The Essential Facts of Essential Performance

Todd Konieczny

Many medical device manufacturers believe that risk has always been a cornerstone in evaluating device compliance with medical standards. The Second Edition of IEC 60601-1 covered risk management, but Third Edition is taking it up a notch – the word “risk” is included in IEC 60601-1’s Third Edition standard more than 600 times. This increased emphasis on risk is a direct result of two elements of the revised standard – the requirement to review both the risk management processes and the risk management file, and the addition of essential performance.

What Is Essential Performance?

Essential performance is the performance necessary to achieve freedom from unacceptable risk. To determine this, the manufacturer must consider the device performance functions and evaluate the presence of acceptable and unacceptable risk. An unacceptable risk leads to a performance function being classified as essential performance. Thus, it is critical to understand the differences between these two types of risk in order to understand essential performance.

Unacceptable risk occurs when a product’s failure will cause harm to a patient operator, or the environment, whereas acceptable risk occurs when a product’s failure will not cause harm. To illustrate the difference, think of a battery-operated thermometer. Failing to display the patient’s temperature on the screen could be considered an acceptable risk since it will not cause harm to the patient. While it would be frustrating for the doctor, this malfunction does not physically hurt anyone

On the other hand, what would happen if the thermometer displayed the patient’s temperature incorrectly? What if the thermometer incorrectly measured the patient’s temperature at 99 degrees, when the patient was actually suffering from a severe 105 degree fever? A wrong temperature reading could indeed be detrimental to the patient, because the doctor would be unaware of the severity of the patient’s condition and would not likely administer proper treatment – at no fault of their own.

What all of this – essential performance and unacceptable risk – boils down to is that a product’s behavior must not cause harm to a person, place or thing if

something goes wrong. It is not about a part working properly, but rather the behavior of many parts working together to create essential performance. Before you try hunting for every possible risk that your product holds though, it is important to remember that every product does not necessarily have essential performance functions.

What Does It Mean For Manufacturers?

The determination of what is and is not an essential performance function is actually up to the manufacturer. In the risk management file (RMF), the manufacturer will indicate which performance functions are essential performance functions and explain the unacceptable risks of that function. During the testing and certification process, the testing partner will review the RMF to find what essential performance functions are indicated and evaluate these during the tests to determine if the essential performance functions are maintained during the operation of the product. Having a compliant RMF will assist when certifying to ISO 13485, which is required to ensure it meets industry requirements for medical device production. The product will pass inspection only after the entire RMF is evaluated and the device is deemed free from unacceptable risk, or when a risk/benefit analysis shows that the medical benefits outweigh the unacceptable risk of the product.

To increase the likelihood that a product will pass certification, manufacturers can submit an initial design and RMF for review prior to testing. During the preliminary design review, the test engineers will review all performance functions to verify they have been documented and allow essential performance to be determined in the RMF. This knowledge will allow the manufacturer to reevaluate the product before moving forward in the production process.

It is key for manufacturers to understand the importance of essential performance in the Third Edition standard so they can successfully create RMFs that are ISO 14971 compliant and do not need to be revised repeatedly, wasting time and money when the product could otherwise be available on the market. The development of the RMF and completion of a risk assessment for all performance functions of products is one of many ways manufacturers can gain a deeper understanding of the essential performance of their products and satisfy the new requirements of Third Edition. .

Todd Konieczny is the North American medical technical leader at Intertek. [1]

Source URL (retrieved on *07/26/2014 - 12:45pm*):
http://www.mdtmag.com/blogs/2012/06/essential-facts-essential-performance?qt-recent_content=0

Links:
[1] http://www.intertek.com/medical