Choices - IEC 60601-1
3rd edition and component selection
Executive Summary

Abstract - When the 3rd edition of IEC 60601-1 was published, it marked the beginning of a new era. The standard now incorporates the concept and application of risk management in the design and production of devices. Implementation of risk management has implications for not only the end-product manufacturer, but component providers as well, and further cascades through the entire supply chain. All parties now face a series of choices and opportunities in determining how best to ensure, for the entire lifetime of a device, that basic safety and essential performance are preserved. This article explores some of those choices and their consequences.

The publication of the 3rd Edition of IEC 60601 sparked debate and discussion about the need to perform a risk management assessment of component power supplies that will be used in medical electrical equipment.

In reality, this is not a new concern. Many regulators have long required manufacturers to incorporate risk management in the design and production of medical devices. For example, the U.S. Food and Drug Administration’s (FDA) quality system regulation (QSR) requires manufacturers to, (as noted in 21 CFR 820.30(c) - Design Inputs)

“… ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient …”

And in 21 CFR 820.30(g) - Design Validation:

“… shall include software validation and risk analysis (emphasis added) …”

In practice, some manufacturers have relied on third-party certification to ensure adequacy of design of supplied components. With certain qualifiers, the FDA has acknowledged this approach. According to the preamble to the 1996 quality systems regulation (comment No. 103):

“… [FDA] cautions manufacturers against relying solely on certification by third parties as evidence that suppliers have the capability to provide quality products or services … third party certification should not be relied on exclusively in initially evaluating a supplier. If a device manufacturer has established confidence in the supplier’s ability to provide acceptable products or services, certification with test data may be acceptable.”

The national and international standards used to certify these components have also provided a solid foundation to ensure the safety of medical devices.
Going Forward

To ensure the safety and effectiveness of the finished device after the design phase, the finished device manufacturers must control all contractors. In the past, end-product manufacturers have, to some degree, relied on the certifications of off-the-shelf components to ensure safety. Because of the reliance on certifications, original equipment manufacturers (OEM) may not have had detailed knowledge of design features at the component level. However, to truly manage the risks involved in the application of a component within an overall system additional analysis, and knowledge of design details and construction features of the component, may be needed.

According to clause 4.2 of ISO 14971 (Application of Risk Management to Medical Devices):

“… The manufacturer shall identify and document those qualitative and quantitative characteristics that could affect the safety of the medical device and, where appropriate, their defined limits. This documentation shall be maintained in the risk management file.”

And according to clause 4.3 of ISO 14971:

“The manufacturer shall compile documentation on known and foreseeable hazards associated with the medical device in both normal and fault conditions. This documentation shall be maintained in the risk management file.”

Therefore, if a manufacturer’s risk management process has identified a certain feature as critical to basic safety or essential performance, it is the manufacturer’s responsibility to ensure that the feature is preserved through the expected service life of a device.

In the past, if a feature was dependent on a particular construction within an outsourced component, the end-product manufacturer relied on compliance of the component with national and international standards and their certifications. Theoretically, if component manufacturers had risk management processes in place, and if it were possible for them to know the intended use and essential performance of the ultimate end product, this approach could continue. However, many component manufacturers are not familiar with these risk management requirements and may never take the initiative to learn them. It is then an OEM’s responsibility to follow through and ensure appropriate risk-management measures are taken. To see what this actually means, it is necessary to dig deeper.

From the rationale to Sub clause 4.2 of IEC 60601-1:2005:

“...The MANUFACTURER is responsible for ensuring that the design and construction of the ME EQUIPMENT renders it suitable for its INTENDED PURPOSE and that any RISKS that are associated with its use are acceptable when weighed against the benefits...”

“...The MANUFACTURER of ME SYSTEMS should make this determination on a system level. The MANUFACTURER should assess RISKS resulting from the fact that individual system components have been integrated into one system. This assessment should include all aspects of the information exchanged between the system components...” (emphasis added)
This latter statement makes it clear that the risk assessment needs to consider the intended function of a device and how it may relate to a device’s essential performance.

The rationale continues:

“...Even when these components are non-me electrical components, the potential RISK related to the integration of these components into the ME SYSTEM need to be considered. Further requirements for the integration of non-medical equipment into a ME SYSTEM are described in clause 16. It gives the requirements for an ME SYSTEM and how RISKS associated with non-ME EQUIPMENT are addressed...”

From 16.1 of IEC 60601-1:2005:

“...An ME SYSTEM shall provide:
  • within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this standard; and
  • outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective IEC or ISO safety standards...”

Additional details apply, but the net effect is that a manufacturer must pay close attention to where and under what conditions a given component is to be employed. In some cases, compliance with an applicable component safety standard alone may be sufficient. In other cases, a manufacturer must identify associated hazards and estimate and evaluate the risks they carry. A manufacturer must take action to control those risks and monitor the effectiveness of the controls.

**Business Implications**

Of course, there are business implications associated with the selection of components, and they are more extensive when risk management is required. This is true for both a component supplier and OEM. With regard to risk management for medical devices, there are two basic scenarios: either a component supplier elects to perform the risk management or not.

At least initially, most component suppliers will probably not perform risk management. This means that, for them, business will continue as usual with regard to design, development and production processes.

However if a component is purchased by a medical device manufacturer and its application requires risk management, an OEM will need information about the component beyond its ratings and certifications. This might include design details of the component construction, e.g. transformer bobbin construction and material, creepage and clearance distances, and dielectric strength.
To fulfill applicable regulatory obligations and follow their risk management process, OEMs may also require some level of supplier control over a component to preserve basic safety and essential performance. This may involve second-party audits by an OEM, which may also need to understand how a component manufacturer's suppliers are controlled. The certification agency evaluating a finished device may also need access to such information. If this same component is then sold to other end-product medical device manufacturers for similar purposes, suppliers may find themselves duplicating such assessments and information sharing processes.

From the OEM’s perspective, they must demonstrate compliance with clause 4.8 of IEC 60601-1:2005, which states in part: “All components, including wiring, the failure of which could result in a HAZARDOUS SITUATION shall be used in accordance with their specified ratings unless a specific exception is made in this standard or through the RISK MANAGEMENT PROCESS...”

With this information in hand, an OEM will need to determine whether any supplemental actions or end-product design changes are needed to maintain an acceptable level of risk on an ongoing basis. OEMs may impose vendor requirements (such as supplier controls) on suppliers to maintain an acceptable level of risk.

As discussed previously, some suppliers follow a risk management process when developing components. This presents challenges to the component supplier, but also offers some distinct benefits. With respect to challenges, the single biggest hurdle may be implementation of an ISO 14971 process, or at the least, putting processes and procedures in place that support the information needs and actions of an end-product manufacturer’s ISO 14971 process. Since many component manufacturers have quality management systems in place, there are resources that can assist. The Global Harmonization Task Force (GHTF) produced document GHTF/SG3/N15R8 titled “Implementation of risk management principles and activities within a Quality Management System.” This document discusses and supports the implementation and integration of a risk management system within a medical device manufacturer’s quality management system and provides practical explanations and examples.

Another challenge, perhaps better stated as an additional requirement, is establishing and communicating the design intent of a component. Previously, a supplier could produce a component with certain features and ratings, and it was up to the OEM to determine whether the component was acceptable for the ultimate end use. However, a foundational element of risk management for any device is a clear statement of intended use and a declaration of the essential performance. These establish the basis for design features, performance characteristics, and the identification of any limitations for a device. The risk management process is then used to define, establish and implement any necessary risk mitigation to preserve the essential performance and basic safety of the ultimate end-product.
The information that is developed in answer to the challenges provides the key benefits of implementing a risk management program—namely, a supplier’s ability to demonstrate due diligence to a purchaser in the form of objective evidence of compliance with the relevant parts of Clauses 4.2, 4.8 and others of IEC 60601-1. Suppliers that are able to provide a clear statement of intended use and a definition of essential performance for a component, as well as details of the risk analysis and mitigation actions performed, put OEMs in a much better position to complete their risk management processes. Because of this, OEMs may prefer vendors that can offer such risk management documentation because they can reduce the OEM’s burden in terms of cost and time.

Suppliers may find additional intangible benefits to implementing a risk management process. Specifically, manufacturers that develop components with the aid of a risk management analysis will find a clear and comprehensive understanding of the actual risks associated with its declared intended use. As a result, the risk controls applied to product design features and characteristics will be focused right where they need to be — on preserving basic safety and essential performance. This, in turn, can result in a more efficient allocation of resources, a reduction in field issues, and greater profitability. OEMs that work with suppliers that have implemented a risk management process will see distinct advantages beyond being able to demonstrate compliance with a safety standard. This begins with supplier assessments. As noted in the FDA’s QSR, Sec. 820.50 on purchasing controls:

“Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

• Evaluation of suppliers, contractors, and consultants. Each manufacturer shall establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants.

Each manufacturer shall:

• Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.”

A supplier with an ISO 14971-compliant process could readily produce the information and documentation needed to support and simplify an OEM’s efforts to evaluate and select suppliers.

There are additional potential benefits for OEMs, including the following:

• Reduced effort to identify component design features and characteristics that may have an impact on basic safety and essential performance.

• Clear identification of any features or characteristics that may be candidates for some level of supplier control.

• Reduced overhead to maintain the device risk management file, due to the availability of information regarding the purchased component.

In short, when both an OEM and a supplier have an ISO 14971 process in place, communication between the two is greatly enhanced. Both parties will have a more comprehensive understanding of the design and production risks associated with the finished device. This offers the opportunity for reduced duplication of effort, making the entire supply chain leaner, and focusing activities on the preservation of basic safety and essential performance. This is in line with the imperative of regulators around the world for good manufacturing practices.
Medical devices certified according to the 3rd edition of IEC 60601-1 must be developed under a process compliant with ISO 14971. This is also true for critical outsourced components. This presents an end-product manufacturer and a component provider alike a choice: OEMs must decide if they are going to require outsourced components to be developed under an ISO 14971 process. Similarly, component providers must decide if they’re going to implement an ISO 14971 process.

Clearly these choices represent the potential for significant change in the industry, and the options faced by OEMs and component providers must be weighed carefully. However as history has demonstrated, change also brings opportunity; and with the 3rd edition of IEC 60601-1, change is upon the industry.

For more information on how UL’s testing services can help your company meet the changes of IEC 60601-1 3rd + Amendment 1 Edition, visit UL.com/Healthcare or contact us at Medical.Inquiry@ul.com.