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FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

FDA OFFICIAL COUNCILS AND COMMITTEES

FDA DATA STANDARDS COUNCIL

Effective Date: 07/01/2004

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1. PURPOSE.

The purpose of the FDA Data Standards Council (DSC) is to coordinate the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency and the standards are consistent with those used outside the FDA. This is accomplished through strategically focused and systematic analysis of health and regulatory data standards requirements, evaluation of existing standards and adoption or development and maintenance of standards. This function operates at the direction of the FDA Management Council through the Business Process Planning Group (BPP) and provides timely, accurate and comprehensive analysis to BPP.

2. BACKGROUND.

The Clinger-Cohen Act, the President's Management Agenda, the Department policy of "One HHS," and the need for a coordinated counter-terrorism strategy are driving the Agency toward the establishment of a Federal Enterprise Architecture. FDA's strategic plan calls for agency-wide consolidation of information systems for realizing FDA policy goals and objectives. Data standards from a corporate agency-wide perspective are required for these systems to be effective and work efficiently.

Prior to the establishment of the FDA Data Standards Council, standards adoption, development and maintenance have been made at the Center level or lower. There has been relatively little coordination of these activities. Formation of agency wide activity such as the FDA Management Council and BPP serving as the principal developer of common agency business process requirements reinforce the need to coordinate the standardization of health and regulatory data. This is based on the understanding that many agency processes cross organization lines and cross-agency

data standards would enable the agency to decrease duplicative data requests and do cross-system analysis. It is anticipated that the FDA Data Standards Council function will support improved FDA' business processes and the information systems supporting those processes.

3. SCOPE.

The processes listed in this document are those for operating a health and regulatory data standardization function being implemented in FDA. The DSC serves as a resource to the FDA Management Council through the BPP Group on issues relating to the coordination, planning and development of health and regulatory related standards. The DSC works with both internal and external customers.

4. STRUCTURE.

DSC is an agency-wide group coordinated by the DSC Chair who reports to the Assistant Commissioner for Planning. The DSC is comprised of voting members and liaison members. Voting members include a representative from each agency Center, the Office of Regulatory Affairs and the Office of Planning - Business Process Planning. Liaison members include a representative from Office of International Activities and Strategic Initiatives, Office of Chief Council, and the Office of Chief Information Officer.

Administrative Support will be comprised of a Project Manager and Project Specialist. In addition, the work of the DSC will be closely coordinated where needed with the work of the BPP.

The FDA Management Council appoints the Chair for the DSC. The Chair will serve an unlimited number of terms until a replacement is appointed by the FDA Management Council. The Chair of the DSC or another designee of the Chair, serves as the FDA representative to the HHS Data Council and other non-FDA committees related to health and regulatory data standards. A DSC Project Manager is nominated by the DSC Chair and approved by the FDA Management Council. The DSC Project Manager will serve an unlimited number of terms until a replacement is nominated by the DSC Chair and approved by the Assistant Commissioner of Planning. The Project Manager provides support to the DSC and serves as an alternate for the Chair.

The DSC Chair makes recommendations to the Centers and ORA for nominees to serve as voting members. The voting members also serve as the chair for their individual Center's working group for assisting in the work of DSC (see organization structure below).

Expert work groups are formed by the DSC Chair as needed and chartered by the DSC to address specific area of need and will be tasked to provide feedback including evaluations, reports and/or presentations to the full DSC. Additionally the Work

Group Chair will be responsible for reporting activity results to the DSC Chair or appointed alternate.

5. RESPONSIBILITY.

The FDA Data Standards Council is responsible for coordinating the evaluation, adoption and/or development and maintenance of health and regulatory data standards supporting the Agency's mission. To accomplish its mission, the FDA Data Standards Council will:

a. Promote the coordination, adoption, and/or development, and maintenance of data and terminology standards to support health and regulatory needs.

b. Provide effective and accurate information to BPP groups, and FDA Management Council, assuring appropriate communication and early input from Agency key stakeholders who would be affected by contemplated changes.

c. Work with the FDA Enterprise Architect to promote the development of agency-wide integrated data element architecture to address the health and regulatory needs of the agency.

d. Coordinate with the Department, other agencies, and interested parties in the standardization of health and regulatory data to benefit the public health.

e. Provide a forum for resolving issues related to health and regulatory data element architecture, data standards, and terminology.

f. Address specific data standards policy issues raised at the Council for the Application of Healthcare Information Technology, HHS Data Council, Consolidated Health Informatics and other non-FDA groups.

g. Provide timely results of research and recommendations to the BPP.

h. Ensure the formation of work groups with knowledgeable experts from relevant program areas.

6. PROCEDURES.

The FDA Data Standards Council reports to the BPP. The Council's process will include the following elements.

Functional

a. Standards evaluation and approval

1. Propose: Project proposals are presented to the FDA Data Council outlining the business need, benefits, concept or solution, issues and dependencies and resource estimates.

2. Analyze: Work Groups will be formed by the DSC Chair as needed and chartered by the DSC. Each work group will address a specific area of need and will be tasked to provide feedback including evaluation, report and presentation to the DSC.

3. Review: Evaluation documentation for each standard should include rationale and purpose, business need /use case, actions needed for approval, goals, stakeholders, existing standards, business process supported by the standard, maintenance processes and specifications.

4. Comment: Negative comments should be accompanied by potential solutions.

5. Approve: Proposed standards are approved by vote in the DSC. Approved standards are sent to the FDA Enterprise Architect for entering into the agency Enterprise Architecture.

b. Work groups will be established to address specific areas of need. The DSC Chair will select membership for the DSC. A charter will be developed to define the scope of the activity of the work group.

c. Work groups will provide results in the form of analysis, evaluation and assessment reports and presentations to the DSC.

Meetings

d. The DSC will meet monthly or more frequently as needed.

e. The DSC Chair or alternate (as requested) will be responsible for setting the agenda, considering submitted agenda modification requests, determining the final agenda, and communicating to any individual's request excluded from agenda.

f. The Project Manager will be responsible for sending out the meeting agenda to the members.

g. The Project Manager will chair meetings in the absence of the DSC Chair and will participate in the planning of the agenda for the meetings.

h. The voting members of the DSC will include the DSC Chair and Center/Office representatives. Subject matter experts will not be voting members of the DSC. If a voting member is unable to attend the meeting, an

alternate representative should be sent to the meeting and will represent their Center/Office in voting and decision-making processes.

i. A quorum will consist of a majority of the members. Decisions will be reached by majority decision. If a majority decision is not reached within the DSC, the divergent conclusions and recommendations will be included in a report to the BPP and/or FDA Management Council as appropriate for resolution.

Communication

j. The DSC Chair will be responsible for regular briefings of the BPP work groups, and as needed, the FDA Management Council, to ensure timely communication and support for FDA management decisions.

k. The DSC Project Manager is responsible for recording minutes including noting decisions, due dates for action items and other important information for the meeting.

l. Work group members will participate in and provide status at the meetings. Work group progress in meeting objectives will be reviewed at least annually.

m. DSC representatives will be responsible for the dissemination of information to the appropriate contacts in their Centers.

7. EFFECTIVE DATE.

The effective date of this guide is July 1, 2004. Upon signature, this charter will be valid until five years after the effective date at which time, the charter will be certified as current or revised as needed.