

# AORN Guidance Statement: The Role of the Health Care Industry Representative in the Perioperative Setting

## Introduction

The purpose of this statement is to provide general guidelines to assist the individual facility in developing policies relating to the role of the health care industry representative in the perioperative setting. The term health care industry representative refers to all health care industry employees who provide services in the perioperative setting (eg, clinical consultants, sales representatives, technicians, repair/maintenance personnel). A systematic method of providing education, training, and instruction related to new technology, equipment, techniques, and procedures is essential for perioperative staff to provide safe patient care. The health care industry representative who possesses the requisite education, knowledge, and expertise can play a vital role in providing technical assistance, instruction, and training to perioperative team members.

## Background

It may be hazardous to both patients and perioperative team members when clinicians use equipment with which they are unfamiliar. Misuse of complex technology can cause patient injury and even death. Incidents involving new technology and the presence of the health care industry representative in the perioperative setting have been highly publicized, especially when the end result is patient injury or death.<sup>1</sup> Hospitals have been cited and fined for allowing the use of surgical equipment not approved by the hospital; not providing formal training to physicians, nurses, and other perioperative team members on the proper use of the equipment; and permitting an unauthorized person from the medical device company to participate in a procedure.<sup>2</sup>

Tragic incidents have drawn attention to the need for individual facility policies to address formal instruction of physicians, nurses, and other members of the perioperative team on the operation of new medical devices before their use. Policies and procedures should be in place to authorize the introduction of new equipment and the admittance of nonmedical professionals into the room where the surgical or other invasive procedure will be performed. These policies and procedures should delineate acceptable activities and conduct of the health care industry representative in the perioperative setting. The role of the health care industry representative is to provide essential technical training and assistance related to the device for the safe care of the patient. The health care industry representative should not be considered part of the clinical team and should not be requested to perform tasks outside his or her approved role.<sup>1</sup>

All perioperative team members are responsible for acquiring instruction on new procedures, techniques, technology, and equipment with which they are not familiar, before their use in a surgical procedure. The health care industry representative, who has completed specialized training to provide technical instruction and support to the perioperative surgical team expedites the procedure and facilitates desired safe patient outcomes. Health care industry representatives have a valid, but restricted, role in the perioperative setting.<sup>3</sup>

## Guidance Statement

A health care industry representative may be present during a surgical procedure under conditions prescribed by the health care organization, in accordance with accreditation requirements, and in compliance with local, state, and federal regulations. In consideration of patient safety and confidentiality, AORN recommends the following precepts to guide policy development.

Perioperative team members are responsible for acquiring instruction on new procedures, techniques, technology, and equipment before their use in a surgical procedure. This instruction may be provided by a health care industry representative and may take place in a formal inservice program or as one-on-one instruction. The facility should maintain evidence of documented competencies for perioperative team members, especially when introducing new procedures, techniques, technology, and equipment.<sup>4</sup>

As the patient's advocate, the RN responsible for the patient's care during the procedure is accountable for maintaining the patient's safety, privacy, dignity, and confidentiality. The RN should monitor the health care industry representative's activities whenever possible and facilitate the representative's service to the perioperative team during the procedure. The RN should monitor and limit the movement and number of people in the operating room during the procedure to prevent increased airborne contamination.<sup>5</sup> The RN should be informed before the procedure that a health care industry representative will be present during a specific procedure as well as the purpose for being in attendance.

Policies should be developed in collaboration with the facility's risk manager and/or legal counsel to ensure compliance with applicable local, state, and federal laws.<sup>2</sup>

Conditions should be specified under which the health care industry representative may be present during a surgical or other invasive procedure.

Each facility should develop a system that clearly delineates limits on the health care industry