

The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice guidelines and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice guidelines and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice guideline and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council. The practice guidelines and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice guideline and technical standard by those entities not providing these services is not authorized.

Revised 2005 (Res. 43)*

ACR PRACTICE GUIDELINE FOR ADULT SEDATION/ANALGESIA

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

This guideline has been developed to assist radiologists in the safe administration and monitoring of sedation/analgesia in adults outside the operating room. The goal of this guideline is to help radiologists provide their patients with the benefits of sedation/analgesia while minimizing the associated risks. Sedation/analgesia allows patients to tolerate unpleasant procedures by relieving anxiety, discomfort, or pain. It facilitates and optimizes imaging and interventional procedures that require patient cooperation.

II. DEFINITIONS

Light sedation or anxiolysis is defined by the Joint Commission and the American Society of Anesthesiologists (ASA) as “the administration of oral medications for the reduction of anxiety” and “a drug-induced state during which the patient responds normally to verbal commands.” The ASA states further that “although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.” Examples of drugs administered orally that might be considered for this use are sedative-hypnotics, anxiolytics, benzodiazepines, antihistamines, and narcotics.

Moderate or “conscious” sedation/analgesia is a minimally depressed level of consciousness induced by the administration of pharmacologic agents in which the patient retains continuous and independent ability to maintain protective reflexes and a patent airway and to be aroused by physical or verbal stimulation.

Deep sedation/analgesia is a controlled state of depressed consciousness or unconsciousness from which the patient is not easily aroused; it may be accompanied by a partial or complete loss of protective reflexes, including the ability to maintain a patent airway independently and to respond purposefully to repeated or painful stimulation.

General anesthesia is a controlled state of unconsciousness in which there is a complete loss of protective reflexes, including the ability to maintain a patent airway independently and to respond appropriately to painful stimulation.

Regardless of the intended level of sedation or route of drug administration, the sedation of a patient represents a continuum and may result in the loss of the patient's protective reflexes. All sedated patients should be monitored and treated appropriately regardless of the intended level of sedation. The personnel and equipment considered appropriate for monitoring depend on the acuity level and potential response of the patient to the procedure or intervention proposed.

III. SCOPE

The monitoring guidelines in this guidance document apply only to adult patients who receive moderate or deep sedation for any diagnostic, therapeutic, or interventional procedure.

Patients receiving a single dose of a medication to produce light sedation for anxiolysis should be observed long enough to assess their response to the medication. If they do not enter a state of moderate sedation they do not need to be continuously monitored as described below.

The administration of deep sedation/analgesia for more painful procedures requires a greater level of skill and experience and more intensive monitoring than is described here. Many patients enter deep sedation even when moderate sedation is the goal. Like those patients with moderate sedation, they are monitored in the same fashion.

General anesthesia should be performed by an anesthesiologist or nurse anesthetist.

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Supervising Physician

The supervising physician should:

1. Have sufficient knowledge of the pharmacology, indications, and contraindications for the use of sedative agents to enable safe administration and have the ability to recognize and initiate treatment for adverse reactions, including the appropriateness of reversal agents.
2. Have appropriate continuing education in accordance with the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#).
3. Demonstrate the skills in basic life support and have the knowledge and skills to intervene in the event of complications. The physician caring for the patient in the imaging/interventional suite should meet the credentialing requirements of the facility.

B. Health Professional Responsible for Monitoring the Patient

This professional should:

1. Be a physician, nurse, or other licensed healthcare provider authorized by the facility whose primary job is to monitor the patient.
2. Be certified according to the pathway appropriate to the profession.
3. Be trained and competent in basic resuscitation measures.
4. Be knowledgeable in the use, side effects, and complications of the sedative agent(s) and reversal agents to be administered.
5. Be knowledgeable and experienced in monitoring vital signs, using pulse oximetry, and cardiac monitoring, including the recognition of cardiac arrhythmias.
6. Meet the credentialing requirements of the facility.

The monitoring, medicating, and care of the patient should be the primary focus of this professional, with minimal other duties during the procedure. This health professional must be someone other than the person who performs the procedure.

It is recommended that an individual qualified in advanced cardiac life support be on-site.

V. PATIENT SELECTION

Adult patients who are ASA class I or II qualify for sedation/analgesia when imaging procedures are required (see Appendix A).

These guidelines specifically exclude the following:

1. Patients who are not undergoing an imaging diagnostic or therapeutic procedure.
2. Perioperative management of patients undergoing general anesthesia.
3. Patients undergoing mechanical ventilation in a critical care environment.
4. Patients who are ASA class III or IV (Appendix A). Such patients require individual consideration and are not considered in these standards.
5. Patients who are ASA class V. Such patients should not be sedated by nonanesthesiologists.

VI. RISK FACTORS

All patients referred for sedation should be appropriately screened by a physician, registered nurse, nurse practitioner, physician's assistant, or other appropriately trained individual for the presence of risk factors that may increase the likelihood of an adverse effect. If risk factors are present, alternatives such as supervision by an anesthesiologist may be considered.

Risk factors include, but are not limited to, congenital or acquired abnormalities of the airway, liver failure, underlying lung disease, congestive heart failure, clinical brain stem dysfunction, apnea or hypotonia, history of adverse reaction to sedating medications, and severe gastroesophageal reflux. Positive pressure ventilation, with or without endotracheal intubation, may be necessary if respiratory compromise develops during sedation/analgesia. This may be more difficult in patients with atypical airway anatomy, and some airway abnormalities may increase the likelihood of airway obstruction during spontaneous ventilation (see Appendix B).

VII. PATIENT EVALUATION AND MANAGEMENT

A. Patient Preparation Before Moderate Sedation

1. Electrocardiogram tracings and relevant laboratory values, when appropriate, should be available for review.
2. For elective procedures, the patient should not ingest solid food for 6 hours or clear liquids for 2 hours before the administration of moderate sedation.

3. The need for written informed consent shall follow institutional policies and procedures and state requirements.

B. Evaluation Before Moderate Sedation

1. If not already available, a focused history and physical examination should be performed. They should include previous experience with sedation/analgesia, current medical problems, current medications, drug allergies, and the presence of morbid obesity. A physician, nurse practitioner, or physician assistant should perform the presedation evaluation.
2. At the time of the procedure, an assessment of recent oral intake, recent illness, pulmonary status (including upper airway), cardiac status, baseline vital signs, level of consciousness, pulse oximetry, and electrocardiogram (when applicable) should be performed and recorded.

C. Management During Moderate Sedation

1. Intravenous access must be maintained.
2. All patients shall be continuously monitored throughout the procedure by physiologic measurements that should be recorded (at least every 15 minutes). These measurements include, but are not limited to, level of consciousness, respiratory function, pulse oximetry, blood pressure (as indicated), heart rate, and cardiac rhythm.
3. Supplemental oxygen with size-appropriate equipment shall be immediately available and administered as needed.
4. Suction shall be immediately available.
5. A defibrillator with back-up emergency power and emergency cart, including equipment for intubation and ventilation, shall be immediately available.
6. The route, dosage, and time of all sedation and reversal medications shall be documented on the sedation record by the health professional responsible for monitoring the patient.
7. Drug antagonists and intravenous fluids should be immediately available.

D. Recovery Following Moderate Sedation

1. The patient must recover in an area where continuous monitoring and resuscitative equipment (e.g., suction, oxygen, hemodynamic monitoring) are available. Monitoring should include, but is not limited to, level of consciousness, respiratory function, pulse oximetry, blood pressure (if indicated), and heart rate.

2. Levels of consciousness and vital signs must be monitored at intervals consistent with recovery status until both return to levels acceptable for discharge. A patient may not leave the recovery area without accompanying monitoring personnel until vital signs and level of consciousness are at acceptable levels as determined by the healthcare professional responsible for monitoring the patient or by hospital policy.
3. If use of reversal agents was required, the level of consciousness and vital signs should return to acceptable levels for a period of 2 hours from the time of administration of the reversal agent before discontinuation of monitoring ends. (Use of reversal agents may be associated with relapse into deep sedation after apparent recovery.)
4. The monitoring personnel will notify the supervising physician (who shall remain available until recovery is complete) of any significant change in the patient's clinical status.
5. Qualified monitoring personnel (as described in section IV) must be immediately available to the patient from the initiation of sedation until the patient has adequately recovered or has been turned over to the appropriate personnel delivering recovery care.

VIII. DISCHARGE CRITERIA

A. The patient should not be discharged until vital signs, level of consciousness, and motor function have returned to acceptable levels, as determined by the healthcare professional responsible for monitoring the patient and dependent on the patient's destination.

B. When discharge is to home, written discharge instructions will be given to the patient/family. The written discharge instructions should include, but not necessarily be limited to:

1. Physician contact information for postprocedure problems.
2. Advice against driving or operating dangerous machinery for a minimum of 12 hours.
3. Possible adverse effects of medications given and the treatment required.

IX. DOCUMENTATION

Adequate documentation of all aspects of patient evaluation and monitoring is essential for high-quality patient care. This documentation should include, but is not limited to:

1. Dosage, route, site, and time of administered drugs.

2. Patient's response to medication and the procedure.
3. Inspired concentrations of oxygen, its rate and duration, and method of administration.
4. Physiological data from monitoring.
5. Any interventions such as oxygen or intravenous therapy and the patient's response.
6. Any untoward reactions and their resolution.

Reporting should be in accordance with the [Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures](#).

X. EQUIPMENT

There must be documented policies for monitoring and evaluating the function of all equipment. Any location in which sedation is performed must have ready access to equipment and drugs for emergency resuscitation. It is critical that a complete range of sizes of emergency and monitoring equipment be available. The equipment should include:

1. Oxygen supply from a portable or permanent source.
2. Airway maintenance and oxygen delivery equipment appropriate to patient age and size, including nasal cannulas, masks, and oral airways and resuscitation equipment (e.g., AMBU bag, laryngoscopes, ventilating masks, and endotracheal tubes). A mask capable of delivering 100% oxygen is necessary (nonrebreather mask).
3. Suction apparatus capable of producing continuous suction at a negative pressure of 150 mm Hg and checked for adequacy just prior to sedation. Suction catheters appropriate for patient's airway.
4. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications. The equipment and medications should be monitored for inventory and drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and/or sizes in the patient population.
5. Monitors
 - a. Pulse oximetry with probes appropriate for the patient's size. Pulse oximeter should have both digital and auditory display.
 - b. Blood pressure measuring device with cuffs appropriate for the patient's size.
 - c. EKG as appropriate for medical history.
 - d. A means of monitoring ventilation, either visually or mechanically.
6. A stethoscope.

7. A defibrillator should be available in close proximity.

XI. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns appearing elsewhere in the ACR Practice Guidelines and Technical Standards book.

A record should be kept for all patients receiving sedation, indicating sedation failure and adverse effects (e.g., vomiting, hypoxic events, resuscitation, and 24-hour follow-up when possible) and possible explanations for adverse outcomes. Patient care areas using sedation and analgesia should have policies and procedures for reporting complications encountered during sedation and analgesia to the quality-assurance committee.

ACKNOWLEDGEMENTS

This guideline was revised according to the process described in the ACR Practice Guidelines and Technical Standards book by the Guidelines and Standards Committee of the Commission on Interventional and Cardiovascular Radiology.

Principal Reviewer: Richard B. Towbin, MD

Guidelines and Standards Committee

John F. Cardella, MD, Chair
 John D. Barr, MD
 Daniel B. Brown, MD
 Drew M. Caplin, MD
 Christine Chao, MD
 James S. Donaldson, MD
 Kyran Dowling, MD
 Clement J. Grassi, MD
 Patrick C. Malloy, MD
 Louis G. Martin, MD
 Timothy P. Murphy, MD
 Reed A. Omary, MD
 James L. Swischuk, MD
 Matthew A. Mauro, MD, Chair, Commission

Comments Reconciliation Committee

Charles E. Mueller, MD, Chair, CSC
 Paul H. Ellenbogen, MD
 Paul A. Larson, MD
 John F. Cardella, MD
 James S. Donaldson, MD
 Lawrence A. Liebscher, MD

Richard B. Towbin, MD

Suggested Reading

1. American College of Emergency Physicians. Clinical policy for procedural sedation and analgesia in the emergency department. *Ann Emerg Med* 1998;31:663-677.
2. American Society of Anesthesiologists. Continuum of depth of sedation. *Definition of General Anesthesia and Levels of Sedation/Analgesia*. Directory of members; 1999:497.
3. American Society of Anesthesiologists Task Force on sedation and analgesia by non-anesthesiologists. Practice guideline for sedation and analgesia by non-anesthesiologists. *Anesthesiology* 1996;84:459-471.
4. Bush WH, Krecke KN, King BF, et al, eds. *Radiology Life Support: a Practical Approach*. New York, NY: Oxford University Press; 1999.
5. Chudnofsky CR. Safety and efficacy of flumazenil in reversing conscious sedation in the emergency department. Emergency Medicine Conscious Study Group. *Acad Emerg Med* 1997;4:944-950.
6. Comprehensive accreditation manual for hospitals: official handbook. Oakbrook Terrace, IL: *JCAHO*; 2000:TX15-17, TX 71-79.
7. Kankaria A, Lewis JH, Ginsberg G, et al. Flumazenil reversal of psychomotor impairment due to midazolam or diazepam for conscious sedation for upper endoscopy. *Gastrointest Endosc* 1996;44:416-421.
8. Martin ML, Lennox PH. Sedation and analgesia in the interventional radiology department. *J Vasc Interv Radiol* 2003;14:1119-1128.
9. Trotteur G, Stockx L, Dondelinger RF. Sedation analgesia and anesthesia for interventional radiological procedures in adults. *JBR-BTR* 2000;83:111-115.

APPENDIX A

American Society of Anesthesiologists (ASA) Physical Status Classification

Class I	A normal healthy patient.
Class II	A patient with mild systemic disease.
Class III	A patient with severe systemic disease.
Class IV	A patient with severe systemic disease that is a constant threat to life.
Class V	A moribund patient who is not expected to survive without the operation.
Class VI	A declared brain-dead patient whose organs are being removed for donor purposes.

APPENDIX B

Factors that may be associated with difficulty in airway management include, but are not limited to:

- Previous problems with anesthesia or sedation.
- Stridor.
- Snoring or apnea.
- Dysmorphic facial features (e.g., Pierre Robin syndrome, trisomy 21).
- Craniocervical abnormalities.
- Significant obesity (especially involving the neck and facial structures).
- Short neck, limited neck extension, neck mass.
- Tracheal deviation.
- Small mouth, protruding incisors, loose or capped teeth, high arched palate.
- Macroglossia.
- Tonsillar hypertrophy.
- Nonvisible uvula.
- Micrognathia.
- Retrognathia.
- Trismus.

*Guidelines and standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Guideline

1995 (Resolution 13)

Revised 2000 (Resolution 17)

Revised 2005 (Resolution 43)