The Joint Commission

October 26, 2010

Joan S. Antokol
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Dear Ms. Antokol,

Thank you for your recent inquiry regarding the applicability of The Joint Commission's Tissue Storage and Issuance standards (TS) to the SIS products manufactured by Cook Biotech.

As background information, the Tissue Storage and Issuance standards are intended to support healthcare organizations with the development and implementation of procedures for managing the potential transmission of infectious disease associated with the use of tissue products. The introduction published in our accreditation manual for standards TS.03.01.01 – TS.03.03.01 states the Tissue Storage and Issuance standards "apply to human and nonhuman cellular-based transplantable and implantable products whether classified by the U.S. Food and Drug Administration (FDA) as a tissue or a medical device." Manufacturer instructions commonly note the risks associated with the use of tissue and cellular based products and their potential to transmit infectious disease. For this reason, the Joint Commission TS standards specifically apply to biologics which contain cellular elements at the time of implant.

As the SIS products manufactured by Cook Biotech are rendered acellular at the time of use for the patient and the manufacturing process significantly reduces the potential risk of transmission of an infectious disease, they are not subject to the Joint Commission's Tissue Storage and Issuance standards.

The Joint Commission encourages healthcare organizations to review the Tissue Storage and Issuance standards and consider if it is beneficial to have similar procedures in place for medical devices. The essential themes of the Tissue Storage and Issuance standards are similar to those required of healthcare organizations for other compliance activities, such as those related to managing medications and blood products. These essential themes are: 1) Oversight, 2) Standardized procedures, 3) Tracking and 4) Adverse event investigation. While acellular medical devices are not subject to the same stringent Joint Commission standards for tracking documentation as are applicable to tissue products, some level of tracking and management is required by the FDA in the event of a recall. In recognition of this broader implication, some tissue tracking software vendors include medical devices in the design of their systems.

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The Joint Commission has no specific plans to require additional record keeping for medical devices now or in the future. However, it is important to note that the evolution of the electronic medical record and integrated record keeping databases will enable healthcare organizations to maintain more detailed documentation, possibly influencing the FDA's oversight abilities and requirements.

Please let me know if I can be of further assistance.

Sincerely,

Megan E. Sawchuk

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