INFORMATION TECHNOLOGY

Nomenclature Standards Committee (NSC)

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PURPOSE

This MAPP describes the role and responsibilities of the Nomenclature Standards Committee (NSC).

BACKGROUND

The Nomenclature Standards Committee has been operating since the early 1980s and serves as a forum throughout the Center to discuss and standardize corporate data elements, which are collected and described in CDER's *Data Standards Manual*. This manual is available in hard copy and on CDER's home page at http://www.fda.gov/cder/dsm/index.htm.

DEFINITIONS

- **Corporate Data Elements.** Corporate data elements are designations for data that are critical to the mission of the Center, mandated by statute or regulations, mandated by the Center to make executive decisions, or used for reporting to external customers. Examples of corporate data elements include the terms *street, city, state, country, dosage form, route of administration, height,*

weight, race, gender, and *marital status*.

- *Data Standards Manual.* A CDER manual containing nomenclature policy and approved and pending nomenclature standards.

- **Lexicographer.** An author or editor of a dictionary.

- **Nomenclature.** A name; a system of terms used in a particular science, discipline, or art. CDER nomenclature is a nomenclature subset that encompasses names that are used in both regulatory oversight and personnel management.

POLICY

- Nomenclature control is essential to the successful operation of individual information systems and to ensure compatibility of numerous information systems within CDER. Nomenclature control ensures consistent interpretation and accurate, comprehensive retrieval of data. To achieve nomenclature control, a Center-level, NSC has been established. In cooperation with other Agency and Center working groups, this committee will establish nomenclature policy (but not regulatory policy), coordinate implementation of that policy, and monitor to ensure compliance with such policy.

RESPONSIBILITIES

The NSC as a whole is responsible for:

- Reviewing, approving, and revising nomenclature standards and nomenclature policy as it relates to all corporate databases.

- Coordinating with nomenclature standards initiatives that are part of CDER's activities with the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The NSC also is responsible for coordinating with nomenclature activities in other Centers, the Agency, other Federal agencies, or private nomenclature standards-setting bodies.

- Facilitating database management by establishing new nomenclature standards

and by harmonizing and standardizing existing terminology as it relates to all corporate databases.

- Monitoring the adoption of nomenclature standards by Center databases.

- Recommending to its Chair the creation of subcommittees and their membership.

Individual NSC Members and Alternates are responsible for:

- Representing and expressing the views of their Offices at all NSC meetings.

- Distributing NSC minutes as well as pertinent policy and initiatives within their Offices within 10 days of receipt.

- Maintaining an updated copy of the CDER *Data Standards Manual*, making its existence known in their Office, and promoting its use in their Office when automated tables are created or revised.

- Executing applicable NSC action items in a timely manner.

The Center Lexicographer is responsible for:

- Chairing the NSC, including determining when and where to meet, establishing the agenda, conducting the meeting, making assignments, and appointing an Executive Secretary to write minutes.

- Communicating any items requiring immediate attention to the NSC members and to the Director, Office of Information Technology.

- Incorporating approved nomenclature standards into the CDER Data Standards Manual.

- Disseminating the CDER *Data Standards Manual* to NSC members in both hard copy and electronic format and making the Manual available to staff and the public through electronic media, such as the World Wide Web.

- Creating subcommittees and appointing subcommittee membership with the advice of the Committee.

- Representing or appointing individuals to represent the NSC within CDER at

meetings addressing the receipt, interpretation, and manipulation of data. The NSC also should be represented at all levels within the Agency (e.g., Information Standards Steering Committee) and at meetings outside the Agency (e.g., United States Pharmacopeial Convention's Nomenclature Committee).

The NSC Executive Secretary is responsible for:

- Determining when the full NSC, or one of its Subcommittees, will meet and securing a suitable meeting room.
- Notifying each NSC member or alternate (or subcommittee member or alternate) of a meeting at least one week prior to its scheduled date.
- Distributing a meeting agenda.
- Preparing and distributing accurate minutes.
- Maintaining files of minutes and other documents pertaining to NSC/subcommittee decisions.
- Serving as the focal point for all correspondence.

Office Directors (other than Office of Information Technology) are responsible for:

- Working with the NSC chair to select one member and one alternate to represent their office at NSC meetings. Such membership is open to Center managers and others reliant upon electronic files who have an interest in nomenclature standards.

The Director, Office of Information Technology is responsible for:

- Selecting one member and one alternate to represent each major corporate database under OIT auspices.

The Information Technology Coordinating Committee (ITCC) is responsible for:

- Serving as an appeals body when organizational areas disagree with Committee decisions.

PROCEDURES

- **Membership -** shall consist of one member and one alternate from each of the following organizational areas**:**

  - Each CDER Office other than the Office of Information Technology.
  - Each organizational component in the Office of Information Technology that maintains a corporate database.

  Each member and alternate should be knowledgeable about the databases that their office uses and their office's nomenclature needs.

- **Subcommittee(s) -** shall consist of those individuals who are appointed by the Chair with the recommendations of the Committee membership. Subcommittee members serve as the functional complement of the Committee by assisting in the determination or implementation of Committee nomenclature policy or standards.

- **Quorum -** is established by having at least one-half of the currently appointed membership present. In addition, the composition of the quorum should be balanced.

- **Voting -** can be accomplished either at formal meetings or, as the need arises, through E-mail. Only the NSC member or that member's alternate may vote (but not both). Voting shall be the means to determine when a consensus opinion has been achieved.

- **Advisors and Consultants** - from within the Agency, or from the private sector, may serve on the Committee and subcommittee(s) at the discretion of the full Committee to serve as a resource in resolving issues that are beyond the scope of the membership.

- **Open Meetings** - Committee and subcommittee meetings shall be open for all interested Agency personnel to attend.

- **Frequency of Meetings** - The Committee and subcommittee(s) will meet as needed for the purposes of policy and goal development.

- **Minutes** - will be prepared and distributed describing the intentions, methods,

and plans of the Committee as well as the membership's consenting and dissenting viewpoints on salient issues and policy.

- **Function** - The Committee will review all manual and automated dictionaries currently available in the Center; develop policy and guidance for the preparation of new nomenclature dictionaries that are compatible with all Center corporate databases; and make recommendations regarding nomenclature standardization within the Center. The Committee serves as the arbitration body in the maintenance of existing nomenclature tables to ensure compatibility, consistency, and quality of all terminology.

- **Appeals** - The Information Technology Coordinating Committee will serve as an appeals board. Decisions of the Committee may be appealed to this board.

EFFECTIVE DATE

This MAPP is effective upon date of publication.