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ACR–SIR PRACTICE PARAMETER FOR SEDATION/ANALGESIA

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents 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 practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, 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 this document 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 this document. However, a practitioner who employs an approach substantially different from the guidance in this document 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 the guidance in this document 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 this document is to assist practitioners in achieving this objective.

¹ *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing*, ___ N.W.2d ___ (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

This practice parameter 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 better tolerate diagnostic imaging and image-guided 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. SCOPE

The monitoring practice parameters in this guidance document apply to patients who receive minimal sedation beyond anxiolysis, or moderate sedation. Patients receiving a single anxiolytic agent in appropriate doses do not require monitoring [1].

The administration of deep sedation/analgesia 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 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 American Society of Anesthesiologist (ASA) Practice Advisory on Anesthetic Care for Magnetic Resonance Imaging [2].

III. DEFINITIONS

Sedation is a dynamic continuum ranging from minimal sedation/anxiolysis to general anesthesia. Minimal sedation or anxiolysis is defined by the Joint Commission and the ASA as “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” [1].

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. Planned levels of sedation/analgesia beyond moderate sedation are outside the scope of this document.

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Sedation/analgesia may be administered by a physician, or by a nurse or licensed independent practitioner under the supervision of a physician. Appropriately trained medical personnel should be immediately available to treat any sedation-related adverse event.

A. Supervising Physician

The supervising physician should maintain the following:

1. Sufficient knowledge of preprocedural workup, patient monitoring equipment, medications and their reversal agents, and postsedation management
2. Appropriate continuing education in accordance with the [ACR Practice Parameter for Continuing Medical Education \(CME\)](#) [3]
3. Current Basic Life Support (BLS) certification. For pediatric sedation, have Pediatric Advanced Life Support (PALS) certification [4]. For adult sedation, have Advanced Cardiac Life Support (ACLS) certification or have an individual with ACLS certification or institutionally approved alternative (e.g., Advanced Radiology Life Support) available with a response time of less than 5 minutes [1].

4. Privileges to perform sedation at their health care institution

B. Health Professional Responsible for Monitoring the Patient

There must be a physician, licensed independent practitioner, or nurse other than the practitioner performing the procedure present to monitor the patient during 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, licensed independent practitioner, or nurse authorized by the facility, whose primary job is to monitor the patient.
2. Be appropriately privileged by the institution
3. Have current certification in ACLS or institutionally approved alternative (e.g., Advanced Radiology Life Support). If children are being sedated, certification in PALS is needed as well
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 and treating associated complications.
6. Meet the credentialing requirements of the facility

V. PATIENT SELECTION

Patients who are ASA class I or II qualify for sedation/analgesia outside the operating room; ie, by personnel other than anesthesiologists (See Appendix A.). Patients who are ASA class III or IV may require additional consideration. When the patient's history and comorbidities, current condition, and expected goals and objectives of sedation, either before or during the procedure, exceed the experience or resources of nonanesthesiology sedation personnel, there should be a low threshold for consultation with an experienced anesthesiologist.

These practice parameters specifically exclude the following:

1. Patients whose sedation is 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.

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.).

Additional risk factors include, but are not limited to, the following:

- Recent catastrophic event, ICU admission, surgery, or interventions
- Sedation or anesthesia within 24 to 48 hours of the planned sedation

- Septicemia
- Polypharmacy and polyintravenous therapy
- Lung disease
- Respiratory impairment
- Cardiovascular disease
- Critical aortic stenosis
- Congestive heart failure
- Congenital heart disease
- Hemodynamic instability
- Neuromuscular and metabolic diseases
- Symptomatic brain stem dysfunction
- Apnea or hypotonia
- Liver failure
- Restricted hepatic and renal clearance
- Symptomatic gastroesophageal reflux or poor gastric emptying

VII. PATIENT EVALUATION AND MANAGEMENT

Sedation as described in this practice parameter should be performed in accordance with ASA guidelines, as described below [1].

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 and provide their assent as appropriate. The requirement for written informed consent should follow facility policies and procedures and state and local laws and regulations.

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 pre sedation 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, capnography (if available), and electrocardiogram (when applicable) should be performed and recorded.
4. For all outpatient procedures, the person responsible for accompanying the patient after discharge and who will be receiving postprocedure instructions must be clearly identified and contact information obtained.

C. Management During Sedation

Qualitative clinical signs such as chest excursion and auscultation of breath sounds are useful. During moderate or deep sedation the adequacy of ventilation should be evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment [5].

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 backup emergency power and an emergency cart, including equipment for intubation and ventilation, should be immediately available.
8. The route, dosage, and time of all sedation and reversal agents 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 (eg, oral, rectal, intramuscular, inhaled), 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. In smaller adults, weight-based dosing may be considered.
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 (eg, 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 (eg, suction, oxygen) are immediately available. A code cart must be 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 presedation levels. 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 intravenous access is used during the procedure it should be maintained until the patient is ready for discharge.
4. 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.)

5. 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.
6. 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, the following:

1. Presedation assessment
2. Dose, route, site, and time of administered drugs must be part of the permanent medical record.
3. Patient's response to medication and the procedure
4. Inspired concentrations of medical gases, such as oxygen and nitrous oxide, their rate and duration, and method of administration
5. Physiological data from monitoring
6. Any rescue interventions, including ventilatory support, or use of reversal agents, and the patient's response
7. Any significant adverse reactions and their management

Reporting should be in accordance with the [ACR–SIR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures](#) [6].

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, as determined by the health care professional responsible for monitoring the patient, and dependent on the patient's destination. Recovery according a standardized scoring system (such as the Aldrete score) should be documented [7,8].

B. When discharge is to home, discharge instructions must be given to the patient or accompanying responsible adult. The discharge instructions should include, but not necessarily be limited to, the following:

1. Physician contact information, including after-hours contact information, in the event of postprocedure problems
2. Advice against driving or operating machinery for a minimum of 12 hours
3. Advice against alcohol intake for 24 hours
4. Advice regarding diet and activity
5. Advice regarding follow-up
6. The patient should be advised of possible sedation-related adverse effects and when to seek medical attention

X. EQUIPMENT

Facility policies for monitoring and evaluating the function of all equipment should be followed. Any location where sedation is administered and recovery from sedation is provided must have equipment and drugs for emergency resuscitation readily available [2]. 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 the following:

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 (eg, an Ambu bag, laryngoscopes, ventilation masks, and endotracheal tubes). A mask capable of delivering 100% oxygen is necessary (eg, a nonrebreather mask).
3. Suction apparatus capable of producing continuous suction at a negative pressure of 150 mm Hg that is regularly checked for adequacy according to facility policies. Suction catheters appropriate for patients' airways 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. Multilead electrocardiographic monitors as appropriate for the patient's medical history
 - d. A means of monitoring ventilation, either visually or through a device
 - e. Capnography (if available)
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 [Practice Advisory on Anesthetic Care for Magnetic Resonance Imaging: An Updated Report by the American Society of Anesthesiologists Task Force on Anesthetic Care for Magnetic Resonance Imaging](#).

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 website (<http://www.acr.org/guidelines>).

A record should be kept for all patients receiving sedation, indicating sedation failure and adverse effects (eg, 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.

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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, the following:

- Previous problems with anesthesia or sedation
- Stridor
- Snoring or apnea
- Dysmorphic facial features (eg, 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

	Solids and Nonclear Liquids**	Clear Liquids
Children <6 months	4 to 6 hr	2 hr
Children 6 to 36 months	6 hr	2 to 4 hr
Children >36 months	6 to 8 hr	2 to 4 hr

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

*Practice parameters and technical 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 practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

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