Information Retrieval System
GHTF	Global Harmonization Task Force
HL7	Health Level Seven
ICSP	Interagency Committee on Standards Policy
IEEE	Institute of Electrical and Electronic Engineers
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
IEC	International Electrotechnical Commission
IPPC	International Plant Protection Convention
ISO	International Standards Organization
MAPP	Manual of Policies and Procedures
NGO	Non-government Organizations
NTTAA	National Technology Transfer and Advancement Act (PL 104-113)
OECD	Organization of Economic Cooperation and Development
OIE	World Organization for Animal Health

SMG 9100.1 APPENDIX 6 – Glossary

Term	Definition
OIP	FDA Office of International Programs (FDA/OC/OIP)
OCS	FDA Office of Chief Scientist (FDA/OC/OCS)
PAHO	Pan American Health Organization
SIMS	Standards Information Management System
SDO	Standards Development Organization
SOPP	Standard Operating Procedures and Policies
USP	United States Pharmacopoeia
VICH	International Cooperation on Harmonisation of Technical Requirements for Regulation of Veterinary Products
WHO	World Health Organization