ACR–SIR PRACTICE PARAMETER FOR MINIMAL AND/OR MODERATE SEDATION/ANALGESIA

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The American College of Radiology will periodically define new practice parameters 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 parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter 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 and approval. The practice parameters 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 parameter and technical standard by those entities not providing these services is not authorized.

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 care[1]. 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 considering 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 variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and 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 purpose of this document is to assist practitioners in achieving this objective.

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[1] *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (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).

The goal of this practice parameter is to assist physicians in the safe administration of sedation/analgesia and the monitoring of patients receiving sedation/analgesia without the participation of an anesthesiologist or a certified registered nurse anesthetist. 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.

This document refers to the guidelines published in 2018, "Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018" [1], a document endorsed by the ACR and SIR as well as other nonanesthesiology specialty societies whose members use moderate sedation and analgesia.

The monitoring practice parameters in this guidance document apply to patients who receive minimal sedation or moderate sedation. Patients receiving a single, low-dose anxiolytic agent under usual circumstances do not necessarily require monitoring [1].

The administration of deep sedation and analgesia requires a greater level of skill and experience and more intensive monitoring than is described herein. 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 Anesthesiologists (ASA) Practice Advisory on Anesthetic Care for Magnetic Resonance Imaging [2].

Sedation is a dynamic continuum ranging from minimal sedation and 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 further states that "although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected" [1].

Moderate sedation and 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 can be aroused by physical or verbal stimulation. Planned levels of sedation or analgesia beyond moderate sedation are outside the scope of this document.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Core Privileging: This procedure is considered part of or amendable to image-guided core privileging.

Sedation and analgesia may be administered by a physician, 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, including at least one individual in the procedure room with the knowledge and skills to recognize and treat airway complications.

A. Supervising Physician

The supervising physician should maintain the following:

1. Sufficient knowledge of preprocedural workup, patient monitoring equipment, airway management, sedation 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 certification. For pediatric sedation, personnel certified in Pediatric Advanced Life Support (PALS) should be present [4]. For adult sedation, personnel certified in Advanced Cardiac Life Support (ACLS) or an institutionally approved alternative (eg, Advanced Radiology Life Support) must be in the room or immediately available [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 throughout the period of sedation and analgesia. This individual must not be a member of the procedure team [1]. This individual may administer the medications used for sedation and analgesia and may assist with minor, interruptible tasks during the

procedure if the patient's level of sedation and analgesia is appropriate and vital signs are stable [1].

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 an institutionally approved alternative (eg, 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 capnography when appropriate, and cardiac monitoring, including recognizing apnea, airway obstruction, and cardiac dysrhythmias, and treating associated complications
6. In addition to recognizing and treating adverse events, professionals should be able to identify and escalate the need for advanced care, involving other teams in accordance with institutional protocols
7. Meet the credentialing requirements of the facility

III. PATIENT SELECTION

Patients who are ASA class I or II qualify for sedation and analgesia outside the operating room, that is, by personnel other than anesthesiologists [5] . Patients who are ASA class III or IV may require additional consideration. Similarly, the Mallampati score is a simple test that can be a good predictor of sleep apnea and difficulty with bag-mask ventilation and intubation, should it be necessary. In addition, patients with Mallampati Class III or IV should be given additional consideration [5]. 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 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 be sedated by anesthesiologists

IV. RISK FACTORS

All patients referred for sedation should be appropriately screened by a physician, registered nurse, nurse practitioner, registered radiologist assistant (RRA), physician 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 should be considered.

Positive-pressure ventilation, with or without endotracheal intubation, may be necessary if respiratory compromise develops during sedation and analgesia. This may be more difficult in patients with an airway abnormality, which may increase the likelihood of airway obstruction during spontaneous ventilation [5].

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

- Adverse experience with sedation or analgesia, as well as regional or general anesthesia
- Respiratory impairment
- Critical aortic stenosis
- Hemodynamic instability
- Neuromuscular and metabolic diseases
- Symptomatic brain stem dysfunction
- Apnea or hypotonia
- Sleep apnea or snoring

- Facial deformity or airway defect (birth defect or from trauma), which would be difficult for bag valve mask resuscitation or intubation
- Liver failure
- Restricted hepatic and renal clearance
- Symptomatic gastroesophageal reflux or poor gastric emptying
- Head and neck tumors compromising the airway
- Prolonged prior intubation or tracheostomy with risk of tracheal stenosis
- Achalasia or prominent hiatal hernia
- Impaired protective airway reflexes

V. 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 and 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 as well as state and local laws and regulations.

A. Patient Preparation Before Sedation

Hospital guidelines for preprocedural fasting should be followed [1].

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. This should include evaluation and documentation of ASA and Mallampati score. It should include the patient's previous experience with sedation and analgesia, current medical problems, current medications, drug allergies, history of a difficult airway, frequent or repeated exposure to sedation and analgesic agents, any significant comorbidities, and pregnancy, as appropriate. A physician or advanced practice provider should perform the presedation evaluation.
3. Prior to initiating sedation, an assessment of recent oral intake [1] , 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. A responsible adult must accompany outpatients after discharge. This adult will provide contact information and receive clear postprocedure instructions including methods by which to contact medical personnel if needed.

C. Management During Sedation

1. Qualitative clinical signs, such as chest excursion, should be monitored.
2. During moderate 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's clinical status, procedure, or equipment [2].
3. Intravenous access must be maintained.
4. Normothermia should be preserved.
5. Patients should be protected from pressure-related and position-related injuries.
6. 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, capnography (if available), blood pressure (as indicated), heart rate, and cardiac rhythm. The types of measurements taken

should comply with facility policies. Capnography should be used in accordance with institutional policies and guidelines. Its ability to detect hypoventilation early makes it a valuable tool for monitoring patient safety during procedures requiring sedation.
7. Supplemental oxygen with size-appropriate equipment.
8. Suction equipment.
9. Defibrillator with backup emergency power and an emergency cart, including equipment for intubation and ventilation.
10. 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.
11. Drug antagonists and intravenous fluids.
12. For pediatric patients, intravenous sedative and analgesic drugs should be given based on the patient's body weight in incremental doses that are titrated to the desired end points 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 assess each dose's effect 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.
13. In adult patients, intravenous sedative and analgesic drugs are given in incremental doses that are titrated to the desired endpoints of sedation or analgesia. For smaller adults, weight-based dosing may be considered.
14. Combinations of sedative and analgesic agents should be administered as appropriate for the procedure being performed and the patient's medical condition. 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 combination 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 also 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 and the patient meets established discharge criteria. A patient may not leave the recovery area without accompanying monitoring personnel until vital signs and level of consciousness are acceptable 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 the 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 the successful rescue, and repeated doses may be required).
5. The monitoring personnel will notify a supervising physician (who should remain immediately available within the facility 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.

VI. SEDATION-RELATED DOCUMENTATION

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

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, including ASA criteria and airway assessment (such as Mallampati score) and pregnancy
2. Preprocedure timeout documentation
3. Dose, route, site, and time of drug administration must be part of the permanent medical record
4. Patient's response to medication and the procedure
5. Inspired concentrations of medical gases (eg, oxygen, nitrous oxide) and their rate, duration, and method of administration
6. Physiological data from monitoring
7. Any rescue interventions, including ventilatory support, or use of reversal agents as well as the patient's response
8. Any significant adverse reactions and their management

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.

VII. DISCHARGE CRITERIA

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 to a standardized scoring system (such as the Aldrete score) should be documented [7, 8].

For outpatients, 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, for postprocedure adverse events
2. Advise against driving or operating machinery for a minimum of 12 hours
3. Advise against alcohol intake for 24 hours
4. Advice regarding appropriate diet and activity
5. Advice regarding follow-up instructions
6. Advice regarding sedation-related adverse effects and when to seek medical attention
7. Instructions regarding preexisting and/or new medications

VIII. 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 emergency and monitoring equipment be available in the immediate area for all ages and sizes of patients treated at the facility. The equipment may be in a code cart and 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, oral airways, and resuscitation equipment (eg, manual resuscitator, laryngoscopes, ventilation masks, and endotracheal tubes). A mask capable of delivering 100% oxygen (eg, a nonrebreather mask) is necessary.

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 regularly according to facility policies. Equipment checks should be documented in accordance with facility policies.

5. Monitors
   a. Pulse oximeter with both visual and audible outputs and probes appropriate for the patient's size
   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 supply (or battery backup) for all electrical equipment listed above

For sedation performed in the MRI 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 [2].

IX. 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 *ACR Position Statement on Quality Control and Improvement, Safety, Infection Control, and Patient Education* on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

ACKNOWLEDGEMENTS

This practice parameter was revised according to the process described under the heading *The Process for Developing ACR Practice Parameters and Technical Standards* on the ACR website (https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards) by the Committee on Practice Parameters – Interventional and Cardiovascular Radiology of the ACR Commission on Interventional and Cardiovascular Radiology in collaboration with the SIR.

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*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.

Development Chronology for this Practice Parameter
1995 (Resolution 13)
Revised 2000 (Resolution 17)
Revised 2005 (Resolution 43)
Revised 2010 (Resolution 45)

Amended 2014 (Resolution 39)
Revised 2025 (Resolution 22)
Revised 2015 (Resolution 23)
Amended 2018 (Resolution 44)
Revised 2020 (Resolution 39)
Amended 2023 (Resolution 2c)
Revised 2025 (Resolution 22)