



AORN Position Statement on the Role of the Health Care Industry Representative in the Perioperative Setting

POSITION STATEMENT

AORN acknowledges and values the role of the health care industry representative in perioperative settings. AORN believes a health care industry representative may be present during an operative or other invasive procedure under conditions prescribed by the health care organization and in compliance with accreditation requirements and local, state, and federal regulations. AORN believes that perioperative registered nurses (RNs), perioperative administrators, and health care industry representatives are all accountable to advocate for patient safety; workplace safety; and the patient's right to information, privacy, and confidentiality when a health care industry representative is present during an operative or other invasive procedure. The following precepts should be used to guide a multidisciplinary team in developing and periodically reviewing policies and procedures related to health care industry representatives in operating or invasive procedure settings.

Role of the Perioperative Nurse

The perioperative RN is accountable for the patient's nursing care during the operative or other invasive procedure. Core nursing activities (eg, assessment, diagnosis, outcome identification, planning, evaluation) as indicated by licensure, may not be performed by anyone who is not a nurse employed by the health care organization. Perioperative RNs should take the following measures when a health care industry representative is present during an operative or other invasive procedure:

- Advocate for the patient's safety, privacy, dignity, and confidentiality in all phases of perioperative care.^{1,2}
- Verify that all members of the perioperative team have received education and completed competency verification on new procedures, techniques, technology, and equipment before their use in an operative or other invasive procedure.
- Verify that new or loaned equipment has been approved by the health care organization's service provider and loaned instruments have been through the internal terminal sterilization process before use.³
- Verify that the patient has been informed about the presence of the health care industry representative during the operative or other invasive procedure^{4,5} and has given written consent according to local, state, and federal regulations.⁶
- Verify that the health care industry representative has been credentialed according to the health care organization's policy.^{7,8}
- Verify that the health care industry representative is wearing identification, preferably a photo identification badge; surgical attire; and personal protective equipment as described in the AORN recommended practices and the health care organization's policies.⁹⁻¹¹
- Monitor the health care industry representative's activities and facilitate the representative's service to the perioperative team during the operative or other invasive procedure.^{5,12}

- Monitor infection prevention practices and limit the movement and number of people in the operating or invasive procedure room during the procedure to prevent increased airborne contamination.¹²⁻¹⁴
- Document the health care industry representative's presence, including name, company, and time in the room, in the intraoperative nursing record according to the health care organization's policy.

Role of the Perioperative Administrator

The perioperative administrator is accountable for ensuring that a structured process exists to provide education on procedures, techniques, technology, and equipment to health care professionals practicing within operative or other invasive procedure settings.¹ Perioperative administrators also are accountable for implementing policies and procedures to ensure that every patient is informed about the presence of a health care industry representative in the operating or invasive procedure room during an operative or other invasive procedure^{4,5,15} and that the patient gives written informed consent according to local, state, and federal regulations.⁶ Administrators should collaborate with the organization's risk manager or legal counsel to develop policies and procedures that are specific to the health care industry representative's role in the operating or invasive procedure room; advocate for patient safety and workplace safety; and ensure compliance with applicable local, state, and federal laws.¹⁵⁻¹⁹ These policies and procedures should include the following:

- Specific conditions under which the health care industry representative may be present during an operative or other invasive procedure.^{5,7,8}
- Consistent procedures, whether or not the health care industry representative has previous perioperative experience (eg, RN, surgical technologist), so that all representatives are expected to follow the same guidelines and restrictions.
- Restrictions specifying that health care industry representatives do not provide direct patient care and are not allowed to participate in sterile field activities.
- Processes for approving health care industry representatives with specialized education to perform calibration or synchronization to adjust or program devices (eg, implanted electronic devices, radio-frequency devices, lasers) under the direction of the physician.
- Processes for notifying the health care organization's designated authority in advance when persons in training from the representative's organization will be accompanying an experienced health care industry representative for the purposes of orientation.
- Processes for informing the perioperative team that a health care industry representative will be present during a specific procedure.
- Processes for inspecting loaned equipment or sterilizing loaned instruments before the invasive procedure.⁵
- Requirements for and documentation of tuberculosis (TB) testing and vaccinations as recommended by AORN and the health care organization's infection prevention personnel.^{7,8,11,20}
- Orientation requirements for health care industry representatives that include education in the following areas:
 - relevant devices, equipment, or supplies specific to the procedure in which they will be involved^{7,8};

- compliance with the Health Insurance Portability and Accountability Act (HIPAA)⁶ and all matters relating to patient rights and confidentiality¹;
- expected attire⁹ in the perioperative invasive procedure area (eg, requiring a different colored hat for health care industry representatives in addition to photo identification and surgical attire);
- traffic patterns in the perioperative suite¹³;
- compliance with hand hygiene practices¹⁴;
- expected conduct related to aseptic principles and sterile techniques^{7,8,12};
- compliance with Occupational Safety and Health Administration (OSHA) requirements²¹ for prevention of infectious disease transmission and exposure to bloodborne pathogens^{11,21};
- compliance with occupational safety information (eg, biohazardous waste, electrical, radiation) and other safety protocols^{7,8,10,22};
- fire safety and evacuation routes²²; and
- conduct consistent with the *AdvaMed Code of Ethics on Interactions with Health Care Professionals*.^{7,8,23}
- Designated individuals (eg, supply chain management personnel) who are responsible for authorizing the health care industry representative's presence.
- Criteria on which to base the approval of the health care industry representative's presence, including
 - time limit during which the health care industry representative will be allowed in the perioperative suite,⁵
 - appropriate identification (ie, photo identification badge),^{5,9}
 - completion of orientation requirements (eg, AORN OR protocol course²⁴) as designated in the health care organization's policies and procedures,^{5,7,8} and
 - attestation from the health care industry representative's company that a background verification was performed upon hire.^{7,8}

Role of the Health Care Industry Representative

AORN believes that by virtue of their education, knowledge, and expertise, health care industry representatives have a valid, but restricted, role in the operative or other invasive procedure setting. Health care industry representatives hold a variety of positions (eg, clinical consultants, sales representatives, technicians, repair/maintenance personnel) in their own organizations. When permitted access to the operating or invasive procedure room, a representative is accountable to advocate for patient safety, workplace safety, and patient privacy and should abide by the following measures:

- Provide technical support in accordance with the health care organization's policies and procedures and local, state, and federal regulations.^{7,8}
- Conduct formal inservice programs or one-on-one instruction for the perioperative team to provide essential education, technical training, and assistance related to the device.
- Provide education for perioperative team members to be educated about new procedures, techniques, technology, and equipment before their use in an operative or other invasive procedure.
- Comply with a defined, restricted role that does not include performing actions as a part of the clinical team, participating in sterile field activities, or accepting requests to perform

tasks outside of his or her approved role as outlined in the health care organization's policies and procedures.⁵

- Present documentation to verify specialized education and the health care organization's approval if he or she will be performing calibration or synchronization to adjust or program devices (eg, implanted electronic devices, radio-frequency devices, lasers) under the supervision of the physician.^{5,7,8}
- Comply with the health care organization's policies and procedures to
 - obtain permission from the surgeon;
 - obtain authorization from the designated authority;
 - obtain authorization in advance from the designated authority for persons from the representative's organization who will be accompanying an experienced health care representative for the purposes of orientation;
 - bring equipment and instruments for inspection or sterilization before use; and
 - wear proper identification, preferably a photo identification badge.^{5,9}
- Update documentation of TB test and vaccinations as required by the health care organization's policies and procedures and infection prevention personnel.^{7,8,11,20}
- Comply with the *AdvaMed Code of Ethics on Interactions with Health Care Professionals*.^{7,8,23}
- Comply with the health care organization's policies and procedures to complete orientation as a health care industry representative and requirements for ongoing education in the following areas:
 - relevant devices, equipment, or supplies specific to the procedure in which he or she will be involved^{7,8};
 - patient rights and confidentiality requirements included in HIPAA⁶;
 - expected attire in the perioperative invasive procedure area⁹;
 - traffic patterns in the perioperative suite¹³;
 - hand hygiene practices¹⁴;
 - expected conduct related to aseptic principles and sterile techniques^{7,8,12};
 - prevention of infectious disease transmission and exposure to bloodborne pathogens according to OSHA requirements^{7,8,11,21};
 - occupational safety information (eg, biohazardous waste, electrical, radiation) and other relevant safety protocols^{7,8,10,22}; and
 - fire safety and evacuation routes.²²

RATIONALE

Tragic incidents have drawn attention to the need for individual facility policies to address formal education for physicians, nurses, and other members of the perioperative team on the use of new medical devices before they are used for direct patient care.^{25,26} When clinicians use equipment with which they are unfamiliar, it may be hazardous to both patients and perioperative team members. Misuse of complex technology can cause injury to patients 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 a patient's injury or death.¹⁶ Hospitals have been cited and fined for allowing the use of surgical equipment that is not approved by the hospital; not providing formal education to physicians, nurses, and other perioperative team members on the proper use of the equipment; and permitting an

unauthorized person from a medical device company to participate in an invasive procedure.^{16,18,27}

Operating and invasive procedure rooms are among the most potentially hazardous of all clinical environments and are subject to strict regulations, clinical practice guidelines, and standards of care to preserve patient safety. The primary responsibility of both the RN and the administrator in operative or other invasive procedure rooms is to ensure the safety and privacy of patients undergoing operative or other invasive procedures. When policies and procedures that address the role of the health care industry representative in the operating or invasive procedure room are implemented, RNs, administrators, and health care industry representatives can be consistent in advocating for patient safety and workplace safety; preventing health care-associated infections; and maintaining patients' rights to information, privacy, and confidentiality when health care industry representatives are present during operative or other invasive procedures.

Using a systematic method to provide perioperative team members with education, training, and instruction related to new technology, equipment, techniques, and procedures is essential for safe patient care. Health care industry representatives who possess the requisite education, knowledge, and expertise can play a vital role in providing technical assistance, instruction, and education to perioperative team members. When health care industry representatives provide technical support to the perioperative team for new technologies or devices, it can potentially decrease the time of the operative or other invasive procedure and facilitate the attainment of optimal patient outcomes.

National organizations recommend that equipment be inspected and approved by the health care organization's service provider before use²⁸ and that loaned instruments be sterilized by the receiving organization before use.^{3,29} AORN recommends that members of the perioperative team use equipment and supplies according to the manufacturer's instructions for use.^{22,30-34} Health care industry representatives play a key role in educating perioperative team members in the use of new and existing technologies, equipment, and supplies based on the manufacturer's instructions for use. Notifying perioperative leaders in advance and having the equipment or instruments inspected and processed before the time of education, demonstration, and use reduces the risk for delays and facilitates productivity.

GLOSSARY

Health care industry representatives: Employees of the health care industry (eg, clinical consultants, sales representatives, technicians, repair/maintenance personnel).

Service provider: An entity with the responsibility to provide inspection and/or other maintenance services on a specific piece of equipment. A service provider may be a department within the health care organization or a contracted provider.

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