North Dakota Board of Dental Examiners

PO Box 7246
Bismarck, ND 58507-7246

ANESTHESIA ON-SITE INSPECTION AND EVALUATION FORM
Minimal Sedation - Enteral and/or Combination Inhalation-Enteral

Rev. 04/16/2019

MINIMAL SEDATION – a minimally depressed level of consciousness, produced by a pharmacological method that retains the patient's ability to independently and continuously maintain an airway and respond *normally* to tactile stimulation and verbal command. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected. Nitrous oxide/oxygen may be used in combination with a single enteral drug in minimal sedation. **If more than one enteral drug is administered to achieve the desired sedation effect, with or without the concomitant use of nitrous oxide, the guidelines for moderate sedation must apply.**

The drug(s) and/or techniques used should carry a margin of safety wide enough never to render unintended loss of consciousness. Further, patients whose only response is reflex withdrawal from repeated painful stimuli would not be considered to be in a state of minimal sedation. The use of the MRD to guide dosing for minimal sedation is intended to create a margin of safety.

The following definitions apply to administration of minimal sedation:
Maximum recommended dose (MRD) – maximum FDA-recommended dose of a drug, as printed in FDA-approved labeling for unmonitored home use.
Dosing for minimal sedation via the enteral route – minimal sedation may be achieved by the administration ofa a drug, either singly or in divided doses, by the enteral route to achieve the desired clinical effect, not to exceed the MRD.

Evaluator completes pages 1 – 7 on the day of the site evaluation. Applicant returns entire form at least two evaluator 2 weeks prior to site evaluation.

PRINT EVALUATOR(S) NAME			
SITE ADDRESS			
NAME OF PRACTIONER EVALUATED		Email:	
IS THIS A SATELLITE LOCATION Does the practitioner utilize a satellite location?	☐ YES ☐ YES	☐ NO ☐ NO	Location:
ND DENTAL LICENSE NUMBER		DEA NUMBER	
DATE OF EVALUATION			
TIME FRAME OF EVALUATION	START:	COMPLETED BY:	
INITIAL ON-SITE EVALUATION ☐	RE-EVALUATION ☐	RENEWAL ☐	

ON-SITE EVALUATION: All providers of minimal sedation (D) are required to have an evaluation at the location(s) where sedation or anesthesia services are rendered. The purpose of the evaluations is to assess the patient's anesthetic risk and assess a sites ability to provide emergency care; therefore, the site evaluation emphasizes recognition and management of emergencies and complications associated with office administration of sedation (Be prepared to discuss pages 4-6). The fee of $550 plus $0.58 per mile must be paid directly to the board designated site evaluator at the time of the evaluation. The site evaluation fee is for one site and one dentist. If you list more than one facility, a separate evaluation form must be submitted.

INITIAL INSPECTION - An initial inspection must be completed within 60 days of the approval of the initial permit application. It is the applicant's responsibility to schedule office evaluations with the Board's designated anesthesia evaluator (page 8).

RE-EVALUATION: The Anesthesia Committee requires site evaluations within 5 years of the previous evaluation. *It is the Anesthesia Committee's prerogative to suspend privileges if the permit holder's site evaluation is overdue.*

RENEWAL – Both the sedation certificate and the inspection are subject to expiration and renewal. All sedation dentists must have inspections completed once every 5 years following their first inspection date.

NON RENEWAL of PERMIT: Late renewals (postmarked after December 31 of odd numbered years) result in the permit expiring, and require the dentist to suspend sedation services until a reinstatement is completed and formally approved by the Board's Anesthesia Committee.

CRNA's or OTHER QUALIFIED PROVIDERS - Administration of minimal sedation by another qualified dentist or independently practicing anesthesia healthcare provider requires the operating dentist and his/her clinical staff maintain current certification in Basic Life Support for Healthcare Providers. **Each** d**entist utilizing an anesthesia healthcare provider and the sedation provider must be present during the site evaluation.**

SATELLITE OFFICE: All offices where sedation is performed must comply with the minimum standards established by the Board for a sedation practice. Anesthesia or sedation permit holders providing services at satellite clinics are responsible for ensuring that each office location has been evaluated and that auxiliary assisting with sedation are properly trained and authorized to monitor sedated patients.

SITE EVALUATION:

The inspection consists of six parts:

1. Review of the office equipment, records, and emergency medications
2. Simulated emergencies
3. Discussion period: Familiarity with agents, equipment, emergency situations i.e. laryngospasm
4. Surgical/anesthetic techniques review; two anesthesia procedures may be observed.
5 Coordinate procedures accordingly
6. Review of documentation

A. QUALIFIED PERSONNEL: ATTACH A LIST OF AUXILIARY WHO HAVE DIRECT CONTACT WITH SEDATION PATIENTS. PROVIDE COPIES OF AUXILIARY CREDENTIALS. (RDA, RN, CRNA etc., and ACLS, BLS)

1. Provide evidence of doctors' ACLS/PALS or BLS for Healthcare Providers certification.
2. Provide evaluator evidence and dates of:
   - ❑ Successful completion of a **moderate enteral sedation** course as outlined by the **ADA's *Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students***. *Submit evidence of course completion and documentation of 20 managed clinically-oriented experiences 10 of which are live patient clinical experiences.*
     Name of Course _____
     Date of Completion _____/_____/_____
     or;
   - ❑ Successfully completed training to the level of competency in Enteral and/or Combination Inhalation-Enteral Minimal Sedation consistent with that prescribed in the *ADA's* ***Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students***. Initial applicants: *Submit evidence of course completion and documentation of 20 managed clinically-oriented experiences 10 of which are live patient clinical experiences.*
     Name of Course _____
     Date of completion _____/_____/_____
3. Evidence of staff credentials:
   - ❑ Provide photo copy of assisting staff's Board certificate of registration, credentials, training, and current

BLS. A qualified dentist inducing minimum sedation must have at least one additional individual trained in BLS present during the administration of minimal sedation.

B. RECORDS The site evaluator will review random records of patients for whom anesthesia or sedation services were provided. The evaluator will review preoperative, intraoperative, and postoperative anesthesia assessment and monitoring records. Health history of random patients who have been treated in your facility will also be reviewed. Treatment of medically compromised patients will be a point of discussion. The evaluator will check for:

1. RECORDS PRE OPERATIVE

Discuss the following:

- ❑ Health history form adequate
- ❑ Informed consent adequate
- ❑ Pre-operative evaluation procedures, including health standards for sedation cases & documentation of pre-operative evaluation (i.e., baseline vital signs, ASA classifications).
- ❑ Pre-anesthesia instructions given to patients are adequate.
- ❑ Health and physical focused evaluation adequate?

2. RECORDS INTRA OPERATIVE

- ❑ Describe your sedation procedures, discuss and make available all drugs and describe dosages used, average or typical duration, monitoring techniques (i.e., BP, pulse oximeter), maintenance techniques (i.e. supplemental oxygen), personnel utilized, equipment utilized, and types of procedures performed.

3. POST-OPERATIVE and RECOVERY

A dentist, or at the dentist's direction, an appropriately trained individual, must remain in the operatory during active dental treatment to monitor the patient continuously until the patient meets the criteria for discharge to the recovery area. The appropriately trained individual must be familiar with monitoring techniques and equipment. Monitoring must include oxygenation, ventilation, and circulation.

- ❑ Post anesthetic recovery care and monitoring including an explanation of standards for discharge and what follow-up if any, is made satisfactory?
- ❑ Provided post-operative instructions given to patient (or a person caring for the patient)?

C. RECOVERY AREA (recovery area can be the operatory)		
Does recovery area have available oxygen? And ambu bag?	YES	NO
Does recovery area have available adequate suction?	YES	NO
Does recovery area have adequate lighting?	YES	NO
Does recovery area have available adequate electrical outlets?	YES	NO
Can the patient be observed by a member of the staff at all times during the recovery period?	YES	NO

D. OFFICE FACILITY AND REQUIRED EQUIPMENT

- ❑ Source of oxygen and equipment to deliver positive pressure ventilation
- ❑ Respiratory Support Equipment
  - ➢ Oral airway/nasal airway
  - ➢ Laryngoscope (McGill forceps or other suitable instruments)
  - ➢ Endotracheal tubes (adult and children)
  - ➢ Full face mask
  - ➢ LMA
- ❑ Stethoscope
- ❑ Blood pressure cuff (manual or automatic) and stethoscope
- ❑ Defibrillator (manual or automatic) AED
- ❑ Equipment to establish intravenous infusion
- ❑ Pulse oximeter
- ❑ Back-up suction and lighting equipment (non-AC powered)
- ❑ Body temperature measuring device

OVERALL SEDATION EQUIPMENT & FACILITY

☐ **ADEQUATE** ☐ **INADEQUATE** **COMMENT:**

E. EMERGENCY MANAGEMENT & EMERGENCY SCENARIOS

Respiratory anesthetic emergencies are the most common complications encountered during the administration of anesthesia in both the adult and pediatric patient. Regardless of the depth of anesthesia, a comprehensive review of the patients past and present medical history, NPO status, anesthesia history and physical examination, is critical and represents a degree of prudence therefore sedation providers must be able to:

- ❑ Discuss contraindications for enteral and/or combination inhalation-enteral minimal sedation.
- ❑ Discuss prevention, recognition, and management of complications.
- ❑ Describe your emergency protocol and explain what responsibilities your staff members have.
- ❑ Briefly describe your training that relates to the handling of anesthesia related emergencies.

  Do you regularly schedule "mock" code or emergency drills? ☐ Yes ☐ No If yes, how often?
- ❑ Describe your emergency kit. What does it contain? What criterion do you have for its use?
- ❑ Describe your method of keeping contents of emergency drugs and contents current.

Emergency Scenarios — Complete protocols for all scenarios. The DDS/DMD and his/her clinical team must indicate competency (by demonstration or discussion) in treating the following emergencies. If any areas of the mock emergency scenarios need immediate correction, then the CRNA must keep a record of the systems' failures and write a plan to amend the staff protocol. A second mock drill should be conducted and subsequently evaluated.

*** Reminder: Clinical staff involved in the delivery of sedation dental services must be BLS certified ***

RESPIRATORY		
Bronchospasm	☐ Satisfactory	☐ Unsatisfactory
-problem recognition -bronchial dilators -positive pressure oxygen & airway maintenance		
Respiratory Complications	☐ Satisfactory	☐ Unsatisfactory
-hyperventilation -problem recognition & monitoring -proper patient position -oxygen with respiratory support -narcotic antagonist when appropriate -apnea -foreign body obstruction		
Laryngospasm	☐ Satisfactory	☐ Unsatisfactory
-problem recognition -stop procedure & pack off bleeding -evaluation of head position & upper airway -suction -positive pressure oxygen with a full face mask -use of Anectine & appropriate dosage of Anectine -airway maintenance		

Vomiting/Aspiration	☐ Satisfactory	☐ Unsatisfactory

-problem recognition & proper patient positioning
-removal of foreign bodies & adequate suction
-secure & evaluate adequacy of airway
-positive pressure oxygen
-tracheal intubation when necessary
-recognition of complication of associated
-bronchospasm
-activate EMS

NEUROLOGICAL

Convulsion/Seizures	☐ Satisfactory	☐ Unsatisfactory

-problem recognition & etiology
-patient position & supportive measures
-anticonvulsant drug therapy

ALLERGY

Allergic Reaction	☐ Satisfactory	☐ Unsatisfactory

Minor & Anaphylactic
Immediate & Delayed
-Epinephrine
-vasopressors
-bronchodilators
-antihistamines
-corticosteroids

CARDIOVASCULAR

Syncope	☐ Satisfactory	☐ Unsatisfactory

-problem recognition
-patient position
-oxygen
-drug therapy

Hypotension/Hypertension	☐ Satisfactory	☐ Unsatisfactory

-problem recognition; preoperative pulse & blood pressure
-patient position
-oxygen
-continuous monitoring & recording
-drug therapy

Angina Pectoris (chest pain)	☐ Satisfactory	☐ Unsatisfactory

-problem recognition & differential diagnosis
-patient position & supportive measures
-oxygen
-monitoring
-drug therapy, Nitroglycerine & Amyl Nitrate
-transfer when indicated

Bradycardia	☐ Satisfactory	☐ Unsatisfactory

-problem recognition & differentiation of hemo- dynamically significant bradycardia
-monitor & record keeping
-oxygen
-drug therapy, Atropine

Cardiac Arrest	☐ Satisfactory	☐ Unsatisfactory

-Problem recognition & differential diagnosis
BLS and/or -ACLS/PALS to the extent the facility is capable
-activation of EMS

Myocardial Infarction	☐ Satisfactory ☐ Unsatisfactory
-problem recognition of differential diagnosis -oxygen -patient positioning -pain relief -monitoring & record keeping -activation of EMS	
ENDOCRINE	
Hypoglycemia	☐ Satisfactory ☐ Unsatisfactory
-problem recognition & diagnosis -office testing available -oral and/or IV drug therapy	
DRUG OVERDOSE	
Local Anesthetic Overdose	☐ Satisfactory ☐ Unsatisfactory
Sedative Drug Overdose	☐ Satisfactory ☐ Unsatisfactory
-Benzodiazapine overdose i.e., valium vs. narcotic i.e., medazolam	
STROKE	
Cerebrovascular Accident	☐ Satisfactory ☐ Unsatisfactory

F. Sedation Medications

- ☐ **Securely Stored – Is drug cabinet secured to wall or floor?**
- ☐ **Loss prevention of medications is practiced**

Provide evaluator with the drug log. Name(s) of individual responsible for drug log? Describe and demonstrate how/where sedation medications are securely stored, list office staff that has access, and documentation for release of drugs. What steps are taken toward loss prevention of medications? Method of wasting expired drugs?

_____
_____
_____
_____
_____

G. SUGGESTED DRUGS [and expiration dates]

- ❑ Intravenous fluids
  - ➢ Water for injections and/or mixing or dilution of drugs
  - ➢ Intravenous fluids
- ❑ Cardiotonic drugs
- ❑ Vasopressors
- ❑ Anti-arrhythmic agents
- ❑ Antihypertensive agents (immediate)
- ❑ Antagonist (reversal drugs)
- ❑ Accessory drugs (e.g., Isuprel, Phernergan, Atropine, Benadryl)

H. WRITTEN DOCUMENTATION

- ❑ Acceptable written protocols and/or standards of care for managing complications/emergencies [Review the AAOMS 8th Edition Office Anesthesia Evaluation Manual]
- ❑ Time-oriented anesthetic record

I. INFECTION CONTROL - Evaluator will inspect and assess sterilization area and any area sterilized instruments are stored.

Is spore testing completed and logged weekly? Is a functional OSHA compliant eye wash station readily available? ☐ YES ☐ NO

Sterilized packages are not damaged, wet or opened? ☐ YES ☐ NO

Instruments are individually bagged and dated? ☐ YES ☐ NO

Sterilization bags are free from tears, punctures? ☐ YES ☐ NO

Per CDC guidelines a chemical indicator is included in each pouch? ☐ YES ☐ NO
(Some pouches come printed with an external and internal chemical indicator. If the internal indicator is a multi-parameter chemical indicator, there is no need to add a separate indicator strip inside.)

Evaluator recommendations/comments
Deficiencies

Evaluation was satisfactory with no deficiencies _____
Evaluator Initial

OR

I recommend a re-evaluation in 6 months; the site evaluation was incomplete. _____
Evaluator Initial

EVALUATOR USE ONLY: Evaluator Reimbursed $_____

Evaluator Signature _____ Date _____

Site evaluator must submit signed and completed form to:
Rita Sommers, NDBDE Executive Director
1418 Cook Drive
Minot, ND 58701

The site evaluator's contact information for NDBDE moderate and minimal sedation:

Kellie Pierce, CRNA
4012 Edgewater Place
Mandan, ND 58554
piercecrna@aol.com

Applicant: Mail pages 1-10 to the site evaluator at least two weeks prior to your scheduled site evaluation. Review and fill out information on pages 8-10. Do not complete pages 1-7.

APPLICANT NAME: _____ *ND DENTAL LICENSE NUMBER* _____

ADDRESS OF FACILITY WHERE SEDATION SERVICES ARE PROVIDED:

_____

_____ *PHONE:* _____

MAIL a copy of your:

- ❑ Medical history
- ❑ Informed consent
- ❑ A blank sedation monitoring form
- ❑ Pre anesth/sedation instructions
- ❑ Post care instructions
- ❑ Credentials, staff credentials

Enteral and/or Combination Inhalation-Enteral Minimal Sedation

A. Enteral and/or Combination Inhalation-Enteral Minimal Sedation Course Objectives: Upon completion of a competency course in enteral and/or combination inhalation-enteral minimal sedation techniques, the dentist must be able to:

1. Describe the basic components of inhalation sedation equipment.
2. Discuss the function of each of these components.
3. List and discuss the advantages and disadvantages of enteral and/or combination inhalation-enteral minimal sedation (combined minimal sedation).
4. List and discuss the indications and contraindications for the use of enteral and/or combination inhalation-enteral minimal sedation (combined minimal sedation).
5. List the complications associated with enteral and/or combination inhalation-enteral minimal sedation (combined minimal sedation).
6. Discuss the prevention, recognition and management of these complications.
7. Administer enteral and/or combination inhalation-enteral minimal sedation (combined minimal sedation) to patients in a clinical setting in a safe and effective manner.
8. Discuss the abuse potential, occupational hazards and other effects of enteral and inhalation agents.
9. Discuss the pharmacology of the enteral and inhalation drugs selected for administration.
10. Discuss the precautions, contraindications and adverse reactions associated with the enteral and inhalation drugs selected.
11. Describe a protocol for management of emergencies in the dental office and list and discuss the emergency drugs and equipment required for management of life-threatening situations.
12. Demonstrate the ability to manage life-threatening emergency situations, including current certification in Basic Life Support for Healthcare Providers.
13. Discuss the pharmacological effects of combined drug therapy, their implications and their management. Nitrous oxide/oxygen when used in combination with sedative agent(s) may produce minimal, moderate, deep sedation or general anesthesia.
14. Define the criteria for DDS dismissing himself from recovering patient.
15. Discuss qualifications for staff that attends recovering patient.
16. Review and discuss pre-op assessment and form, discuss w/ evaluator
17. What is the max rec dose of_____? How soon can you re-dose?
18. What is clinical affective ½ life of _____? What is the ½ life of _____?

19. Discuss the scenario:
    Patient cardiac arrests your 1st steps would be_____
    Patient respiratory arrests your first response would be_____
    Patient is in chair and complains of chest pain. You_____
20. Discuss the health and physical/ what is patient assessment?
21. Describe how you would classify airway.
22. Describe your discharge criterion.
23. Address your staff meetings: Do you discuss IF control, CPR, emergency protocols.
24. Identify signs and symptoms of local toxicity.
25. Who provides your pre anesthetic instructions?

PROVIDE A LIST OF ALL LOCAL ANESTHETICS USED IN THIS FACILITY

_____
_____

LIST ALL SEDATION DRUGS YOUR PRACTICES USES

_____
_____
_____

LIST ANY SEDATION DRUGS YOUR PRACTICE PERSCRIBES TO PATIENTS PRIOR TO THE PROCEDURE AND PRIOR TO THE DAY OF THE PROCEDURE

_____
_____
_____

LIST ALL RESCUE DRUGS THAT YOUR PRACTICE HAS ON SITE

_____
_____
_____

EQUIPMENT AND BRAND

1. **BP Non invasive BP monitor**
   a. _____
   b. _____
2. **ECG**
   a. __ _____
   b. _____
3. **Defibrillator/Automated External Defibrillator**
   a. _____
   b. _____
4. **Pulse Oximeter**
   a. _____
   b. _____
5. **How are respiratory gases monitored? Capnography? or list other:**
   a. _____ _____
   b. _____

ADA CLINICAL GUIDELINES –DISCUSSION POINTS

1. Patient Evaluation

Patients considered for minimal sedation must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II) this may consist of a review of their current medical history and medication use. However, patients with significant medical considerations (ASA III, IV) may require consultation with their primary care physician or consulting medical specialist.

2. Pre-Operative Preparation

- The patient, parent, guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative agents and informed consent for the proposed sedation must be obtained.
- Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.
- Baseline vital signs must be obtained unless the patient's behavior prohibits such determination.
- A focused physical evaluation must be performed as deemed appropriate.
- Preoperative dietary restrictions must be considered based on the sedative technique prescribed.
- Pre-operative verbal and written instructions must be given to the patient, parent, escort, guardian or care giver

3. Personnel and Equipment Requirements

Personnel:

- At least one additional person trained in Basic Life Support for Healthcare Providers must be present in addition to the dentist.

Equipment:

- A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.
- When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either
  (1) a functioning device that prohibits the delivery of less than 30% oxygen or
  (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.
- An appropriate scavenging system must be available if gases other than oxygen or air are used.

4. Monitoring and Documentation

Monitoring: a dentist, or at the dentist's direction, an **appropriately trained individual**, must **remain In the operatory during active dental treatment to monitor the patient continuously** until the patient meets the criteria for discharge to the recovery area. The appropriately trained individual must be familiar with monitoring techniques and equipment. Monitoring must include:

Oxygenation:

- Color of mucosa, skin or blood must be evaluated continually.
- Oxygen saturation by pulse oximetry may be clinically useful and should be considered/evaluated.

Ventilation:

- The dentist and/or appropriately trained individual must observe chest excursions continually.
- The dentist/and/or appropriately trained individual must verify respirations continually.

Circulation:

- Blood pressure and heart rate should be evaluated pre-operatively, post-operatively and intraoperatively as necessary (unless the patient is unable to tolerate such monitoring).

Documentation:

- An appropriate sedative record must be maintained, including the names of all drugs administered, including local anesthetics, dosages, and monitored physiological parameters.

5. Recovery and Discharge

- Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
- The qualified dentist or **appropriately trained clinical staff must monitor the patient during recovery** until the patient is ready for discharge by the dentist.
- The qualified dentist must determine and document that level of consciousness, oxygenation, ventilation and circulation are satisfactory prior to discharge.
- Post-operative **verbal and written instructions** must be given to the patient, parent, escort, guardian or care giver.

6. Emergency Management - If a patient enters a deeper level of sedation than the dentist is qualified to provide, the dentist must stop the dental procedure until the patient returns to the intended level of sedation. The qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of minimal sedation and providing the equipment and protocols for patient rescue.

7. Management of Children - For children 12 years of age and under; American Academy of Pediatrics/American Academy of Pediatric Dentistry Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.