other six facilities. In fact, Center E had already reduced its own linen sharps contamination (by using techniques such as magnetic surgical drapes) during the past few years as a result of the data collection initiated in 1988,[1] and this valuable corrective action, in turn, recently has been shared with other members of the consolidated laundry program. Sharps data tracking will continue in the same format in the future, thus ensuring proper historical trending of recovered foreign objects.

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REFERENCE

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FDA Issues Regulations for Screening Tissues for Transplantation

by Gina Pugliese, RN, MS
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The Food and Drug Administration (FDA) has stepped in for the first time to regulate the $100 million tissue-transplantation field, especially in the area of musculoskeletal tissue. The FDA issued interim rules in the *Federal Register* on December 14, 1993, that are effective upon publication and require all donors of tissue for human use to be evaluated with laboratory tests and risk factor screening related to infectious disease before the tissue is made available. The agency also will have the authority to conduct inspections of facilities that process, store or distribute such tissue. FDA has said that the rule is aimed at minimizing the risk of disease transmission from certain human tissues that are without direct or active federal oversight. Specifically, these materials include bone, ligaments, tendons, fascia, cartilage, corneas, and skin.

Following the interim rule, the agency is proposing a second regulation of the tissue banking community that would require all entities engaged in tissue banking to register with the FDA and be subjected to certain requirements for screening tissue and recordkeeping.

In issuing these regulations, the FDA recognizes the voluntary concerted effort within the private sector to develop voluntary quality assurance programs, such as the voluntary standards developed by the American Association of Tissue Banks (AATB) to improve testing and screening practices. According to the AATB, most tissues in the United States are procured and processed under these standards. Nevertheless, in issuing these regulations, the agency believes that mandated compliance with generally accepted practices is needed for tissue banking, particularly musculoskeletal tissue banking.

The rules do not affect physicians and hospitals that store tissue intended only for use in their facility. The FDA has cautioned the healthcare community not to use any tissues for transplantation unless adequate donor testing and adequate risk factor screening have been documented. In addition, no one should import tissues from abroad without first contacting the FDA's Office of Health Affairs at (301) 443-4480.

Written comments on the interim rule are due on March 14, 1994, and should be submitted to the Dockets Management Branch (HFA-305) Food and Drug Administration, Room l-23, 12420 Parklawn Dr., Rockville, MD 20857.

FROM: *Federal Register* December 14, 1993;58:65514-65521.

https://doi.org/10.1017/S0195941700020245 Published online by Cambridge University Press