Classifying Medical Device Data Systems in the US

Diane Mandell Horwitz examines the US FDA's proposal to classify medical device data systems and to update its policy on software in devices.

The US Food and Drug Administration recently published a proposed rule for lowering the classification of some medical device data systems[1,2]. The development is important because MDDSs – described as "systems that provide electronic transfer, storage, exchange, retrieval, display and conversion of medical device data" – were previously considered by default as Class III devices, and now some are proposed as Class I. This is significant for some manufacturers who may be unaware, it seems, that they are working in a regulated industry.

The FDA currently classifies medical devices using a tiered system determined by the level of control necessary to ensure safe and effective use. Certain MDDSs are proposed to be Class I devices, the lowest of the three medical device classification levels in the US. The proposed new classification, 21 CFR 880.6310, is shown below in Table 1.

This article describes the MDDS Class I category and summarises the FDA's reclassification petition, comments on which were due by 8 May. It also describes why the FDA has taken this step and how it will affect manufacturers.

MDDSs are medical devices

Computer software is an important component of many devices and is in some cases itself considered a medical device. This is the case, for example, with internet-based blood glucose data management systems and patient charting software.

As with other medical devices, the FDA regulates software according to the risk to the patient if the software were to fail, as outlined in its 1989 Draft Software Policy[3]. The FDA has realised that there is a need to further define and update the requirements for medical software because of the ongoing proliferation of new types of software-based medical devices.

The *Federal Register* notice where the rule is proposed[4] provides a detailed description of which MDDSs fall into the Class I category, with examples. The salient points in the Class I description are that:

- the MDDS transfers data, and allows storage and retrieval of data, and/or visualisation and display of data from a medical device without changing the function of any of the connected devices;
- electronic conversion of data must be conducted according to a preset specification;
- medical device data can represent a variety of clinical information, but the MDDS does not perform real-time monitoring of patient function and does not provide clinical decision-making;
- an MDDS can record an alarm function from the parent device, but cannot generate a new alarm based on incoming data;
- a Class I MDDS cannot be related to a home-use device and is only for computer systems used by a healthcare professional; and
- a Class I MDDS cannot perform irreversible data compression.

Table 1. 21 CFR Sec. 880.6310 Medical Device Data System – Proposed description

(a) Identification

(1) An MDDS is a device intended to provide one or more of the following uses:
(i) The electronic transfer or exchange of medical device data from a medical device, without altering the function or parameters of any connected devices.
(ii) The electronic storage and retrieval of medical device data from a medical device, without altering the function or parameters of connected devices.
(iii) The electronic display of medical device data from a medical device, without altering the function or parameters of connected devices.
(iv) The electronic conversion of medical device data from one format to another format in accordance with a preset specification.

(2) Medical device data consists of numerical or other information available from a medical device in a form suitable for processing by computer. Medical device data can represent any type of information or knowledge, eg clinical values, alarm conditions, error messages. This identification does not include a device that creates diagnostic, decision support, or alarm functions. It also does not include the report-writing functions of a data system that allows for the manual input of data by practitioners. This identification does not include devices with any real time, active, or online patient monitoring.

(b) Classification. Class I (general controls). When the device is indicated for use only by a healthcare professional and does not perform irreversible data compression, it is exempt from the premarket notification procedures in Subpart E of Part 807, subject to the limitations in Sec. 880.9. When the device is indicated to be prescribed by a healthcare professional for use by a lay user, or performs irreversible data compression, or for over-the-counter use by a lay user, the device requires the submission and clearance of a premarket notification.

Diane Mandell Horwitz, PhD, RAC is the president of Mandell Horwitz Consultants LLC, based in Washington, DC.

The *Federal Register* notice further explains that, if any of the above conditions are not met, the classification of the MDDS is elevated to Class II, requiring that the sponsor submit a premarket notification application (510(k)) to the agency.

The description of Class I-exempt MDDSs seems narrow, but actually includes the many computerised data storage systems in physicians' offices and hospitals, and other data management systems used by healthcare professionals to consolidate and display healthcare data.

The limitation of Class I to software devices for healthcare professionals only is based on the FDA's expectation that professionals will understand the clinical implication of the software output, while a home user may not (thereby increasing the risk and requiring a greater level of regulatory control over the device for safe and effective use). The FDA believes that submission of a 510(k) for home-use devices will enable the agency to ensure that the data output is appropriate to the home user.

The FDA has already called on companies, sometimes directly, to require that these regulatory requirements be fulfilled. The reclassification petition serves as a reminder to emphasise the importance of proper quality design and controls in the industry. It may also serve to "level the playing field", expecting all software manufacturers to conform to the same level of quality system regulation and other regulatory requirements.

General controls are necessary

General controls form the baseline requirement for all medical devices in the US and include employment of a functional quality system, that certain reporting and registration and listing requirements are fulfilled, and that the device not be misbranded or adulterated. However, it seems that the FDA expresses an unrealistic view of software developers when it states in the *Federal Register* notice that "based on experience with this and similar devices, FDA believes that most manufacturers of these devices already have quality systems in place as part of good business practices".

This is probably an optimistic statement. Although the FDA's assumption is correct, as a functional quality system would indeed be part of good business practices, it is certain that many sponsors do not have quality systems in place and will not initially see the benefit of implementing the proposed FDA requirements. Nonetheless, general controls are an important part of the development and marketing plan for new and existing MDDS devices, and if the proposed rule becomes final, the quality and safety of these devices will indeed be elevated.

References

1. *Federal Register*, 8 February 2008, **73**(27), 7498-7503, www.fda.gov/OHRMS/DOCKETS/98fr/E8-2325.pdf
2. *The Regulatory Affairs Journal – Devices*, 2008, **16**(2), 117
3. FDA Policy for the Regulation of Computer Products (draft), 13 November 1989 (removed from the FDA website in 2006)
4. See Reference 1