Statement by the Council
on Surgical and Perioperative Safety
Health Care Industry Representatives
in the Operating Room

The ACS recognizes the need for a structured system within the perioperative setting for education, training, and introduction of procedures, techniques, technology, and equipment to the surgical health care team. Health care industry representatives (HCIR), by virtue of their training, knowledge, and expertise, can provide technical assistance to the surgical team, which expedites the procedure and facilitates the safe and effective application of surgical products and technologies. The purposes of this statement is to supply guidelines to health care facilities and members of the perioperative health care team to ensure an optimal surgical outcome, as well as the patient's safety, right to privacy, and confidentiality when a HCIR is present during a surgical procedure.

Institutional Policies
Surgical department administrators in all facilities, including the acute care hospital, ambulatory surgery facility, and office based operating room (OR) settings should establish specific written policies governing the presence of HCIRs in the operating room. These policies should define: 1) the requirements and procedures for manufacturers' representatives to be present in the OR, and 2) the role and limitations of the HCIR in the perioperative setting. These policies should comply with applicable state laws and regulations, should be consistent with the organization's existing policies, such as those promulgated by the OR and/or credentialing/privileging committees, and should include, but not be limited to, the following elements:

Facility requirements and procedures for manufacturers' representatives to be present in the OR should include:

1. The institution should designate an authority for approving a HCIRs presence in the OR. A time frame for securing this approval should be established. This authority should:
    -   Supply a time-limited approval and appropriate identification (to be worn at all times) for the HCIR
    -   Ensure orientation to the facility is provided

- Verify the documentation that certifies the HCIR has had education and training in:
- HIPAA compliance and all matter related to patients rights and confidentiality
- Appropriate conduct and attire in the OR environment
- Aseptic principles and sterile techniques
- Infectious disease and blood borne pathogens
- Occupational Safety: biohazardous waste, fire, electrical, radiation and other safety protocols
- Other applicable practices that may be related to the operation

2. The HCIR should be present at the request of the operating surgeon. The HCIR should be introduced to the entire OR team and the purpose of the visit explained. If the surgeon did not initiate the request, the surgeon should be notified and approve the visit prior to the operation.

3. The patient should be informed of the presence and purpose of the HCIR in the OR and give written, informed consent. This should be documented within the medical records.

Roles and limitations of the HCIR in the OR.
The HCIR is present as an advisor to the perioperative team to ensure the safe and effective application of surgical devices and technologies. The presence of the HCIR in the operating room is not an appropriate substitute for preoperative training of the surgical team. The surgical team must have the theoretical understanding and knowledge, training and skills necessary for the application of these surgical devices and technologies prior to surgery. In the role of educator and facilitator the HCIR:
- Should not engage in the practice of surgery, nursing or medical decision making
- Should not scrub or be involved in direct patient contact
- May be involved in the remote calibration or adjustment of medical devices to the surgeons and manufacturers' specifications (e.g. pacemakers, laser technicians)
- Should have his or her activities monitored and supported by the surgeon (or, at the surgeon's discretion) by the perioperative nurse responsible for the patient's care