

# GUIDELINES

Guidelines for...

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## Optimal Ambulatory Surgical Care and Office-based Surgery

Third Edition

Developed by the Board of Governors  
Committee on Ambulatory Surgical Care



American College of Surgeons



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This manual has been revised through the efforts of the Committee on Ambulatory Surgical Care of the Board of Governors, American College of Surgeons.

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# Foreword

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The Board of Governors Committee on Ambulatory Surgical Care of the American College of Surgeons developed a set of guidelines in 1994 and revised them in 1996. The guidelines were designed to help the surgeons who performed surgical procedures in their offices to offer these services to patients in an appropriate manner and in a safe environment. The initial publication was developed under the leadership of Charles F. Frey, MD, FACS, Chair of the Board of Governors Committee on Ambulatory Surgical Care; and Charles W. Logan, MD, FACS, Chair of the Subcommittee on Guidelines Development. The 1996 revision was developed under the leadership of Richard B. Reiling, MD, FACS, Chair of the Board of Governors Committee on Ambulatory Surgical Care; and Frank A. Folk, MD, FACS, Chair of the Subcommittee on Quality Assurance. Both editions have been widely distributed and well received. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has published a crosswalk between the guidelines and its requirements. The complex nature of standards and guidelines requires persistent reevaluation and assessment. Thus, the Committee on Ambulatory Surgical Care has again revised the manual to incorporate needed changes.

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The relative absence of published guidelines for small surgical practices and the inherent need for some mode of assurance of the quality of care provided by such practices are the reasons for this manual. Surgeons have requested guidelines that are practical and financially feasible for a small practice. Since the last revision, the size and organization of office-based facilities have evolved. While many facilities have remained rather simple in size and organization, others have become larger and resemble freestanding ambulatory surgical facilities. Some have facilities and personnel to allow for postoperative overnight care. This evolution has been taken into consideration in this revision. The Board of Governors had requested at the 1995 Clinical Congress that the College promote the guidelines presented in this manual as “guidelines” for office-based surgical facilities and that compliance with these guidelines be considered satisfactory for ensuring that the facility provides high-quality surgical care.

The American College of Surgeons is not, and does not intend to be, an accrediting organization. However, these guidelines could become the acceptable standard for office-based surgery. Thus, the guidelines have been developed and revised by surgeons who practice in facilities in which all levels of ambulatory surgical care are provided. It only seems appropriate that surgeons should develop the guidelines for surgical care. The College has maintained a mission of ensuring that quality surgical care is provided to all surgical patients, and it is in that spirit that these guidelines are presented.

The members of the Committee on Ambulatory Surgical Care seek feedback and advice from the Fellowship on these guidelines and on other aspects of surgical care in the ambulatory setting.

We appreciate the diligence of the subcommittee in revising and updating these guidelines and hope that you will find this manual helpful.

Ronald B. Berggren, MD, FACS

*Chair*

*Board of Governors Committee on Ambulatory Surgical Care*

# Preamble

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Office-based ambulatory care is assuming an ever-greater position of importance in our current and evolving medical system. At present, there are three major accrediting bodies for surgical facilities, each with a somewhat different perspective (see Appendix A, page 25). Many facilities are not accredited, and Congress is considering federal guidelines. Several states have taken legislative action to establish guidelines for ambulatory surgical facilities, including those that are office-based. More states are considering such action. The American College of Surgeons and its Board of Governors Committee on Ambulatory Surgical Care have recognized that it is our responsibility as surgeons to ensure the delivery of high-quality patient care by developing reasonable and uniform educational guidelines for ambulatory surgical facilities, including those that are office-based.

## Definitions

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- A. **American College of Surgeons.** The American College of Surgeons is a scientific and educational association of surgeons that was founded in 1913 to raise the standards of surgical practice and to improve the care of surgical patients. The College is dedicated to the ethical and competent practice of surgery. With more than 63,000 members, the College is the largest association of surgeons in the world. The College's achievements have significantly influenced the course of scientific surgery in America and have established it as an important advocate for all surgical patients.
- B. **Office Surgical Facility (OSF).** Any surgical facility organized in or for the surgeon's office for the purpose of providing invasive surgical care to patients with the expectation that they will be recovered sufficiently to be discharged within a reasonable amount of time is considered an OSF.
- C. **Ambulatory Surgical Facility (ASF).** Any surgical facility organized for the purpose of providing invasive surgical care to patients with the expectation that they will be recovered sufficiently to be discharged within a reasonable amount of time is an ASF. ASFs include OSFs.

## Guidelines Manual

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The guidelines established and printed in this manual are intended to ensure and maintain superior quality of care for the surgical patient who undergoes an outpatient surgical procedure in an office-based or ambulatory surgical facility. Guidelines addressing direct patient care issues, such as bloodborne pathogens and infection controls, are necessary for the delivery of superior quality care, even for minor surgical procedures. These rules and guidelines are not intended to replace any federal, state, or local regulations that are applicable to performing surgery in the office surgical facility environment. *This manual of guidelines for ambulatory and office-based surgery represents the highest optimal standards that can be utilized. Surgeons who perform only minor surgical procedures with local anesthesia in their offices may provide superior quality care without implementing certain of these requirements, such as the structural recommendations.*

In preparing this manual, the authors have utilized published manuals containing both the guidelines and the accreditation standards of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF), and the Accreditation Association for Ambulatory Health Care, Inc. (AAAHHC). Outpatient surgical experience and expertise and the manuals of each of these organizations have been utilized as references in developing the present guidelines. The members of the committee recognize and credit these organizations with format and content suggestions for this manual on guidelines for ambulatory and office-based surgery.

# Administration

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## A. Governance

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In this chapter, we will deal with the administrative framework of an ambulatory surgical facility (ASF).

As is the case with all aspects of a surgical practice, clear and concise documentation of the governance is needed. Legal assistance is also recommended, so that local and state variances can be identified and appropriately incorporated into the existing or newly established practice. In the later chapters, guidelines will be discussed with regard to the physical facility, ancillary services, surgical care, and quality assurance. The community standards will be the final determinant.

**Governance** refers to the rules and regulations that are established by the surgical practice, executive committee, board of directors, the entire group of physicians, or even an individual to detail the manner in which the facility will do business. The governing rules, if adequately documented, will guide the individual physicians in the facility in dealing with each other and with external parties, which include, but are not limited to, third-party payers, the Medicare program, managed care organizations, health maintenance organizations, and so on. Most importantly, the governing rules will cover the physicians' roles in dealing with their patients.

These rules and regulations should be carefully thought out and documented. In addition, each physician practicing in the facility should consent to them in writing addressed to the authority of the governing body of the facility. These rules and regulations should be reviewed periodically—usually annually—and should be revised to include appropriate changes in the facility. The weak points of the organization, especially with regard to the deliverance of quality care, should definitely be identified and remedied. Other changes may be directed from the experience of the operation of the ASF or in compliance with external pressures for change. Minutes of this review should be kept and filed with the original governing rules and regulations.

Usually, an OSF will be established in a preexisting surgical practice, in which case the legal structure of the practice, whether it includes a single surgeon or a number of surgeons, will govern the OSF. Even when an office surgical facility consists of only one surgeon, such a review is mandatory for the continuation of a quality operation, as well as one that complies with all of the standards that are expected of the practice.

Clearly, the ultimate authority of the practice should lie with the governing body. Therefore, the governing body is responsible for the management of the office personnel, including administrative personnel, if applicable. The lines of authority should be clearly defined.

Some of the details of the documentation in the governance manual should include:

1. Specifying mission and goals, including the types of services provided.
2. Defining organizational structure.
3. Adopting policies and procedures for the orderly conduct of the ASF.
4. Adopting a quality assurance program.
5. Reviewing and taking appropriate action on all legal affairs of the unit and its staff.
6. Ensuring financial management and accountability.
7. Establishing a policy on patients' rights.
8. Approving all arrangements for ancillary medical care delivered in the ASF, including laboratory, radiologic, pathologic, and anesthesia services.
9. Conducting the operation of the unit without discrimination on any basis, including compliance with applicable provisions of the Americans with Disabilities Act (ADA).

## **B. Personnel**

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The appointment of any administrative personnel should be documented. The facility should have a medical director, and all health care practitioners accredited by the facility should have valid licenses or certificates. The staff members should participate in ongoing, continuous quality improvement and risk management activity, including recognition of a statement on basic human rights of the patients. The job description of each member of the staff should be written out and should include the obvious directives of responsibility and discipline. A timely review of performance is needed. To reduce the administrative work of the surgeon, a member of the office practice may be appointed as the ASF manager. In a solo practice, the surgeon can function as the office manager and/or medical director, but this fact should be documented.

The administrator should be responsible for:

1. Employing qualified personnel.
2. Ensuring the deliverance of quality care.
3. Protecting the assets of the practice.
4. Establishing and controlling the medical records of the practice.

The responsibilities of any student personnel used in the office practice, especially in the ASF, must be clearly defined and clarified in writing.

The governing body is responsible for the approval of the physicians who use the ASF and should define the scope of the intended use of the unit, as well as the appropriate ancillary support needed for the planned surgical procedures. Staff privileges should be delineated based upon the experience and education needed to utilize the unit. Documentation of the physician's experience and continuing medical education (CME) activities must be kept. Privileges should be reviewed on a periodic basis. This review will be determined by the changes in the practice and the changes in the physician's experience and education. Evidence of relevant continuing medical education should be kept with the files of each utilizing physician.

## C. Patients' Rights

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As an organization delivering medical care, the ASF should recognize the basic human rights of its patients. There are many sources of written patients' rights. The ASF's patients' rights document should be available for the patient to review. Accessibility of such a document will help to protect the practice, as well as promote the quality of the practice to future patients.

For the most part, the rights of the patient are obvious and self-evident, but it is worthwhile in this manual to reiterate some of the characteristics that a patients' rights document may contain.

1. The patient has the right to dignity, respect, and consideration of legitimate concerns.
2. The patient has the right to privacy and confidentiality.
3. The patient has the right to information about the current diagnosis, treatment, and prognosis. If it is not medically advisable to give such information to the patient, it should be available to an appropriate custodian.
4. The patient has the right to refuse any diagnostic procedure or treatment and to be advised of the medical consequences of such refusal.
5. The patient has the right to participate in the decisions involving his or her health care, unless this participation is not indicated for medical reasons.
6. The patient has the right to know who will be delivering the care. In the case of teaching units, the patient has the right to know the extent to which the student and/or resident physician will be involved.
7. The patient has the right to change the primary physician if other qualified physicians are available.
8. The patient has the right to inspect and obtain a copy of his or her personal medical records. In addition, the patient has the right to expect a reasonable and timely transfer of information from one physician to another.
9. The patient has the right to request information concerning the bill for services, regardless of the source of payment.
10. The patient has the right not to be misled by the claims made by the ASF to promote the organization. The patient has the right to request information about alternate sources of qualified care.
11. The patient has the right to be assured that the proposed care will be delivered in a timely, efficient, and cost-effective manner and that the expected results can be reasonably anticipated.
12. The patient has the right to know about the expectations of the ASF with regard to personal conduct and the consequences of failure to comply with expectations.

A covering statement with regard to the ASF can be helpful in directing the patient to the expectations and capabilities of the unit. An appropriate statement, such as the statement developed by the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF), can be utilized:

“No catalog of rights can guarantee for the patient the kind of treatment he has the right to expect. This facility has many functions to perform,

including the prevention and treatment of disease, the education of both health professionals and patients, and the conduct of clinical research. All of these activities must be conducted with an overriding concern for the patient, and, above all, the recognition of [one's] dignity as a human being. Success in achieving this recognition ensures success in defense of the rights of the patient.”

It is appropriate to explain to the patient his or her responsibilities with regard to participating in the delivery of care and complying with the requests and directives of the physician, such as taking medications, protecting the surgical incision, dressing management, and other therapies.

# Facility Design

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*An ambulatory surgical facility will provide a functionally safe and sanitary environment for patients, personnel, and the public. Each facility will incorporate a safety management program to maintain a physical environment free of hazards and to reduce the risk of human injury.*

## A. Building Technology

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### The medical director will ensure that each facility:

1. Complies with all applicable state (provincial) and local building codes and regulations.
2. Complies with applicable state (provincial) and local fire prevention regulations. (The NFPA 101 “Life Safety Code,” published by the National Fire Protection Association, Inc., is a commonly accepted guideline among states and localities.\*)
3. Complies with applicable federal regulations, including, but not limited to, the Occupational Safety and Health Administration (OSHA) Standards for Exposure to Bloodborne Pathogens (OSHA Bulletin 3127. U.S. Dept. of Labor, 1992).
4. Contains fire-fighting equipment to control a limited fire, including appropriately maintained and placed fire extinguishers of the proper type.
5. Has illuminated signs with emergency power capability at all exits from each floor or hall.
6. Has emergency lighting, as appropriate to the facility, to provide adequate evacuation of patients and staff in case of an emergency.
7. Complies with the requirements of the Americans with Disabilities Act (ADA) as appropriate to the facility. Title III of the ADA addresses access requirements for public accommodations for clinics, hospitals, and physician offices. The Physical Access Requirements for Existing Buildings might include adding a ramp over a step, grab bars, and raised letter and Braille markings to elevator control buttons.

Rest room access includes removing obstacles in the path to the rest room, modifying doors or hinges, widening stalls, and installing a raised toilet seat and grab bars. The staff should know the location of the nearest accessible rest room if it is not in the OSF.

A greater degree of accessibility is required for new construction, with specific guidelines outlined in the ADA (see page 26 for further information).

\*Life Safety Code and NFPA 101 are registered trademarks of the National Fire Protection Association, Inc., Quincy, MA.

Although elevators are not generally required in facilities under three stories with less than 3,000 square feet per floor, they are required in a new building that will be a shopping mall or that will contain a professional office of a health care provider.

8. Reception areas, toilets, and telephones are provided in accordance with patient and visitor volume.
9. All examination rooms, dressing rooms, and reception areas are constructed and maintained in a manner that ensures patient privacy during interviews, examinations, treatment, and consultations.
10. Adequate lighting and ventilation are provided in all areas.
11. Facilities are clean and properly maintained.
12. Food, snack services, and refreshments provided to patients meet their clinical needs and are prepared, stored, served, and disposed of in compliance with local health department requirements.

## **B. Safety Management**

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Each office surgical facility will provide the necessary personnel, equipment, and procedures to handle medical and other emergencies that may arise in connection with services sought or provided. At a minimum, the facility provides:

- 6 1. Periodic instruction of all personnel in the proper use of safety, emergency, and fire-extinguishing equipment.
2. A comprehensive emergency plan to address internal and external emergencies, including:
  - a. A provision for the safe evacuation of patients during an internal emergency, especially patients who might have difficulty walking.
  - b. A provision for the most efficient use of facilities and services during an external emergency.
  - c. A provision for periodic drills of the internal emergency plan.
  - d. A fire prevention policy must be stated in a manual, and portable fire extinguishers must be strategically located.
3. Prohibition of smoking in the office surgical facility, except in designated areas.
4. Elimination of hazards that might lead to slipping, falling, electrical shock, burns, poisoning, or other trauma.
5. Procedures to minimize the sources and transmission of infections, including adequate surveillance techniques.
6. A system for the proper identification, management, handling, transport, treatment, and disposition of hazardous materials and wastes, whether solid, liquid, or gas.

7. The containers holding biohazardous material must be located at a height that will prevent access by children.
8. Adequate space for a particular function or service and for the activities performed therein, including space allocated for pathology and medical laboratory services, radiology services, pharmaceutical services, examination and treatment rooms, offices, operating rooms, recovery areas, storage rooms, reception areas, clinical records, and other special-function areas.
9. Appropriate and readily accessible emergency equipment and supplies in all areas.
10. Proper maintenance and periodic testing of emergency equipment.
11. Alternate power adequate for the protection of the life and safety of patients and staff.

# Ancillary Services

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## Introduction

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The educational guidelines for establishing ancillary services in the ambulatory surgical facility (On-Site Services) are contained within this manual. Most facilities will find that the majority of ancillary services, which include laboratory, pathology, radiology, and pharmaceutical services, can best be handled by contracting these services out to established accredited facilities (Off-Site Services) in the community. In the latter situation, the administration of the facility should be assured that guidelines of the facility are acceptable and satisfactory. Generally, accredited facilities comply with all requirements and provide quality services.

### On-Site Services:

- A. The medical staff's financial involvement in any laboratory, pathology, radiation, or pharmaceutical service should be fully disclosed to the patient, whether this financial position be on site or through a community-certified facility.
- B. All ancillary services located in the office surgical facility must meet the standards for OSHA and CLIA, as well as other state and federal standards (see Appendix B, page 27, for regional offices).

### Off-Site Services:

- A. If on-site services are not utilized, evidence of consultant support from fully accredited laboratory, pathology, or pharmaceutical services should be documented and reported in the patient's office records.
- B. The majority of these ancillary services can best be handled for the office surgical facility through a contractual arrangement with established, certified facilities in the community.

## A. Pharmaceutical Services

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Pharmaceutical services provided or made available by a surgical facility must meet the needs of the patient and physicians in accordance with ethical and professional practices and legal requirements of the state and community.

1. Pharmaceutical services provided must be appropriate to the needs of the patient and must adequately support the physician's capabilities and training.
2. Pharmaceutical services must be provided in accordance with ethical and professional practice and applicable federal and state (provincial) laws.
3. Staff must demonstrate knowledge of applicable state and federal pharmaceutical laws.

4. Records and security must be maintained to ensure the control and safe dispensing of drugs in compliance with federal and state laws. Records must include detailed documentation of controlled drugs to provide accurate reconciliation.
5. Pharmaceutical services provided by the organization must be supervised by a licensed pharmacist, by a surgeon, or by an anesthesiologist who is qualified to assume professional, organizational, and administrative responsibility for the quality of services rendered.
6. A pharmacy that is owned or operated by the ASF must be supervised by a licensed pharmacist.
7. Pharmaceutical services made available by the organization through a contractual agreement must be provided in accordance with the same ethical and professional practices and legal requirements that would be required if such services were provided directly by the ASF.
8. Patients must not be required to use a pharmacy that is owned or operated by the ASF.
9. The quality and appropriateness of medication usage must be monitored and evaluated as part of the quality assessment and improvements program.

## **B. Laboratory Services and Pathology Guidelines**

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### **Standard**

Pathology and medical laboratory services provided or made available by the surgical facility must be designed to meet the needs of patients and physicians and be provided in accordance with professional practices and legal requirements of the state and community.

### **Required Characteristics**

1. Pathology and medical laboratory services provided or made available must adequately support the office surgical facility capabilities.
2. Appropriate CLIA regulations must be implemented by the laboratory director (physician or designated director).
3. Pathology and medical laboratory services must include, but need not be limited to, the following:
  - a. Conducting laboratory procedures that are appropriate to the needs of the patient's medical condition and planned surgical procedure.
  - b. Performing and documenting appropriate quality control procedures, including validating test results through the use of standardized controls.
  - c. Including authenticated (documented review by surgeon—for example, initial or sign report), dated reports of all laboratory examinations performed in the patient's medical record.
  - d. Directing of pathology and medical laboratory services provided by the ASF by a physician who is qualified to assume professional, organizational, and administrative responsibility for the laboratory.

- e. Competent personnel appropriately trained and educated to conduct laboratory work.
- f. Following of established procedures in obtaining, identifying, storing, and transporting specimens.
- g. Having in place a facility insurance program to monitor the entire laboratory operation on an ongoing basis to ensure the accuracy and reliability of the tests conducted.

### C. Diagnostic Imaging Services

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Diagnostic imaging services provided or made available in an ASF must meet the needs of patients and physicians and must be provided in accordance with ethical and professional practices and legal requirements of the state and community.

1. Diagnostic imaging services provided must adequately support the surgeon's capabilities and planned surgical procedures.
2. Diagnostic imaging services must include, but not be limited to:
  - a. Providing radiographic, fluoroscopic, ultrasound, or other diagnostic imaging services that are needed for the scope of surgical work.
  - b. Interpreting diagnostic images and supplying reports in a timely manner.
  - c. Maintaining old records, dated reports of service, and diagnostic images in patient records and/or a readily accessible location.
3. A radiologist should authenticate all examination reports, except reports of specific procedures that may be authenticated by the physician who has
  - (1) been evaluated and determined to be qualified to authenticate the reports or
  - (2) had documented residency training or postgraduate certification. With the recent popularity of new and emerging technology, acceptable training should be documented. Quality assurance must be ascertained by periodic review.
4. Diagnostic imaging services provided by the ASF must be directed by the physician who is qualified to assume professional, organizational, and administrative responsibility for the quality of the services rendered.
5. Adequately trained and certified personnel must be available to supervise and conduct the work of the diagnostic imaging services.
6. Policies that address the quality aspects of the imaging services include, but are not limited to:
  - a. Performing imaging services only upon the order of a physician.
  - b. Limiting the use of radioactive or other potentially harmful material to physicians who have been granted privileges for such use on the basis of their education, training, experience, and current competence.
7. Policies that address the safety aspects of the imaging services include, but are not limited to (see section on OSHA, page 11):
  - a. Regulation of the use, removal, handling, and storage of potentially hazardous materials.
  - b. Precautions against electrical, mechanical, magnetic, ultrasonic, radiation, and other potential hazards.

- c. Proper shielding where radiation, magnetic field, and other potentially hazardous energy sources are used.
  - d. Acceptable monitoring devices must be used by all personnel who might be exposed to radiation, magnetic fields, or otherwise harmful energy, and personnel exposure records must be maintained as required by the Nuclear Regulatory Commission and applicable state laws and/or regulations.
8. Proper warning signs must be posted to alert the public and ASF personnel to the presence of hazardous energy fields (X-ray, laser, magnetic, electrical), emphasizing concern for:
- a. Pregnant women
  - b. Patients with pacemakers

## **D. OSHA**

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The Occupational Safety and Health Administration (OSHA), a division of the U.S. Department of Labor, enforces the health and safety standards promulgated in accordance with the OSHA Act of 1970. OSHA has the authority to assess fines for violation of these regulations. These fines vary from as little as \$100 for minor infractions to as much as \$70,000 for “willful” violations.

Medical practices are currently subject to the OSHA Hazard Communication Standard (29CFR1910.1200) and the Bloodborne Pathogen Standard (29CFR1910.1030). Both of these standards have very specific requirements, and both standards require written policy manuals and formal training regarding the standards, along with documentation of each training session. (Complete copies of these documents may be obtained from the OSHA Publications Office, 200 Constitution Avenue, NW, Washington, DC 20210. Send a self-addressed mailing label with the request. In addition, these documents are available on the Internet [www.osha.gov].)

Following are some of the major requirements for each standard. This listing is not complete, and adhering only to this list will not bring your practice into total compliance with OSHA’s requirements.

### **Hazard Communication Standard (29CFR1910.1200)**

1. Annual training sessions must be held regarding hazardous chemicals used in the medical practice, their disposal, specific physical and health hazards of each material, measures to be taken by employees to protect themselves, and what to do in case of spills. Additional training is required for introduction into the workplace of any new substance that is considered hazardous. There must be a written program describing this training, including the method for implementation of the program. The individuals responsible for specific tasks (for example, labeling, training, procurement) and the location and availability of the program should be cited.
2. A list of hazardous chemicals used in each location of the medical practice must be prepared that includes the information previously described plus information on the use of each chemical. This list must also indicate the location of each chemical.

3. All hazardous chemical containers must be labeled (for extra safety, all containers should be labeled, whether hazardous or not). Labels should include:
  - a. Brand name
  - b. Chemical name
  - c. Manufacturer's name and address
  - d. Hazard warning
4. Manufacturers are required to prepare a material safety data sheet (MSDS) for each product they make. An MSDS must be obtained for each hazardous chemical and kept in an MSDS file in a central location.

### **Bloodborne Pathogen Standard (29CFR1910.1030)**

1. A written exposure control plan must be available. It must include identification of jobs and tasks where there is exposure to blood and other potentially infectious materials, a schedule for how and when the provisions of the plan will be implemented, and a system of record keeping. Engineering, work practice controls, personal protective equipment, and housekeeping should also be delineated.
2. Annual training sessions in universal precautions for all "at-risk" employees must be held and must be documented.
3. Hepatitis B immunization must be offered free of charge to all employees who have occupational exposure. Any employee refusing inoculation must sign an informed refusal form.
4. Protective clothing and equipment must be provided. Examples of the appropriate supplies include:
  - a. Gloves
  - b. Gowns
  - c. Goggles
  - d. Masks
  - e. Resuscitation equipment
5. Used needles must not be recapped. These needles and other sharp items are to be placed in appropriate sharps containers. Sharps containers must be puncture-resistant and leakproof, must have tight-fitting lids, and must be marked with a biohazard tag or label. These containers must also be located at a height that will prevent access by children.
6. Containers for biohazard (infectious) waste must be marked with the international biohazard symbol or in color-coded containers. The containers must be lined with red bags and have tight-fitting lids. Waste must be sorted into infectious and noninfectious (general) wastes and disposed of separately. State laws vary regarding disposal of biohazard wastes outside the medical facility.

## E. CLIA

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The Clinical Laboratory Improvement Amendments (CLIA) of 1988 are administered by the Health Care Financing Administration (HCFA) (regional offices are listed in Appendix B, page 27). Each state has a local office, and the regional office can provide the appropriate address. CLIA compliance is required for all entities providing laboratory services. It is advised that an OSF providing laboratory services seek consultation for establishment of the line of services and compliance with regulations. Local laboratories, especially in hospitals, can direct the facility's staff to qualified consultation. Several organizations are now listed on the Internet (search the Internet for "CLIA"). The state agency can also assist with certification and compliance.

Through the state offices, HCFA has been inspecting physicians' offices since 1992. Deficiencies are noted, and the U.S. government inspectors can impose penalties (see *Federal Register*, Vol. 57, No. 40, February 28, 1992) if the laboratory facility is not brought into compliance within a specified time.

Some considerations about CLIA:

1. Because certification is a site-neutral, complexity-based regulation that CLIA '88 requires, the regulatory distinctions that traditionally have separated hospital, independent, and physician office laboratories have all but disappeared.
2. Physicians' offices performing laboratory tests are required by CLIA '88 to have in effect either a waiver, a PPM certificate, or a registration certificate in the office to operate legally.
3. After filing for the CLIA identification number, the physician must determine which type of laboratory will be in operation at that time:
  - a. Waived (see *Federal Register* cited above)
  - b. Moderately complex
  - c. Highly complex
  - d. Physician-performed tests (see *Federal Register* cited above)
  - e. The certificate must be at the highest level of testing performed.
4. HCFA also requires that the CLIA identification number be used on all claim forms when billing Medicare and Medicaid for laboratory services.
5. The laboratory must meet requirements applicable to the test complexity and laboratory services performed.

# Surgical Care

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*This chapter will describe the basic requirements for a facility—personnel, equipment, and techniques necessary for the provision of quality ambulatory surgical care.*

## Definitions

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**Qualified Surgeon.** Any physician who has an unrestricted license to practice medicine and surgery in his or her locale, who has satisfactorily completed a training program recognized by the Accreditation Council for Graduate Medical Education (ACGME), or who has initiated or completed the process of becoming certified by an American Board of Medical Specialties (ABMS)–recognized board. The surgeon should also have admitting privileges in a hospital where he or she can perform the same procedures that may be performed in an ASF.

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**Anesthesiologist.** A physician who has an unrestricted license to practice medicine and surgery in his or her locale, who has satisfactorily completed a training program recognized by the Accreditation Council for Graduate Medical Education (ACGME), or who has initiated or completed the process of becoming certified by the American Board of Anesthesiology and has privileges to administer anesthesia in an accredited local facility.

**CRNA.** A certified registered nurse anesthetist who holds a valid license within that jurisdiction.

**Registered nurse.** A person holding a valid license to practice nursing within that jurisdiction.

**Licensed practical nurse.** A person holding a valid license to practice practical nursing within that jurisdiction.

**Licensed vocational nurse.** A person holding a license to practice vocational nursing in that locale.

**Certified surgical technologist.** A person holding a valid certificate from the Liaison Council on Certification for the Surgical Technologist.

**Physician’s assistant.** A person holding a valid license or registration to practice as a physician’s assistant in that jurisdiction.

**Surgical technician.** A person who has been taught to perform specific tasks, but who has not been certified.

## A. Surgical General Standards

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**Types of Cases.** Only those procedures should be done in which there is the expectation of discharge from the facility within a reasonably short period of time. The procedure must be one that is generally recognized as falling within the scope of practice of the surgeon providing the care. Ordinarily, privileges for performing such procedures have been granted at the surgeon's primary hospital.

1. **Patient Care.** The ASF must provide the highest quality technical care in an environment that is supportive of the patient's individual comfort, rights, and dignity.
2. **Classes of Surgical Facilities.\*** All levels of care are not required by all patients at all times, and, therefore, three general classes of care are recognized:

**Class A**—Provides for minor surgical procedures performed under topical and local infiltration blocks with or without oral or intramuscular preoperative sedation. Excluded are spinal, epidural, axillary, stellate ganglion blocks, regional blocks (such as interscalene), supraclavicular, infraclavicular, and intravenous regional anesthesia. These methods are appropriate for Class B and C facilities.

**Class B**—Provides for minor or major surgical procedures performed in conjunction with oral, parenteral, or intravenous sedation or under analgesic or dissociative drugs.

**Class C**—Provides for major surgical procedures that require general or regional block anesthesia and support of vital bodily functions.

### 3. Selection of Patients.

- a. Condition of the patient and potential risks should be considered. This judgment is based on history, physical examination, and such laboratory studies as determined by the physician (Class A) and/or anesthesiologist (Class B,C). A classification such as the American Society of Anesthesiologists (ASA) physical status may be useful:

Rank	Physical Status
ASA #1	Normal, healthy patient
ASA #2	Patient with mild systemic disease that does not limit physical activity
ASA #3	Patient with severe systemic disease that limits normal activity
ASA #4	Patient with severe systemic disease that is a constant threat to life
ASA #5	Moribund patient not expected to survive with or without the operation; usually not appropriate for outpatient surgery

Patients who by reason of preexisting medical or other conditions may be at undue risk for complications and should be referred to an appropriate facility for performance of the procedure and administration of anesthesia.

\* Those facilities meeting the guidelines for Class B procedures automatically qualify for Class A procedures, and those facilities meeting the guidelines for Class C automatically qualify for Classes A and B.

b. Appropriate Facility:

The appropriate facility for a given patient will depend on the condition of the patient, the procedure to be carried out, the type of anesthesia to be used, and the resources of the facility. A physician qualified to evaluate the influence of these factors upon the safety and well-being of the patient must make this determination.

Class A facilities usually provide care for ASA #1 and #2 patients.

Class B and C facilities require written (documented) evidence of preoperative evaluation by a physician (surgeon and/or anesthesiologist) for ASA #3 and #4 patients.

## B. Facility Standards

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### General:

Facility Classification	Standards
A,B,C	1. Appropriate history, physical examination, and laboratory tests must be completed prior to the operation, as determined by the surgeon. Patient identification and informed consent are accomplished prior to the operation.
A,B,C	2. Specific prior arrangements must be in place for obtaining appropriate laboratory, radiologic, and/or other services.
A,B,C	3. Appropriate monitoring and resuscitation equipment must be available and suited for each level of facility. Personnel who are appropriately qualified to interpret the monitoring equipment and to intervene should be readily available throughout the perioperative period. Qualified personnel may be another physician or nurse appropriately trained in resuscitation and treatment of serious perioperative events.
A,B,C	4. Acceptable standards of cleanliness and sterility must be maintained. Sterilization of operating room materials must be adequate.
B,C	5. The facility must have the capability of providing suitable intravenous fluid support.
B,C	6. Appropriate postoperative observation and monitoring must be provided. In Class A, B, and C facilities, a qualified physician should supervise the postoperative care of patients.
A,B,C	7. Operative reports are dictated or written in the medical record immediately after operation and contain a description of the findings, technical procedures used, specimens removed, postoperative diagnosis, and names of the primary surgeon and assistants. Unusual events and complications should be included in the report.
A	Class A: Written progress note acceptable.
B,C	Class B,C: Formal operative report required. The appropriate report or note giving appropriate detail shall be written or dictated immediately following the procedure.

- A,B,C 8. Each patient and his/her accompanying responsible adult are given instruction in follow-up care, including how to obtain appropriate help if needed postoperatively (for example, complications). These instructions are to be written and reviewed with the patient and his/her accompanying adult.
- A,B,C 9. A licensed independent practitioner, who has appropriate clinical privileges, is responsible for the decision to discharge the patient.
- A,B,C 10. Tissues and other specimens removed at operation shall be examined by a qualified pathologist. Certain predetermined exceptions (for example, teeth, nails, and so on) should be specified in procedure protocol.

**Specific:**

Facility Classification

Standards

- |       |   |
|-------|---|
| A,B,C | 1. Each ASF must have a physical plant adequate for its level of service.   |
| A,B,C | 2. There shall be a minimum of one adequately sized operating room that is used exclusively for surgery. A general treatment room is not adequate.  |
| B,C   | 3. There must be an adequately sized recovery room or area separate from the rest of the public areas of the facility.  |
| A,B,C | 4. There must be adequate space, equipment, and personnel to provide for aseptic treatment and prevention of cross-contamination among patients.  |
| A,B,C | 5. Suitable surgical lighting must be present, and an adequate emergency lighting source must be available.   |
| A,B,C | 6. An operating table must be present that is adequate for all types of cases scheduled.  |
| A     | 7. Adequate resuscitation equipment must be present.<br><b>Class A</b> —Airways, bag mask respirator, oxygen source, suction equipment, and age-appropriate resuscitative drugs.  |
| B,C   | <b>Class B,C</b> —Airways, endotracheal tubes, laryngoscope, oxygen delivery capability under positive pressure, suction equipment, and suitable resuscitative drugs.   |
| B,C   | 8. All room surfaces (including ceilings) must be smooth and washable. Acoustic ceiling tile is not acceptable. Tile flooring must be sealed. Surfaces should be cleansed and disinfected on a predetermined schedule and whenever necessitated by exposure to contamination. |
| A,B,C | 9. Adequate scrub and toilet facilities must be present. No sinks or drains in Class B,C operatories.   |
| A,B,C | 10. Fresh cloth or disposable towels must be available for each hand washing.   |

A,B,C

11. Any opening to the outer air must be adequately controlled to prevent the entrance of insects. Ventilation and temperature must be adequately controlled.

A,B,C

12. All premises must be kept neat and clean, and a cleaning schedule must be maintained that is adequate to prevent cross-contamination.

13. Appropriate monitoring equipment must be available.

Class A,B,C— Size-specific blood pressure apparatus and stethoscopes

ECG oscilloscopes

When pediatric patients are treated, size-specific emergency equipment and medications must be available.

Class B,C— Defibrillator

Pulse oximeter with alarm

Temperature monitor

Class C— When inhalation anesthesia is used, an anesthesia machine that is monitored consistent with the standards recommended by the American Society of Anesthesiologists.

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B,C

14. Appropriate intravenous fluids and administration equipment must be available.

B,C

15. Appropriate stretchers and wheelchairs must be available.

B,C

16. Dressing and lounge areas that do not adversely affect the care of patients must be provided for surgical personnel.

A,B,C

17. The facility must provide adequate patient and family waiting areas, examination rooms, and storage areas.

B,C

18. Corridors must be adequate to allow for ready passage of wheelchairs, stretchers, and emergency equipment.

A,B,C

19. Smoking must be prohibited in surgical treatment areas.

B,C

20. An adequate emergency power source for surgical, anesthesia, and monitoring equipment must be available.

B,C

21. All equipment must be maintained, tested, and inspected according to manufacturers' guidelines and local and state health facilities regulations.

B,C

22. Provisions should be made for the use of isolation precautions or for transfer, when indicated, of patients known or suspected of having transmissible disease. Patients requiring isolation are best not operated upon in Class A facilities.

## Personnel:

### Facility Classification

### Standards

A,B,C	1. The facility should be under the supervision of a qualified physician.
A,B,C	2. All physicians utilizing the facility must meet the standards set out in Chapter V, A. Credentialing, item 1.
B,C	3. A responsible individual must be designated who will manage all areas of the surgical facility with respect to personnel, cleanliness, aseptic techniques, supplies, patient supervision, and so on. In Class B and C facilities, this person must be certified in operating room techniques, such as an RN, LPN or registered surgical technologist, physician's assistant, or licensed vocational nurse.
A,B,C	4. All personnel, such as nurses and technicians, should be currently licensed in their respective fields. Any surgical technician not licensed must be under the immediate supervision of an MD or an RN.
A,B,C	5. All medical personnel must be certified in basic life support (CPR) and recertified as required by their community standard at not less than three-year intervals. Physicians in Class B and C facilities must be certified in ACLS and recertified as required by community standards at not less than three-year intervals.
A,B,C	6. All surgical personnel must be trained in basic aseptic techniques.
A,B,C	7. All surgical personnel must wear suitable attire, such as scrub suits, caps, masks, shoe coverings, and protective eye wear.

## C. Anesthesia

1. Administration of any anesthetic must be done or directly supervised by a qualified physician.
2. In Class C facilities, when inhalation anesthesia is used, an anesthesia machine that is monitored consistent with the standards of the American Society of Anesthesiologists must be present.
3. No explosive anesthetics should be used.
4. The administration of local or regional block anesthesia, with or without sedation or a dissociative drug, must be under the direct supervision of a qualified physician. General or spinal anesthesia must be supervised by a board-certified anesthesiologist, a physician eligible to take the anesthesiology board examination, or a registered CRNA under physician supervision, as required by current regulations for the jurisdiction in which the facility is located.

These individuals will be responsible for preoperative evaluation, patient preparation, induction and monitoring of the anesthetic, and postoperative monitoring and care until the patient is ready for discharge.

## D. Guidelines for Preoperative and Postoperative Care

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### Preoperative

There must be adequate facilities to conduct examinations and discussions with patients and families. Appropriate radiologic and laboratory support must be available. Appropriate monitoring equipment must be available.

### Operative

**On site**—A recovery area staffed and supplied for the level of support and monitoring care needed must be present in Class B and C facilities.

**Off site**—Provisions must be in place to provide extra care in a more comprehensively outfitted and staffed facility should it be needed. Examples would consist of calling 911 for extraordinary urgent care and having prior written arrangements made to transport patients to a fully privileged acute care hospital should ongoing or other specialty care be needed.

### Overnight Postoperative Stays

1. Physicians admitting patients to overnight facilities must be readily available and directly responsible for patient care.
2. The capability for in-patient monitoring and treatment of patients in the overnight facility must be the same as that of in-patient hospital capability acceptable in the region.
3. Policies and procedures should be clearly detailed as to eligibility for admission, backup emergency care, and a written transfer agreement with appropriate nearby health care facilities, as needed.
4. Nursing personnel, including RNs, LPNs, and technicians, should have appropriate training, supervision, and credentials and be available in a staff-to-patient ratio appropriate for good patient care.
5. Isolation procedures and policies are recommended.
6. Food service and housekeeping should be held to the same standards as the nearby in-patient hospital facility.

**Patient discharge**—If sedation, regional block, or general anesthesia has been used, a responsible adult must accompany the patient and be instructed with regard to the patient's care. Discharge of the patient is the responsibility of the surgeon or the anesthesiologist and can only occur when the patient has met criteria. Criteria should include stable vital signs, responsiveness and orientation, ability to move voluntarily, modest pain, and limited nausea and vomiting. Written instructions must be provided to the patient.

# Quality Assurance

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## A. Credentialing

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Quality of process and outcome should be the goal of all ASFs, as it is in any surgical facility. Outside control should be reasonable in scope, self-imposed, and cost-effective in order to maintain high-quality care.

1. The physician shall have appropriate documentation of accredited training to perform the procedures offered in the facility. He or she shall be board-certified or recognized by the board to be admissible for examination. The physician shall have privileges to perform equivalent or greater procedures at an accredited hospital or ambulatory care facility. It shall be documented that:
  - a. Each physician using the facility is credentialed by the appropriate governing body and qualified for the procedures he or she performs.
    - i. Procedure-specific competence should be documented and should include the demonstration of compliance with the following:
      - (a) adherence to professional society standards; and/or
      - (b) hospital and/or ambulatory surgical privileges for the scope of services performed in the outpatient setting; and/or
      - (c) credentials approved by a nationally recognized accrediting or credentialing organization; and/or
      - (d) completion of a didactic course supplemented by direct hands-on, monitored experience.
  - b. There is a current delineation of surgical privileges for each surgeon.
2. The surgeon and assisting personnel shall be competent to manage emergencies, such as sudden cardiopulmonary arrest or anaphylaxis.

## B. Quality Care

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1. An acceptable cardiopulmonary resuscitative cart will be available for emergencies and shall include at a minimum an AmbuBag, a laryngoscope, and a medication kit. The medication kit will include appropriate medications for treatment of anaphylaxis, cardiac arrhythmia, and cardiorespiratory arrest.
2. Prior arrangements for patient transfer to a nearby facility capable of treating complications shall have been made and documented.
3. Anesthesia usage shall be divided into three classes as described in Chapter IV, A. Surgical General Standards, item 2: Class A—local or topical, with or without oral or intramuscular sedation; Class B—intravenous anesthesia or intravenous sedation with or without local anesthesia, regional anesthesia, spinal anesthesia or epidural block; and Class C—regional anesthesia, spinal anesthesia or epidural block, general anesthesia, under limited circumstances and not administered by the surgeon or under his or her supervision.

4. Appropriate monitoring equipment shall be used when Class B anesthesia is employed and shall include monitors for pulse and oxygen saturation. Defibrillating equipment shall be available. Class C facilities shall include all of these types of equipment plus advanced monitoring equipment and resuscitation equipment as described in Chapter IV.

Recommended guidelines shall include:

1. An explanation of the surgical procedure and the anesthesia shall be provided to the patient. This explanation shall include the benefits, limitations, risks, and complications associated with both the surgery and the anesthesia.
2. An accurate record shall include: (a) preoperative evaluation, (b) an operative note, (c) medications and anesthetic agents used and the amounts, (d) accurate needle count, as appropriate to conform to the standard of care in the local area, and (e) the patient's condition on discharge from the facility.
3. An operative suite in the ASF shall include separate areas for surgical instrument preparation and sterilization and another for preparation and cleaning of used instruments and reusable materials.
4. Used disposable items shall be processed according to standard OSHA regulations.
5. Continuity of care shall be provided after surgery and understood by the patient.
6. Records of complications should be maintained and documented together with resultant outcomes. Complications could include, but would not be limited to:
  - a. Deaths
  - b. Cardiorespiratory events
  - c. Anaphylaxis or adverse drug reaction
  - d. Infections
  - e. Bleeding episodes
  - f. Admission to another facility for treatment of complications of surgery and anesthesia
  - g. Patient satisfaction survey results
7. Transfer of information at the patient's request to other health care providers shall be provided.

## C. Medical Records

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A surgeon engaged in ambulatory surgical practice should have his or her records periodically reviewed. An independent surgeon in the same field, peer review organization, or quality improvement team is recommended to perform the review. The reviewer should meet the following requirements: (1) board-certified or, (2) recognized by the board to be admissible for examination and, if possible, (3) a member of the American College of Surgeons. He or she should practice in the same specialty or field of surgery. He or she will render a report, and this report shall be on file in the facility; it should be signed, dated, and notarized. The evaluation will include identification of undesirable trends in the practice, such as: (1) diagnostic errors, (2) unacceptable results, (3) complications, (4) frequency of transfer to another facility, (5) follow-up of abnormal test results, (6) medication errors, (7) records review of entries, such as preoperative evaluation, pathologic reports, and follow-up visits, (8) technical services, such as laboratory and X-ray reports, and (9) the patient's satisfaction. Finally, findings in the quality assurance evaluation should be incorporated in the organization's educational activity. This report shall be subject to confidentiality protections applicable to peer review procedures.

## D. Clinical Records

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The practice and/or ASF shall maintain a record-keeping system from which information can be properly retrieved. Records shall be legible, documented in a timely manner, and readily accessible. These records should have the following characteristics:

1. An organized record should be maintained for each individual patient.
2. The records shall be collected, contained, and stored in a uniform fashion by a designated member of the facility.
3. The records shall be readily available to authorized health care practitioners and shall be available to the patient.
4. The records shall be confidential, shall be protected from loss and tampering, and shall be released only by prior approval of the patient.
5. Records shall be retired on a predetermined basis.
6. The records shall include histories, physicals, progress notes, operative reports, laboratory reports, and X-ray reports, as well as communications with other medical personnel. If the surgical facility is separate from the surgeon's office, only those records related to the ambulatory surgical procedure need be maintained at the surgical facility.
7. The records shall highlight allergies and untoward drug reactions.
8. Patient entries shall include the purpose of the visit and the clinical findings, any discussion, reports of studies ordered, treatment administered, and the disposition and the operative note, plus follow-up.
9. Significant advice and prescriptions given to a patient by telephone shall be recorded. Any treatment not consistent with an accepted therapy shall be specially noted and documented in the chart.
10. The patient's acceptance and consent to treatment, teaching, and education shall be noted.

## **E. Education**

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Continuing education cannot be enforced by the American College of Surgeons. It is recommended that in an ambulatory surgical facility, continuing education requirements be the physician's or governing body's responsibility and related, as appropriate, to his or her specialty society and/or state or county medical society. Compliance with these recommendations should be documented and kept with the surgeon's personnel file. Continuing education of the facility staff (RNs, LPNs, and surgical assistants) shall be made available at the expense of the facility with reasonable frequency to help ensure adequate performance.

Participation in these educational activities shall be documented in each personnel file and should indicate new skills acquired, as well as the number of hours spent in maintaining proficiency. The office surgical facility or ASF may be associated with an accredited teaching institution, and it may be utilized to provide educational experience for residents, students, nurses, and paramedical personnel.

Research is not considered to be in the purview of this manual, but if the facility is coincidentally engaged, because of an individual surgeon's involvement, with a cooperative study, the patient shall be made aware of this involvement and any possible implications for his or her surgical care and well-being. Such disclosure shall be signed and then placed in the patient's record. Such research shall be approved as required by an Institutional Review Board (IRB) of the facility or an affiliated hospital or an independent research review board.

## **F. Accreditation**

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The ASF should be accredited by state and local criteria, as well as by a national accrediting body, such as the JCAHO, AAAHS, or AAAASF. Periodic accreditation should be carried out at three- to five-year intervals.

# Appendix A

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*Following are the addresses and telephone numbers for the three major accrediting bodies for surgical facilities. Anyone wishing to proceed beyond this guideline manual in establishing a fully accredited ambulatory surgical facility should contact one of these established accrediting organizations.*

**American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF)**

1202 Allanson Road  
Mundelein, IL 60060  
Telephone 847/949-6058  
Fax 847/566-4580  
e-mail: [aaaasf@sprynet.com](mailto:aaaasf@sprynet.com)  
Web site: [www.aaaasf.org](http://www.aaaasf.org)

**Accreditation Association for Ambulatory Health Care, Inc. (AAAH)**

3201 Old Glenview Road, #300  
Wilmette, IL 60091  
Telephone 847/853-6060  
Fax 847/853-9028  
e-mail: [info@aaahc.org](mailto:info@aaahc.org)  
Web site: [www.aaahc.org](http://www.aaahc.org)

**Joint Commission on Accreditation of Healthcare Organizations (JCAHO)**

One Renaissance Boulevard  
Oak Brook Terrace, IL 60181  
Telephone 630/792-5000  
Fax 630/792-5005  
No e-mail  
Web site: [www.jcaho.org](http://www.jcaho.org)

Some legislative requirements will call for more detail than is outlined in this publication. Legislative guidelines are subject to constant changes and updates that should be acquired prior to making a final commitment to the office-based surgical facility. Sources for this information include the following government offices, but much information can be obtained from the Internet, including copies of rules and documentation. Searching the Internet under the appropriate offices and departments will usually locate the needed information. Also, government agencies have regional offices to which many of the questions relating to an OSF are best directed. State and county medical societies usually can help immensely by providing advice and information on contacting the various agencies:

**Occupational Health and Safety Administration (OSHA)**  
Office of Information and Consumer Affairs  
200 Constitution Avenue, NW  
Washington, DC 20210  
Telephone 202/219-8151  
Web site: [www.osha.gov](http://www.osha.gov)

**Clinical Laboratory Improvement Amendments (CLIA) of 1988**  
Administrator, Health Care Financing Administration  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201  
Telephone 202/690-6726  
Web site: [www.hcfa.gov](http://www.hcfa.gov)

### **The Americans with Disabilities Accessibility Guidelines**

For copies of the *Americans with Disabilities Accessibility Guidelines* (ADAG) for new construction and alterations to existing buildings, call the Department of Justice at 202/514-0301 or the Access Board at 1-800/USA-ABLE; fax 202/272-5447.

State and local guidelines, rules, and regulations must be accessed. This information will be available through the departments of health in the individual states. Again, state and local medical societies can be quite helpful in advice and direction.

# Appendix B

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*Following are OSHA's regional offices, which are a division of the U.S. Department of Labor, and CLIA's regional offices, which are a division of the Health Care Financing Administration (HCFA) under the Department of Health and Human Services. The defined regions for OSHA and CLIA are identical, but the offices are different. Contact the regional offices for information, addresses, and other sources in the region. (Please note that telephone numbers and offices change frequently. Contact the national offices if there is a problem.)*

## Regional Offices of the Occupational Safety and Health Administration

### Region I

(CT,\* MA, ME, NH, RI, VT\*)  
Telephone 617/565-7164

### Region II

(NJ, NY,\* PR,\* VI\*)  
Telephone 212/337-2378

### Region III

(DC, DE, MD,\* PA, VA,\* WV)  
Telephone 215/596-1201

### Region IV

(AL, FL, GA, KY,\* MS,  
NC, SC,\* TN\*)  
Telephone 404/347-3573

### Region V

(IL, IN,\* MI,\* MN,\* OH, WI)  
Telephone 312/353-2220

### Region VI

(AR, LA, NM,\* OK, TX)  
Telephone 214/767-4731

### Region VII

(IA,\* KS, MO, NE)  
Telephone 816/426-5861

### Region VIII

(CO, MT, ND, SD, UT,\* WY\*)  
Telephone 303/844-1600

### Region IX

(American Samoa, AZ,\* CA,\* Guam, HI,\*  
NV,\* Trust Territories of the Pacific)  
Telephone 415/975-4310

### Region X

(AK,\* ID, OR,\* WA\*)  
Telephone 206/553-5930

\*These states and territories operate their own OSHA-approved job safety and health programs (Connecticut and New York plans cover public employees only). States with approved programs must have a standard that is identical to, or at least as effective as, the federal standard.

Regional Offices for the Clinical Laboratory Improvement Amendments of 1988 (HCFA/CLIA)†

**Region I**

(CT, MA, ME, NH, RI, VT)  
Telephone 617/565-3308

**Region II**

(NJ, NY, PR, VI)  
Telephone 212/264-1121

**Region III**

(DC, DE, MD, PA, VA, WV)  
Telephone 215/861-4291

**Region IV**

(AL, FL, GA, KY, MS, NC, SC, TN)  
Telephone 404/562-7438

**Region V**

(IL, IN, MI, MN, OH, WI)  
Telephone 312/886-5311

**Region VI**

(AR, LA, NM, OK, TX)  
Telephone 214/767-6322

**Region VII**

(IA, KS, MO, NE)  
Telephone 816/426-3184

**Region VIII**

(CO, MT, ND, SD, UT, WY)  
Telephone 303/844-4722

**Region IX**

(AZ, CA, HI, NV)  
Telephone 415/744-3696

**Region X**

(AK, ID, OR, WA)  
Telephone 206/615-2313

†Each state has a separate office. The telephone number can be obtained from the regional office.









American College of Surgeons  
633 N. Saint Clair St.  
Chicago, IL 60611-3211