

## Recommended Practices for Surgical Tissue Banking

The following recommended practices were developed by the AORN Recommended Practices Committee and have been approved by the AORN Board of Directors. They were presented as proposed recommended practices for comments by members and others. They are effective January 1, 2006.

These recommended practices are intended as achievable recommendations representing what is believed to be an optimal level of practice. Policies and procedures will reflect variations in practice settings and/or clinical situations that determine the degree to which the recommended practices can be implemented.

AORN recognizes the numerous settings in which perioperative nurses practice. These recommended practices are intended as guidelines adaptable to various practice settings. These practice settings include traditional operating rooms, ambulatory surgery centers, physicians' offices, cardiac catheterization suites, endoscopy suites, radiology departments, and all other areas where operative and other invasive procedures may be performed.

### Purpose

Surgical tissue banking encompasses procuring, processing, preserving, and/or storing selected human cells and tissue. Human tissue includes, but is not limited to, bone, cartilage, ligaments, tendons, fascia, dura mater, sclera, corneas, heart valves/conduits, bone marrow, vessels, and skin. It is beyond the scope of these recommended practices to address all areas of tissue banking, solid organ transplantation, or nonhuman tissue. These recommended practices provide guidance for developing organizational policies and procedures that are specific to the needs of surgical patients and address the perioperative practice setting and expertise required of personnel.

A tissue bank should be established only where a need exists. Before the decision is made to establish a tissue bank, consideration should be given to personnel, equipment, and practical operational requirements for providing safe, reliable, and biologically useful products.

In 1997, the US Food and Drug Administration (FDA) announced a program for comprehensive regulatory oversight of tissue banking.<sup>1</sup> In support of this program, the FDA has published proposed guidance documents that were later clarified as

final rules.<sup>2-6</sup> The agency intends to propose more regulations in the future in the form of guidance documents. Adherence to these regulations is required during the development and ongoing operation of a human tissue bank. In addition, the standards published by the American Association of Tissue Banks (AATB)<sup>7</sup> should be referred to for additional direction.

Effective July 1, 2005, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards for tissue banking have been updated in the laboratory accreditation program and additionally applied to ambulatory care, critical access hospital and hospital accreditation programs, and office-based surgery practices. The standards apply to organizations that store or issue human, nonhuman, and synthetic tissue, including surgery and outpatient centers.<sup>8</sup>

### Recommendation I

**Facilities procuring, processing, and/or preserving tissue, and facilities storing tissue for potential transfer to a different facility, must register as tissue banks with the FDA.<sup>4</sup>**

1. A list of types of human cells, tissue, and cellular and tissue-based products must be submitted with the application to the FDA.<sup>4</sup> Facilities that recover, screen, test, process, label, package, and/or distribute human cells or tissue for implantation, transplantation, or infusion must register with the FDA. The registration form includes a list of tissues and cells to be used in this process.<sup>4</sup> Facilities must register within five days after beginning operations, notify the FDA within six months of changes in products, and update the registration annually in December. Facilities storing only purchased tissue for use within the same facility, or those who recover autologous skin or skull bone flaps for later reimplantation into the same patient, are not required to register as tissue banks. Additional clarification is available from the FDA.
2. Facilities should verify that tissue and cells acquired from outside sources have been procured, processed, stored, and distributed by tissue banks registered with the FDA and licensed by state agencies.<sup>8</sup> Depending on the type of tissue being acquired, outside sources of cells or