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.

ACR–SIR PRACTICE GUIDELINE FOR 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 was revised collaboratively by the American College of Radiology (ACR) and the Society of Interventional Radiology (SIR) to assist physicians in the safe administration of sedation/analgesia and monitoring of patients receiving sedation/analgesia outside the operating room. Sedation/analgesia allows patients to tolerate diagnostic imaging, image-guided interventions, and radiation oncology procedures by relieving anxiety, discomfort, or pain. It facilitates and may optimize diagnostic imaging, image-guided interventions, and radiation oncology procedures that require patient cooperation.

II. DEFINITIONS

Minimal 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. Drugs may also be administered by a non-oral route.

Moderate sedation/analgesia is a minimally depressed level of consciousness induced by the administration of pharmacologic agents in which the patient retains a 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 drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

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 route of drug administration, administration of these medications may result in a level of sedation that is lighter than or deeper than the level intended for a patient. Sedation 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 to adult patients who receive moderate sedation and to pediatric patients who receive minimal or moderate sedation for diagnostic imaging, image-guided interventions, or radiation oncology procedures.

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. Deep sedation is within the scope of practice of qualified interventional radiologists but is outside of the scope of this document.

Special consideration should be given to patients undergoing sedation in a magnetic resonance imaging (MRI) environment. Relevant issues are addressed by the ASA’s Practice Advisory on Anesthetic Care for Magnetic Resonance Imaging [1].

### IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Sedation/analgesia should be administered under the supervision of a licensed physician. Appropriately trained medical personnel should be available to treat any adverse event. All persons administering and monitoring sedation are responsible for maintaining proficient skills necessary to provide quality patient care.

#### 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 use of reversal agents.
2. Have appropriate continuing education in accordance with the ACR Practice Guideline for Continuing Medical Education (CME).
3. Have current Basic Life Support (BLS) certification. For pediatric sedation, have Pediatric Advanced Life Support (PALS) certification [2]. For adult sedation, have Advanced Cardiac Life Support (ACLS) certification or have an individual with ACLS certification available with a response time of less than 5 minutes [3].
4. Meet the credentialing requirements of the facility and have privileges to perform sedation.

#### B. Health Professional Responsible for Monitoring the Patient

A physician, nurse, nurse practitioner, registered radiology assistant, or other qualified individual, other than the practitioner performing the procedure, must be present to monitor the patient throughout procedures performed with sedation/analgesia. This individual may administer the medications used for sedation/analgesia and may assist with minor, interruptible tasks during the procedure.

This professional should:

1. Be a physician, nurse, or other licensed health care provider authorized by the facility, whose primary job is to monitor the patient.
2. Be appropriately privileged by the institution.
3. Have current certification in BLS.
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 dysrhythmias.

6. Meet the credentialing requirements of the facility.

The monitoring, medicating, and care of the patient should be the primary focus of this professional. He or she must be someone other than the person who performs the procedure.

V. PATIENT SELECTION

Patients who are ASA class I or II qualify for sedation/analgesia (see Appendix A). Patients who are ASA class III or IV may require additional consideration.

These guidelines specifically exclude the following:

1. Patients managed by the anesthesiology or critical care service.
2. Patients on mechanical ventilation.
3. 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, consultation with an anesthesiologist may be considered.

Risk factors include, but are not limited to, congenital or acquired abnormalities of the airway, liver failure, lung disease, congestive heart failure, symptomatic brain stem dysfunction, apnea or hypotonia, history of adverse reaction to sedating medications, morbid obesity, 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 airway abnormality. Some airway abnormalities may increase the likelihood of airway obstruction during spontaneous ventilation (see Appendix B).

VII. PATIENT EVALUATION AND MANAGEMENT

Sedation should be performed in accordance with ASA guidelines, as described below [3].

Adult patients and legal guardians providing consent should be informed of and agree to the administration of sedation/analgesia before the procedure begins. Minor patients should be informed of the procedure, as appropriate. The requirement for written informed consent should follow facility policies and procedures and state and local laws and regulations.

For outpatients, a responsible adult should accompany the patient on discharge from the facility.

A. Patient Preparation Before Sedation

Hospital guidelines for preprocedure fasting should be followed. A suggested pediatric fasting protocol is given in Appendix C.

B. Evaluation Before Sedation

1. Electrocardiogram tracings and relevant laboratory values, when appropriate, should be available for review.
2. A focused history and physical examination should be performed and recorded. It should include the patient’s previous experience with sedation/analgesia, current medical problems, current medications, drug allergies, and any significant comorbidities. A physician, nurse practitioner, or physician assistant should perform the presedation evaluation.
3. Prior to initiating sedation, 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 Sedation

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

9. Drug antagonists and intravenous fluids should be immediately available; their use should be based on the clinical circumstances.

10. For pediatric patients, intravenous sedative/analgesic drugs should be given based on the patient’s weight in incremental doses that are titrated to the desired endpoints of sedation and analgesia. Weight based dosing should operate within the maximum dose limit guidelines for each medication. For all patients, sufficient time must elapse between doses to allow the effect of each dose to be assessed before subsequent drug administration. When drugs are administered by nonintravenous routes (e.g., oral, rectal, intramuscular), allowance should be made for the time required for drug absorption before supplementation is considered.

11. In adult patients, intravenous sedative/analgesic drugs are given in incremental doses that are titrated to the desired endpoints of sedation and analgesia.

12. Combinations of sedative and analgesic agents should be administered as appropriate for the procedure being performed and the medical condition of the patient. Ideally, each component should be administered individually to achieve the desired effect (e.g., additional analgesic medication to relieve pain, additional sedative medication to decrease awareness or anxiety). The combinations of sedative and analgesic agents may potentiate respiratory depression. This underscores the need to dose each agent appropriately, as well as the need to monitor respiratory function.

D. Recovery Following Sedation

1. The patient must recover in an area where continuous monitoring and resuscitative equipment (e.g., suction, oxygen) are immediately available. Monitoring should include, but is not limited to, the level of consciousness, respiratory rate, pulse oximetry, blood pressure, and heart rate and rhythm, and should comply with facility requirements.

2. Levels of consciousness and vital signs must be monitored at intervals consistent with recovery status until all 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 facility 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 monitoring ends. (Use of reversal agents may be associated with relapse into a deeper level of sedation than intended after successful rescue, and repeated doses may be required.)

4. The monitoring personnel will notify a supervising physician (who should 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. SEDATION-RELATED 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. Dose, route, site, and time of administered drugs.
2. Patient’s response to medication and the procedure.
3. Inspired concentrations of medical gases, such as oxygen and nitrous oxide, their rate and duration, and method of administration.
4. Physiological data from monitoring.
5. Any rescue interventions, including ventilatory support, or use of reversal medications, and the patient’s response.
6. Any untoward reactions and their resolution.

Reporting should be in accordance with the ACR–SIR Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures.

IX DISCHARGE CRITERIA

A. The patient should not be discharged until vital signs, level of consciousness, and motor function have returned to the patient’s preprocedure baseline or an acceptable level, as determined by the health care 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 or accompanying responsible adult. The written discharge instructions should include, but not necessarily be limited to:
1. Physician contact information, including after-hours contact information, in the event of postprocedure problems.
2. Advice against driving or operating dangerous machinery for a minimum of 12 hours.
3. Advice against alcohol intake for 24 hours.
4. Possible adverse effects of medications given and the need to seek medical attention in the event of an adverse effect.

X. EQUIPMENT

Facility policies for monitoring and evaluating the function of all equipment should be followed. Any location where sedation is administered must have equipment and drugs for emergency resuscitation readily available [1]. It is critical that a complete range of sizes of emergency and monitoring equipment be available in the immediate area, for all ages and sizes of patients treated at the facility. The equipment should include:

1. Oxygen supply from a portable or fixed source, with a backup oxygen supply.
2. Airway maintenance and oxygen delivery equipment appropriate to patient age and size, including nasal cannulae, face masks, and oral airways and resuscitation equipment (e.g., an Ambu bag, laryngoscopes, ventilation masks, and endotracheal tubes). A mask capable of delivering 100% oxygen is necessary (e.g., a nonrebreather mask).
3. Suction apparatus capable of producing continuous suction at a negative pressure of 150 mm Hg and regularly checked for adequacy according to facility policies. Suction catheters appropriate for patient’s airway must be available.
4. Appropriate emergency medications and equipment, including a defibrillator, must be immediately available to treat adverse reactions associated with administered medications. The equipment and medications should be monitored according to facility policies. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population. Equipment function should be checked on a regular basis, according to facility policies. Equipment checks should be documented in accordance with facility policies.
5. Monitors
   a. Pulse oximeter with probes appropriate for the patient’s size. Pulse oximeter should have both visual and audible outputs.
   b. Blood pressure measuring device with cuffs appropriate for the patient’s size.
   c. Multi-lead electrocardiographic monitors as appropriate for the patient’s medical history.
   d. A means of monitoring ventilation, either visually or through a device.
6. A stethoscope.
7. A telephone.
8. An emergency light source, such as a flashlight.
9. Emergency electrical power (or battery backup) for all electrical equipment listed above.

For sedation performed in the MR suite, special equipment requirements apply, as indicated in the American Society of Anesthesiology Practice Advisory on Anesthetic Care for Magnetic Resonance Imaging [1].

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 appearing under the heading Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education on the ACR web page (http://www.acr.org/guidelines).

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 under the heading The Process for Developing ACR Practice Guidelines and Technical Standards on the ACR web page (http://www.acr.org/guidelines) by the Guidelines and Standards Committee of the Commission on Interventional and Cardiovascular Radiology in collaboration with the SIR.

Collaborative Committee

ACR
Richard Towbin, MD, Chair
Christine P. Chao, MD
Drew Caplin, MD
Aradhana Venkatesan, MD
REFERENCES


Suggested Reading (Additional articles that are not cited in the document but that the committee recommends for further reading on this topic)


APPENDIX A

American Society of Anesthesiologists (ASA) Physical Status Classification

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

APPENDIX C

Suggested Fasting Protocol

Check the ASA guideline for updated information; reorganize variability

<table>
<thead>
<tr>
<th>Solids and Nonclear Liquids*</th>
<th>Clear Liquids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children &lt;6 months</td>
<td>4 to 6 hr</td>
</tr>
<tr>
<td>Children 6 to 36 months</td>
<td>6 hr</td>
</tr>
<tr>
<td>Children &gt;36 months</td>
<td>6 to 8 hr</td>
</tr>
</tbody>
</table>

*This includes milk, formula, and breast milk (high fat content may delay gastric emptying).

*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)
Revised 2010 (Resolution 45)