April 25, 2008

Darlene A. Christiansen, RN, LNHA, MBA
Executive Director
Accreditation and Certification Services
The Joint Commission
Division of Standards & Survey Methods
Standards Improvement Initiative
One Renaissance Blvd.
Oakbrook Terrace, IL 60181

Dear Ms. Christiansen,

The American Academy of Orthopaedic Surgeons (AAOS/Academy), representing over 17,000 Board certified orthopaedic surgeons, welcomes the opportunity to provide feedback to the Joint Commission on their Standards Improvement Initiative. The AAOS is committed to advocating for patient safety, and believes that the clarification of the tissue issuance and storage standards put forth by the Joint Commission will enhance the safety and quality of the products they govern.

The AAOS has reviewed the proposed revisions of the Transplantation Safety chapter and has a question of clarification relating to TS.02.01.01 Revised EP: 8:

“The [organization] maintains daily records to demonstrate that tissues requiring a controlled environment are stored at the required temperatures. Note: Main types of tissue storage are: “ambient” or room temperature (for example: freeze-dried bone), refrigerated, frozen (for example: deep freezing colder than -40°C), and liquid nitrogen. Follow the tissue source facility’s written instructions for storage requirements.”

As previously written, our understanding for on the shelf tissues stored at ambient or room temperature was that the hospitals need not maintain a daily document of temperatures. The revised text is somewhat ambiguous with respect to the Joint Commission’s requirements for temperature monitoring in the case of tissues stored at ambient or room temperature. We strongly encourage the Joint Commission to clarify the standard to delineate your expectations concerning the maintenance of “daily records” as it pertains to tissue stored at ambient or room temperature.
The AAOS also urges the Joint Commission to consider the need for hospitals to demonstrate the existence of a protocol for tissue storage in the event that ambient or room temperature exceeds the accepted range for those tissues, such as a power failure resulting in loss of environmental heating or cooling for the facility. While it is noted that a standard exists for “Refrigerators, freezers, and other storage equipment used to store tissues at a controlled temperature have functional alarms and emergency back-up power sources” within TS.02.01.01 Revised EP: 9, there is no such comparable standard for the maintenance of ambient temperatures in areas where tissues that may be stored in such an environment are kept.

The Academy appreciates the effort of the Joint Commission to clarify standards language, ensure that standards are program-specific, eliminate redundant or non-essential standards, and consolidate similar standards. We look forward to communicating the final revised standards to our members when they are released.

Sincerely,

E. Anthony Rankin, MD
President
American Academy of Orthopaedic Surgeons