**Effective Date: August 25, 2010**
**Revision Date:**
**Approval signature on file with HS OR CC**

# POLICY AND PROCEDURE

## VENDORS IN THE OPERATING ROOM

**Policy Statement:** The mission of the Ohio State University Health System and its physicians is three-fold: Patient Care, Education and Research. From time to time, in order to fulfill this mission, non-OSU personnel may need to be present in the Operating Room (OR). Vendors may be present in the OR at the request of the Attending Physician/Surgeon, Anesthesiologist, Director of Perioperative Services, Nurse Manager, or representative from Materials Management with the approval of the Physician Director of Perioperative Services.

The purpose of this policy is:

1. To establish and define guidelines for vendors entering the OR.
2. To ensure reasonable control and identification of vendors while in the surgical/procedural areas.
3. To minimize interruptions to patient care and staff/physician productivity through management of vendor-related access.
4. To establish a process to safeguard The Ohio State University Hospitals, property and personnel and provide for patient confidentiality

**Definitions**

**Vendors –** for the purpose of this policy refer to people who sell or, for the purpose of selling, demonstrate products to the OR and who physically visit the OR and at times are present during the surgical procedure

**Approved product** – for the purpose of this policy refers to any product, device or equipment currently approved for purchase

**New, unapproved product** – for the purpose of this policy refers to any product, device or equipment currently not approved for purchase

The scope of this policy refers to all vendors visiting the OR at The Ohio State University Medical Center. This policy is in accordance with requirements defined under Health System **Vendor Access and Control Policy #09-14**

**Procedure:**
**Access Criteria:**
Vendors may be permitted access to the OR to:

**1. Support an existing/approved product, device, or piece of equipment**.

a.) If a vendor is authorized to access the OR for an approved product, all the requirements and procedures outlined in this policy must be met prior to OR access (*See subsequent sections: **Access Requirements** and **Procedural Guidelines and Expectations While in the OR** for specific requirements**)**

b.) Vendors may function as a resource to the surgeon or nursing staff regarding their respective product, device, or equipment. However, vendors may not scrub in or participate in the surgical procedure.

c.) Vendors may visually and audibly verify an item with the surgeon. However, the vendor may not open any item and place it on the sterile field, or otherwise perform the duties of the circulating RN.

d.) All electrical equipment must be evaluated and approved by the Clinical Engineering Department prior to use.

**2. Introduce and trial new products, devices, and equipment:**

a.) If a vendor is authorized to access the OR for a new, unapproved product, all the requirements and procedures outlined in this policy must be met prior to OR access (*See subsequent sections: **Access Requirements** and **Procedural Guidelines and Expectations While in the OR*** for specific criteria)

b.) All new products, devices, and equipment being considered for evaluation or a limited clinical trial must first be pre-approved by the Physician Director of Peri-operative Services, in accordance with the Perioperative Policy on Evaluation of New Products and Technology. For a full approval of a new product, device or equipment, an application must be submitted to either the Supply Evaluation Committee or the Technology Assessment Committee, in accordance with the aforementioned Policy on Evaluation of New Products and Technology.

c.) When an attending surgeon, anesthesiologist, Director of Perioperative Services, Nurse Manager, or representative from Materials Management requests a trial of a product that is not currently approved for purchase, an advanced notice of at least 2 working days is required in order to provide the OSUMC personnel sufficient time to meet with the associated vendor to discuss clinical, financial, and administrative specifics.

d.) Notification must include: the vendor's name, company, intended date of surgery/procedure, reason for vendor visit and evidence of vendor competency in use or application of product/equipment. In addition, information on the FDA approval status of the product, the proposed clinical indication of the product, the purported benefits of the new product over existing alternatives, if any, and any cost savings associated with the new product should be provided. The product to be trialed is usually provided free of charge to the medical center, but in all cases must be accompanied by a purchase order with or without charge, so that the product may be tracked.

e.) The Physician Director of Perioperative Services or designee will contact the requesting sponsor if the vendor access is deemed inappropriate.

f.) No presentations or product trials are permitted without prior approval. For approved trials or use of new products and/or technology, vendors may provide educational information to the relevant physicians and staff in advance of the trial or use.

g.) All electrical equipment must be evaluated and approved by the Clinical Engineering Department prior to use.

**3.** The appropriate conduct of a vendor in the OR environment and the fulfillment of this policy are the responsibility of the sponsoring attending surgeon/physician and the circulating nurse assigned to the room.

**Access Requirements**

1. Vendors may access the Operating Room upon the formal request of the attending Physician/Surgeon, Anesthesiologist, Director of Perioperative Services, Nurse Manager or representatives from Materials Management, with the approval of the Physician Director of Perioperative Services.

2. Prior to the first encounter with any OSU OR, and annually thereafter, vendors are required to create an account in **RepTrax (www.reptrax.com).**

RepTrax will verify the same requirements that OSUMC requires for access to the OR:

a.) provide documentation of company training time and certification of training on equipment and supplies. Documentation must state all equipment and products for which the vendor is competent.

b.) provide date and results of last TB test (within the year). Documentation of a TB skin test read as negative or evidence of a negative chest x-ray in follow up to a positive skin test will be considered acceptable.

c.) provide proof of MMR (measles, mumps, rubella) vaccinations.

d.) review operating room education modules which include but are not limited to: safety, infection control, attire and conduct, patient rights and confidentiality and OR access information. Vendors will also be required to demonstrate education competency by passing an exam with a score of at least 80%.

e.) Contact information (completed by creating an account)

f.) review the following policy and procedures:

- **Vendor Access and Control Policy #09-14**,
- **Vendors in the Operating Room**, **Perioperative Attire Policy**, **Product Evaluation**
  **Policy# 04-13** and sign **Attestation Agreement (Attachment A) and** read and sign the **Vendors Confidentiality Agreement (Attachment B)**

g.) Upon completion of the above stated requirements, vendors will be issued an identification badge from the OSU Security Department. Access requirements will be renewed annually. Identification badges must be visible and worn above the waist.

h.) Vendors without a valid identification badge will not be permitted to enter the Operating Room environment.

i.) Vendors will furnish and maintain their own surgical scrub attire.

3. After successful completion of the OR area access requirements and an identification badge has been obtained, vendors will be allowed entry into a designated OSUMC OR room. The following will be required for every OR area encounter:

a) Vendors will report to the OR designated check-in area and sign the Visitor's Log. Vendors will be required to also show their OSU identification badge for every encounter.

b) Vendors should proceed directly to the appropriate OR or remain in the designated waiting area until the start of the procedure or as called upon by the surgeon/physician or circulating RN.

c) Prior to entrance into the OR, vendors must be suitably attired in clean surgical scrubs, white cover suit zipped closed with associated hair cover and mask in accordance with the **Perioperative Attire Policy**.

d) To insure patient privacy, the patient should be fully draped before the vendor is permitted in the OR.

e) Vendors must remain in their assigned surgical suite. They are not permitted to move freely among the various rooms.

f) Brief cases, satchels, bags, etc. are not to be carried into the OR. Only the approved product(s) that will be used, if being provided by the vendors, can be taken into the OR

g) Vendors may not take any documents (including patient labels) that contain any patient-specific information, including name, social security number or medical record number.

h) Other than calls related to the case in progress, phone usage is limited to the phone in the Nursing Staff Lounge or the phone outside of the OR Control Desk outside of the restricted area. The phones within the OR's are for the sole use of nursing staff, residents, and attending surgeons/physicians and anesthesiologists. Cell phones are expressly prohibited.

i) Unless accompanied by OSU personnel, vendors will not be permitted in the following areas:

  i) the OR Control Desk office area,

  ii) OR Storage Rooms, Sterile Core areas and Surgeons'/Physician's lounge.

j) Vendors are not permitted to distribute or post any type of hand-printed or hand-written invitations, advertisements, signs, or promotional materials unless pre-approved by the Physician Director of Perioperative Services.

k) Financial and administrative arrangements for any product(s) brought into the OR (supplies, equipment, implants, instruments) must be discussed with and approved by the Physician Director of Perioperative Services or designee prior to the start of the procedure. Invoices submitted without prior agreement and approval will not be honored.

l) Vendors of plating systems/implants may need to access the OR during weekend, holiday or evening hours at the request of the Surgeon/Physician. The vendor is expected to meet all aforementioned criteria prior to entering the Operating Room environment.

m) Vendors are invited guests and, as such, non-compliance with any portions of this policy may result in immediate removal from the Operating Room and termination of sales and marketing privileges.

n) Any variance to these guidelines must be brought to the attention of the Operating Room manager.

**References:**

Atkins, L.J. (2000) Berry & Kohn's Operating Room Technique. (10th ed.). St. Louis: Mosby-Year Book, Inc.

Center for Disease Control and Prevention: Infection Control and Hospital Epidemiology: Guidelines for Prevention of Surgical Site Infection, 1999.

*AORN Standard, Recommended Practices and Guidelines*. 2009 ed., Denver, CO: Association of Operating Room Nurses; 2009.

"Occupational exposure to blood-borne pathogens: Final Rule". Federal Register: Rules and Regulations. Vol. 56, No. 235, 12-6-91. 64004-64182.

Rothrock, J. (2007). Alexander's Care of the Patient in Surgery. (13th ed.). St. Louis: Mosby-Yearbook, Inc.

**ATTACHMENTS:**
Attestation Agreement – **Attachment A**
Vendor Confidentiality Agreement – **Attachment B**

**ATTACHMENT A**

## ATTESTATION AGREEMENT

I, the undersigned, acknowledge that I have received a copy of the following policies from the Ohio State University Health System related to vendors in the Operating Room:

- Health system-wide vendor policy 09-14
- Vendors in the OR policy
- Perioperative Attire policy
- Product Evaluation policy

I understand that it is my responsibility to read and comply with the information that has been provided to me before being permitted to enter the Operating Room.

I understand that it is my responsibility to seek clarification, from OSU personnel, for any portion of the information, which I do not fully understand.

_____

Vendor Name (please print)

_____

(Company Represented)

_____Date _____Time_____

Vendor Signature

## ATTACHMENT B

## VENDOR CONFIDENTIALITY AGREEMENT

All vendors and each of their agents or contractors doing business with The Ohio State University Hospitals, its subsidiaries and affiliates will assure CONFIDENTIALITY by acknowledging and maintaining the privacy of ALL information and/or knowledge regarding a patient or employee's medical status, personal affairs, and any business or financial information.

Due to the sensitive nature of this information, the agreement of confidentiality continues to apply even after the vendor's affiliation is terminated.

As part of my duties as a vendor or an agent, employee or contractor thereof doing business with The Ohio State University Hospitals, I may come in contact with confidential information including, but not limited to, certain data records, and/or information systems.

I understand that I have a responsibility to maintain two aspects of security regarding such information: (1) confidentiality and (2) integrity.

I am committed to protect and safeguard from any oral and written disclosure of any and all of The Ohio State University Hospitals confidential information regardless of the type of media on which it is stored (e.g., paper, disk/CD, computer, etc.) in all information systems with which I may come into contact.

I agree that I will not release any confidential information to any unauthorized person and/or permit any person to examine or make copies of any confidential information prepared by me or coming into my possession. I will not use or further disclose The Ohio State University Hospitals Confidential Information other than as permitted by law, including the Health Insurance Portability and Accountability Act (HIPAA) regulations or as permitted by the Agreement.

I understand that any breach of confidentiality, or misuse of information obtained from The Ohio State University Hospitals may result in termination of my access to The Ohio State University Hospitals' facilities, the potential termination of the vendor relationship and/or legal action. Unauthorized disclosure may give rise to irreparable injury to the patient or to the owner of such information and accordingly the patient or owner of such information may seek legal remedies against me.

NAME (please print) _____

(Last) (First) (Middle Initial)

NAME (signature) _____ Date _____

COMPANY _____