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WHAT DOES THIS
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MANUFACTURERS?**

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US FDA RELEASES FINAL RULE ON MEDICAL DEVICE DATA SYSTEMS - WHAT DOES THIS MEAN FOR DEVICE MANUFACTURERS?

Introduction

In 2009, the Consumers Union produced a report entitled, *To Err is Human - To Delay is Deadly*¹, stating that over 100,000 people die annually as a result of preventable medical harm (i.e. failure of a planned action to be completed as intended or the use of the wrong plan). A number of these deaths are attributable to medical device software failures, such as the deaths of 21 Panamanian teletherapy patients in 2000². Unfortunately, it is not only failures in medical devices containing embedded software that can have fatal consequences for patients. In 2009, six patients died and hundreds of adverse events occurred due to errors with Hospital Information Technology (HIT)³. A report completed by The Huffington Post Investigative Fund⁴ identified 237 adverse events associated with HIT over a two-year period. The majority of these problems centred on computerised medical ordering software and systems that supply the software with vital information such as patient medication dosages. Software is used widely within healthcare and examples include:

- embedded software in a medical device;
- standalone software as a medical device;
- HIT;
- mobile device software; *and*
- software used to develop medical devices.

However, as the reliance on software-controlled devices for use in healthcare increases, regulatory control is needed to ensure that medical devices either consisting entirely of software or having a software component are safe. Software used in healthcare falls into one of four categories:

- software as an accessory to a medical device;
- software as a medical device in its own right;
- software as a medical device data system (MDDS); *or*
- software currently unclassified and not subject to specific regulations.

The category into which software falls is dependent on the function that it performs. Regulatory controls have previously been put in place to regulate both medical devices and accessories to medical devices. However, no specific guidance had been provided in relation to the usage of devices that are now classified as MDDSs. These devices were either previously unclassified, classified as accessories to medical devices or medical devices in their own right. The US Food and Drug Administration (FDA) describes an MDDS as being any electronic device used to transfer, store, convert or display medical data that is not intended for active patient monitoring.

In 1981, the FDA began to investigate the use of software in healthcare. Initially the FDA classified medical device software based upon its Draft Software Policy, published in 1987 and revised in 1989 (now withdrawn). However, since then the rate at which computer and software-based products are used in healthcare has grown exponentially. Prior to 16 April 2011, devices that now meet the current definition of being an MDDS were classified as either a Class III device (potentially high risk) or assumed the safety classification of the parent medical device to which they were connected, although the FDA had been operating under its discretionary enforcement policy and therefore had not been enforcing the Class III requirements on all MDDSs⁵.

On 16 April 2011, the FDA rule became effective that classified an MDDS as a Class I, 510(k)-exempt medical device⁶. This ruling came three years after the proposed ruling was issued on 8 February 2008⁷. This final classification modifies Title 21 of the Code of Federal Regulations (21 CFR) Part 880.6310 and describes an MDDS as being:

‘software, electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, interfaces, and a communications protocol’.

The purpose of this article is to provide an overview of the FDA’s final rule on the safety classification of an MDDS, how this rule has been amended in comparison to the proposed rule and what this rule means for MDDS manufacturers. In addition, the authors outline the challenges which medical device manufacturers face when developing safe, reliable devices that conform to the latest regulatory requirements.

Scope of the MDDS classification

Although this ruling has been developed to provide clarity on the regulation of devices that come under the heading of being an MDDS, it has created a level of confusion among manufacturers. Confusion surrounds areas such as device classification, active patient monitoring and the transfer of medical data. This is evident in the comments section of the ruling⁶.

Previous classification

An MDDS is an example of a post-amendment device. Post-amendment devices are devices that were not actively manufactured or sold prior to 28 May 1976. All post-amendment devices were automatically classified as Class III devices until they are reclassified as either Class I or Class II devices. They are deemed to place the patient, clinician or third party at the most potential risk of harm. Devices actively manufactured or sold before 28 May

1976 are known as pre-amendment devices. This was the date of an amendment to the *Federal Food, Drug and Cosmetics Act* (FFD&C Act).

MDDS classified devices

An MDDS is described in 21 CFR Part 880.6310 as:

‘[A] device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:

- (i) The electronic transfer of medical device data;
- (ii) The electronic storage of medical device data;
- (iii) The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or
- (iv) The electronic display of medical device data’.

If a device meets these requirements it can be classified as an MDDS and receives a safety classification of Class I (general controls). However, if a device meets these requirements and also performs additional functionality, such as active patient monitoring, it cannot be considered an MDDS. Devices performing active patient monitoring assume the safety classification of the parent medical device or automatically receive a Class III classification until reclassified by the FDA.

Software as an MDDS

While this ruling includes the use of software in healthcare, not all software can be considered an MDDS. The function performed by the software determines whether or not it comes under the umbrella of being an MDDS.

The FDA has determined that the risk associated with an MDDS originates from inadequate software quality and incorrect functioning of the device. It is envisaged that issues with software that could potentially cause harm would be identified and resolved by the use of a Quality Management System (QMS) as required by the Quality System Regulations (QSR). Examples of

software as an MDDS include:

- software used to pass a control signal to an infusion pump;
- software that stores patient data such as blood pressure readings for review at a later time;
- software that converts digital data generated by a pulse oximeter into a format that can be printed;
- software that displays a previously-stored electrocardiogram for a particular patient;
- software used in healthcare labelled as an MDDS that has been modified in accordance with the manufacturer's guidelines.

Previously unclassified devices

As part of the final rule regarding MDDSs, device manufacturers that were previously unregulated and consequently unclassified are now potentially subject to FDA enforcement if their device meets the definition of an MDDS. Companies that fall into this category are likely to be smaller manufacturers who are less prepared than larger companies in terms of having the necessary QMS in place⁸.

Medical data transfer

Part of the MDDS rule states that devices that transfer data but do not alter the content are considered MDDSs. The ruling states⁶:

'Use of an MDDS for conversion is limited to translation, so that data can be viewed or transmitted in the same form that it was received by the MDDS.'

Examples of translation include converting data into different languages so as to be interpreted by equipment supplied by different vendors. Another example is converting information in HL7 [Health Level 7] format to allow it to be displayed in a spreadsheet. In essence, an MDDS cannot interpret, analyse or modify clinical data in any way.

Mobile device software

The amount of mobile device software used in healthcare is increasing. The Apple Apps store has an entire section containing over 230 healthcare applications⁹. As part of the final rule, mobile device software theoretically comes under the heading of being an MDDS provided that it is not used for active patient monitoring. As part of the proposed rule, a device could only be considered an MDDS when used by a healthcare professional exclusively¹⁰. However, as part of the final rule, a device can be considered an MDDS if used by either a healthcare professional or a lay person. This change means all medical device applications used on any mobile platform are subject to regulatory conformance. However, mobile application developers are avoiding regulatory scrutiny by stating that their software is neither for patient monitoring nor diagnosis¹¹. Whilst manufacturers and developers are attempting to avoid the need for regulatory conformance, this loophole seems set to be closed by the FDA¹².

Beyond the scope of the MDDS classification

As part of the final rule on MDDSs, a number of devices - both hardware and software units that appear to satisfy the criteria for being an MDDS - are beyond the scope of the MDDS classification. Within this section the authors provide a few examples of such devices.

Network infrastructure

Whilst HIT utilises network infrastructure, this infrastructure does not necessarily meet the criteria of being an MDDS. Network infrastructure beyond the scope of the MDDS ruling includes¹³:

- network routers;
- network hubs;
- wireless access points;
- network attached storage;
- storage area networks.

It is clear to see that these devices do perform functions associated with that of an MDDS (i.e. store, transmit or display clinical data). However, they are not developed solely for that purpose and are considered general information technology within a hospital environment.

Software not an MDDS

When the proposed rule was issued, a number of comments arose in relation to software applications used daily in healthcare and whether these software applications would be considered an MDDS. Software applications such as electronic health records (EHRs) and computerised physician order entry (CPOE) are deemed beyond the scope of an MDDS. The reason cited by the FDA in the final ruling (Section III, Comment 7) for this decision is two-fold. First, whilst it appears that an EHR is used to store clinical data, that data must have been either obtained electronically from a medical device or the clinical data stored must be intended for electronic transmission. Second, as with CPOEs, EHRs can potentially order tests for patients. This would lead to the software falling outside the scope of an MDDS as it would be initiating the generation of clinical data.

Also, commercial off-the-shelf (COTS) software not developed to perform the function of an MDDS is not considered an MDDS. This also applies to COTS software that has been modified within the parameters of the developer's guidelines.

Alarms

The area of alarm classification as part of the MDDS ruling has created ambiguity among manufacturers. Alarms connected to a medical device that emit warnings based on the information received from the connected medical device are typically considered accessories to the parent device as they are utilised for active patient monitoring. Essentially, the sounding of an alarm would result in immediate corrective action being taken in regard to patient treatment.

However, not all alarms fall beyond the scope

of an MDDS. Alarms used to monitor the state of an MDDS are considered to be an MDDS and receive a Class I safety classification.

Challenges

One of the main challenges for medical device software companies is to understand the current state of their software development processes in relation to the requirements of the medical device regulations (e.g. the FDA ruling on MDDSs) and standards. To achieve this understanding, adherence to the latest development standards is required. However, current software development standards such as IEC 62304: 2006, *Medical device software - Software life cycle processes* were developed prior to the recent changes in regulatory requirements and as such do not cater for these changes.

Another challenge for medical device companies is in relation to supplier selection. As medical device manufacturers are responsible for the safety of their medical devices, it is essential that they are confident that the software (either as a component of a medical device, as an accessory to a medical device, as a standalone medical device, or as an MDDS) is developed by following defined and approved processes. Hence, whenever the software development component of the medical device is outsourced by the medical device manufacturer it is vital that the manufacturer is confident that safe and effective software will be delivered that has been created through adopting regulatory-compliant software development processes. This therefore presents a challenge for both medical device manufacturers in relation to selecting a software development organisation and also for software development organisations to become recognised medical device software suppliers.

What next?

International medical device regulations

Whilst the MDDS final rule aims to remove ambiguity surrounding the use of different hardware and

software in a healthcare environment, confusion still surrounds some applications of software in healthcare (i.e. EHRs, CPOE and mobile applications). There are informal reports that the FDA is currently drafting guidance to define what aspects of health information technology are considered medical devices (e.g. EHRs and CPOE)¹⁴. In a workshop carried out by the FDA, Margaret Hamburg, Commissioner of Food and Drugs at the FDA, stated that in July 2010 the FDA began drafting a guidance document on mobile health devices and applications¹². This document is expected to be published soon.

On 21 March 2010, the latest amendment to the European Medical Devices Directive came into force¹⁵. One of the changes introduced was the explicit inclusion of software into the definition of a medical device¹⁶. This extended to the use of standalone software as an active medical device. However, this inclusion created uncertainty as to what software would and would not be considered a medical device. An example of such software includes EHRs and HIT applications. A MEDDEV document is expected to be released later this year to provide clarity as to what category different types of healthcare software belong to.

Following the FDA's release of the final MDDS rule, the European Commission has determined that specific guidance is required for these systems and a meeting of the Medical Device Expert Group has been provisionally scheduled for 30 November 2011 and 1 December 2011 to discuss this issue.

Medical device development standards

As discussed, the current standard for the development of medical device software is IEC 62304. The most recent version was released in 2006, prior to the latest regulatory changes in both Europe and the USA. Consequently, it is not sufficiently comprehensive to provide guidance in the development of all types of software used to diagnose, monitor and treat patients. However, IEC 62304 is currently under revision and when a new

version is released, it is expected that it will provide the necessary guidance to medical device manufacturers who develop software for use in healthcare to ensure the latest regulatory requirements are met.

Conclusions

Prior to 16 April 2011 in the USA, all post-amendment devices utilising software and used in connection with patient treatment automatically received a Class III safety classification, or the software adopted the safety classification of the medical device to which it was connected. This classification could only be changed upon application to the FDA. However on 16 April 2011, the FDA's final rule governing the use of MDDSs became effective. This ruling classified device's that were used for storing, displaying, transmitting or translating clinical data as Class I devices. However, a caveat was added to the final rule that if a device performs an additional function such as active patient monitoring it would not meet the definition of being an MDDS and would be subject to different regulatory requirements. An MDDS can be hardware, software or a combination of both. As part of this ruling, manufacturers must adopt a QMS and adhere to the FDA's general controls. The reason cited for this is that the FDA envisages any flaws associated with an MDDS would be software related and would be identified by adopting a QMS. To develop safe software that meets regulatory requirements, adherence to the latest development standard is encouraged. Unfortunately, the current development standard (IEC 62304) was developed prior to this ruling and therefore does not take the changes as part of this ruling into account.

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Medi SPICE is currently being developed by the Regulated Software Research Group at Dundalk Institute of Technology in association with the SPICE User Group. Medi SPICE aims to provide an end-to-end software development framework for medical device software developers to develop safe medical devices that conform to the latest regulatory requirements and to streamline the process of supplier selection.

Medi SPICE is a software process assessment model for the medical device industry that is based upon the structure of the international standard for software process assessment and capability determination (ISO/IEC 15504-5) and provides coverage of the medical device regulatory device software regulations (with a particular focus upon the IEC 62304 standard).

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