

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

INFORMATION RESOURCES MANAGEMENT

FDA DATA COUNCIL - DATA STANDARDS PROGRAM

DATA STANDARDS PROGRAM

Effective Date: 07/24/2003

1. Purpose
2. Reference
3. Definitions
4. Policy
5. Responsibilities
6. Procedures
7. Implementation
8. Effective Date
9. History

1. PURPOSE

The purpose of this Guide is to establish policies, responsibilities, and procedures for the FDA Data Standards Program.

2. REFERENCE

Public Law 89-306 (Brooks Act) requires departments and agencies to implement approved Federal standards and to develop their own internal standards where such efforts contribute to reduced costs or improved services.

3. DEFINITIONS

A. Data Element. A basic unit of identifiable and definable information. It occupies the space provided by a field in a record or a block on a form, and has an identifying name and value or values for expressing a specific fact. A data element is defined by its name, description, source, length, structure, and format.

B. Data Item. Any of the legitimate, unique values that can occupy the space defined as a data element. It is the expression of a particular fact of a data element (e.g., "Blue" is a data item of the data element named "Color of Eyes").

C. Data Standard. A data element with its legitimate data items that has been approved for Agency-wide use by the FDA Data Council. There are two types of data standards: administrative data standards that apply to the general area of internal FDA administration (e.g., financial management, personnel, property management); and scientific data standards that apply to the scientific area of FDA responsibility (e.g., pre-market approval, post-market surveillance, Agency areas of research).

D. FIPS Pubs. Federal Information Processing Standards Publications that are issued by the National Institute of Standards and Technology pursuant to Section 5131 of the Information Technology Management Reform Act of 1996 (Public Law 104-106), and the Computer Security Act of 1987 (Public Law 100-235). They are used to announce standards for Federal information processing, and to provide standards information of general interest and an index of relevant standards publications and specifications.

4. POLICY

It is the policy of the Food and Drug Administration to encourage the development of data standards to assist in linking data and systems across organization and program lines; to promote the effective interchange and sharing of data with private industry and the public; and to avoid unnecessary duplications and incompatibilities in the collection, processing, and dissemination of data.

5. RESPONSIBILITIES

A. FDA Data Council.

The FDA Data Council has the overall responsibility for the Data Standards Program in FDA, including:

1. Assisting in the establishment and continuing operation of groups in each major organizational component to identify, develop, and nominate data standards for adoption on an Agency-wide basis.
2. Managing the Agency's Data Standards Program by coordinating the review, approval, and adoption of proposed standards and maintaining and distributing published standards.
3. Developing, publishing, maintaining, and distributing an Agency Vocabulary Standards Dictionary (VSD).
4. Providing liaison to and serving as primary interface with industry groups having interest in the Data Standards Program.

B. Major Organizational Components.

The Office of the Commissioner, Office of Regulatory Affairs, and the various Centers in FDA, through their FDA Data Council representatives, are responsible for:

1. Developing and nominating data standards from their program areas for adoption on an Agency-wide basis.
2. Appointing review groups, as needed, to evaluate nominated data standards and recommend whether or not they be adopted on an Agency-wide basis.

C. FDA Vocabulary Standards Working Group.

The FDA Vocabulary Standards Working Group (VSWG) is composed of representatives appointed by each major organizational component's FDA Data Council member, and is chaired by a person with background or interest in lexicography appointed by the Chairman of the FDA Data Council. The VSWG is responsible for:

1. Providing liaison between the VSWG and those in interested areas in each major organizational component regarding the evaluation of nominated data standards.
2. Evaluating nominated data standards.
3. Forwarding to the FDA Data Council those data standards recommended for Agency-wide adoption.

6. PROCEDURES

A. Nomination of Data Standards.

1. To nominate a new data standard or change an existing data standard, the following must be identified:
 - a. Data Element Name - The name of the data element to which the standard applies (e.g., "States and Outlying Areas of the United States").
 - b. Description - A statement identifying and explaining the standard in general terms (e.g., "This standard provides names, abbreviations and codes for representing the 50 States, the District of Columbia, and the outlying areas of the United States"). Boundaries or limits

of the standard needed to exclude inappropriate or include legitimate values must be deemed.

- c. Source - Where available, the organization, publication, or other entity having responsibility for maintaining the data element and its data items (e.g., "FIPS Publication 5-1").
- d. Specifications - An identification of the field length, type of data (structure), and format of the data element. For example, the specifications for the data element "Social Security Number" would be:

Field length is 11 characters;

Type of data is alphanumeric; and

Data format is NNN-NN-NNNN.

- e. Relationships - If appropriate, an identification of all broader and/or narrower terms relating to the data element.
- f. (Data Items - An identification of the legitimate, unique values of the data element. As an example, the data element "Sex of Person" would have the following data items:

F = Female;

M = Male.

Definitions may be needed to distinguish the difference between items and to assure consistency in their use. When it is not practicable to include the specifications in their entirety, a source will be cited to indicate where copies may be obtained.

- 2. Nominated data standards should be submitted to a VSWG member or to an FDA Data Council member.

B. Recommendation of Data Standards.

- 1. Nominated data standards are distributed to the VSWG for its review a minimum of two (2) weeks prior to the next scheduled Working Group meeting.
- 2. A three-fourths majority vote of the VSWG members present at a Work Group meeting is required for recommending a data standard to the FDA Data Council for adoption.

3. VSWG members voting against a proposed data standard are required to submit in writing the reason(s) for disapproval.
4. Proposed data standards and their recommendations, including any reasons for disapproval, are distributed to the FDA Data Council for its review a minimum of two (2) weeks prior to the next scheduled FDA Data Council meeting.

C. Adoption of Data Standards.

A data standard is approved as an Agency-wide standard upon ratification by a three-fourths majority vote of the FDA Data Council present at the next scheduled FDA Data Council meeting.

7. IMPLEMENTATION

All systems in operation at the time of adoption of a data standard must incorporate the standard during the next major system modification or within the next five (5) years, whichever occurs first.

8. EFFECTIVE DATE

The effective date of this guide is July 24, 2003.

9. Document History -- SMG 3260.1, Data Standards Program

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	07/24/2003	N/a	Vocabulary Standards Working Group	Randy Levin, Chairman, FDA Data Council