21 NCAC 16Q.0101 GENERAL ANESTHESIA AND SEDATION DEFINITIONS

For the purpose of these Rules relative to the administration of general anesthesia, parenteral minimal conscious sedation, and enteral moderate conscious sedation moderate pediatric conscious sedation or general anesthesia by or under the direction of a dentist, the following definitions shall apply:

1. “Analgesia” – the diminution or elimination of pain.
2. “Anti-anxiety sedative” – a sedative agent administered in a dosage intended to reduce anxiety without diminishing consciousness or protective reflexes.
3. “Anxiolysis” – pharmacological reduction of anxiety through the administration of a minor psychosedative, to children or adults prior to commencement of treatment on the morning of the appointment which allows for uninterrupted interactive ability in a totally awake patient with no compromise in the ability to maintain a patent airway continuously and without assistance.
4. “Behavioral management” – the use of pharmacological or psychological techniques, singly or in combination, to modify behavior to a level that dental treatment can be performed effectively and efficiently.
5. “Competent” – displaying special skill or knowledge derived from training and experience.
6. “Conscious sedation” - an induced state of a depressed level of consciousness that retains the patient’s ability to independently and continuously maintain an airway and respond appropriately to physical stimulation and verbal command, and that is produced by pharmacologic or non-pharmacologic agents, or a combination thereof. In accordance with this particular definition, the drugs or techniques used shall carry a margin of safety wide enough to render unintended loss of consciousness unlikely.
7. “Deep sedation” – an induced state of a depressed level of consciousness accompanied by partial loss of protective reflexes, including the ability to continually maintain an airway independently or respond purposefully to verbal command, and is produced by pharmacological agents.
8. “Direct supervision” – the dentist responsible for the sedation/anesthesia procedure shall be physically present in the facility and shall be continuously aware of the patient’s physical status and well being.
9. “Enteral conscious sedation” is conscious sedation that is achieved by administration of pharmacological agents through the alimentary tract either orally or rectally. Enteral conscious sedation is administered primarily for behavioral management.
10. “Facility” – the location where a permit holder practices dentistry and provides anesthesia/sedation services.
(10) “Facility inspection” - an on-site inspection to determine if a facility where the applicant proposes to provide anesthesia/sedation is supplied, equipped, staffed and maintained in a condition to support provision of anesthesia/sedation services that meet the minimum standard of care.

(11) “General anesthesia” — is the intended controlled state of depressed consciousness produced by pharmacologic agents and accompanied by a partial or complete loss of protective reflexes, including the ability to maintain an airway and respond purposefully to physical stimulation or verbal commands.

(12) “Immediately available” – on-site in the facility and available for immediate use.

(13) “Local anesthesia” – the elimination of sensations, especially pain, in one part of the body by the regional application or injection of a drug.

(14) “May” – indicates freedom or liberty to follow a reasonable alternative.

(15) “Minimal conscious sedation” – conscious sedation provided to patients 13 years or older, by oral or rectal routes of administration of a single pharmacological agent, in one or more doses, not to exceed the manufacturer’s maximum recommended dose, at the time of treatment, possibly in combination with nitrous oxide. Minimal conscious sedation is provided for behavioral management.

(16) “Minor psychosedative/Minor tranquilizer” – pharmacological agents which allow for uninterrupted interactive ability in a patient with no compromise in the ability to maintain a patent airway continuously and without assistance and carry a margin of safety wide enough to render unintended loss of consciousness unlikely.

(17) “Moderate conscious sedation” – conscious sedation provided to patients 13 years or older, by oral, nasal, rectal or parenteral routes of administration of multiple pharmacological agents, in multiple doses, within a 24 hour period, including the time of treatment, possibly in combination with nitrous oxide. Moderate conscious sedation is provided for behavior control.

(18) “Moderate pediatric conscious sedation” – conscious sedation provided to patients under 13 years of age, by oral, nasal, rectal or parenteral routes of administration of single or multiple pharmacological agents, in single or multiple doses, within a 24 hour period, including the time of treatment, possibly in combination with nitrous oxide. Moderate pediatric conscious sedation is provided for behavior control.

(19) “Must” or “shall” – indicates an imperative need or duty or both; an essential or indispensable item; mandatory.

(20) “Parenteral conscious sedation” – conscious sedation achieved by -- the administration of pharmacological agents intravenously, intramuscularly, subcutaneously, submucosally, intranasally, or transdermally. Parenteral conscious sedation is administered primarily for behavioral management.
“Protective reflexes” – includes the ability to swallow and cough.

“Supplemental dosing” – the oral administration of a pharmacological agent that results in an enhanced level of conscious sedation when added to the primary sedative agent that is administered for the purpose of oral moderate conscious sedation, and which, when added to the primary agent, does not exceed the maximum safe dose of either agent, separately or synergistically.

“Vested adult” – a responsible adult who is the legal parent or guardian, or designee of a legal parent or guardian, entrusted with the care of a minor following the administration of general anesthesia or conscious sedation.

History Note: Statutory authority G.S. 90-28; 90-30.1;
Eff. February 1, 1990;
Temporary Amendment Eff. December 11, 2002;
21 NCAC 16Q .0301 is proposed for amendment as follows:

21 NCAC 16Q .0301 MODERATE PARENTERAL CONSCIOUS SEDATION AND
MODERATE CONSCIOUS PEDIATRIC CONSCIOUS SEDATION CREDENTIALS AND
PERMIT
(a) Before a dentist licensed to practice in North Carolina may administer, or supervise a certified
registered nurse anesthetist (CRNA) to administer parenteral moderate conscious sedation to dental patients
on an outpatient basis, the dentist shall obtain a permit from the Board by completing submitting the
required information on an application form provided by the Board and paying a fee of fifty dollars
($50.00). Such permit shall be renewed annually and shall be displayed with the current renewal at all
times in a conspicuous place in the facility of the permit holder.
(b) For a dentist to employ a certified registered nurse anesthetist to administer moderate conscious
sedation or moderate pediatric conscious sedation, the dentist must demonstrate through the permitting
process that he/she is capable of performing all duties and procedures to be delegated to the CRNA, and
must not delegate said CRNA to perform procedures outside of the scope of the technique and purpose of
moderate conscious sedation or moderate pediatric conscious sedation, as defined in .0101 of this
Subchapter.
(c) A dentist may modify his/her moderate conscious sedation permit to include the privilege of moderate
pediatric conscious sedation by completing a pediatric degree or pediatric residency program or obtaining
the equivalent hours of continuing education program in pediatric anesthesia. If said qualifications are
satisfied, it shall be so designated on the dentist’s moderate conscious sedation permit and will be subject to
the renewal requirements stated in .0501(d) of this Subchapter.
(d) A dentist applying for a permit to administer parenteral moderate conscious sedation or moderate
pediatric conscious sedation must meet at least one of the following criteria:
(1) Satisfactory completion of a minimum of 60 hours of didactic training and instruction in
intravenous conscious sedation and satisfactory management of a minimum of 10
patients, under supervision, using intravenous sedation; or
(2) Satisfactory completion of an undergraduate or postgraduate program which included
intravenous conscious sedation training equivalent to that defined in Subparagraph (d)(b)
(1) of this Rule; or
(3) Satisfactory completion of an internship or residency which included intravenous
conscious sedation training equivalent to that defined in Subparagraph (d)(b)(1) of this
Rule; or
(4) Utilization of a certified registered nurse anesthetist under his supervision to administer
intravenous sedation to dental patients, provided that the parenteral conscious sedation is
administered only by the certified registered nurse anesthetist under the permit holder’s
supervision.
To be eligible for a moderate parenteral conscious sedation permit, a dentist must operate within a facility which includes the capability of delivering positive pressure oxygen, staffed with supervised auxiliary personnel for each procedure performed who shall document annual, successful completion of basic life support (BSL) training and be capable of assisting with procedures, problems and emergencies incident thereto.

The Board may authorize the use of parenteral conscious sedation and grant a permit authorizing the use of parenteral conscious sedation to a dentist who has been utilizing parenteral conscious sedation in a competent and effective manner for the past five years preceding the effective date of this Rule, but who has not had the benefit of formal training as outlined in Paragraph (b) of this Rule, provided that said dentist meets all other requirements of this Rule.

Prior to issuance of a parenteral moderate conscious sedation permit the applicant shall undergo an evaluation which includes a facility inspection. The Board shall direct an evaluator to perform this evaluation. The applicant shall be notified in writing that an evaluation and facility inspection is required and provided with the name of the evaluator who shall perform the evaluation and facility inspection. The applicant shall be responsible for successful completion of the evaluation and inspection of his or her facility within three months of notification. An extension of no more than 90 days shall be granted if the designated evaluator or applicant requests one.

A dentist who holds a moderate parenteral conscious sedation permit or moderate pediatric conscious sedation shall not intentionally administer deep sedation although deep sedation may occur briefly and unintentionally.

A dentist who is qualified to administer general anesthesia, moderate parenteral conscious sedation or moderate pediatric conscious sedation and holds a general anesthesia, moderate parenteral conscious sedation permit or a moderate pediatric conscious sedation permit may administer minimal enteral conscious sedation without obtaining a separate minimal enteral conscious sedation permit. A dentist who holds a general anesthesia permit may administer enteral and parenteral conscious sedation without obtaining separate enteral and parenteral conscious sedation permits.
(j) Any dentist who holds an active parenteral conscious sedation permit as of the effective date of these amendments shall be deemed to hold an active moderate conscious sedation permit. Such permits shall be subject to the renewal requirements set out in .0501 of this Subchapter.

History Note:

Authority G.S. 90-28; 90-30.1;
Eff. February 1, 1990;
Amended Eff. April 1, 2001; August 1, 2000; January 1, 1994;
Temporary Amendment Eff. December 11, 2002;
21 NCAC 16 Q .0302 is proposed for amendment as follows:

**21 NCAC 16Q .0302   CLINICAL REQUIREMENTS AND EQUIPMENT**

(a) A dentist administering moderate parenteral conscious sedation or moderate pediatric conscious sedation or supervising the administration of parenteral moderate conscious sedation by a certified registered nurse anesthetist shall ensure that the facility in which the parenteral conscious sedation is to be administered meets the following requirements:

1. The facility is equipped with:
   
   (1) An operatory of size and design to permit access of emergency equipment and personnel and to permit effective emergency management;
   
   (B) A chair or table for emergency treatment, including a chair suitable for CPR or CPR Board;
   
   (C) Lighting as necessary for specific procedures; and
   
   (D) Suction equipment as necessary for specific procedures, including non-electrical back-up suction.

2. The following equipment is maintained:
   
   (A) Positive oxygen delivery system, including full face mask for adults and pediatric patients; back-up E-cylinder portable oxygen tank apart from the central system;
   
   (B) Oral and nasal airways of various sizes;
   
   (C) Blood pressure monitoring device; and
   
   (D) Pulse oximeter.

3. The following emergency equipment is maintained:
   
   (A) I.V. set-up as necessary for specific procedures, including hardware and fluids, if anesthesia is intravenous;
   
   (B) Syringes as necessary for specific procedures; and
   
   (C) Tourniquet & tape.

4. The following drugs are maintained with a current shelf life and within easy accessibility from the operatory and recovery area:
   
   (A) Epinephrine;
   
   (B) Atropine;
   
   (C) Antiarrythmic;
   
   (D) Narcotic antagonist;
   
   (E) Antihistamine;
   
   (F) Corticosteroid;
   
   (G) Nitroglycerine;
   
   (H) Bronchial dilator;
   
   (I) Antiemetic;
(J) Benzodiazepine antagonist;
(K) Muscle relaxant for intubation; and
(L) 50% Dextrose.

(5) Written emergency and patient discharge protocols are maintained and training to
familiarize office personnel in the treatment of clinical emergencies is provided; and
(6) The following records are maintained: maintained for at least 10 years:
(A) Patient’s current written medical history, including known allergies and
previous surgery;
(B) Drugs administered during the procedure, including route of administration,
dosage, strength, time and sequence of administration;
(C) A sedation record which shall include:
   (i) blood pressure;
   (ii) pulse rate;
   (iii) respiration;
   (iv) duration of procedure;
   (v) documentation of complications or morbidity; and
   (vi) status of patient upon discharge.

(b) During an inspection or evaluation, the applicant or permit holder shall demonstrate the administration
of moderate conscious sedation, or where applicable, on a patient moderate pediatric conscious
sedation, including the deployment of an intravenous delivery system, or supervise the administration of
conscious sedation on a patient by a certified registered nurse anesthetist while the evaluator observes.
Practices limited to pediatric dentistry will not be required to demonstrate the deployment of an intravenous
delivery system. Instead, they will orally demonstrate to the evaluator the technique of their training in
intravenous and intraosseous deployment. During the demonstration, the applicant or permit holder shall
demonstrate competency in the following areas:
   (1) Monitoring blood pressure, pulse, and respiration;
   (2) Drug dosage and administration;
   (3) Treatment of untoward reactions including respiratory or cardiac depression, if
      applicable;
   (4) Sterile technique;
   (5) Use of CPR certified personnel;
   (6) Monitoring of patient during recovery; and
   (7) Sufficiency of patient recovery time.

(c) During an inspection or evaluation, the applicant or permit holder shall verbally demonstrate
competency to the evaluator in the treatment of the following clinical emergencies:
   (1) Laryngospasm;
   (2) Bronchospasm;
(3) Emesis and aspiration;
(4) Respiratory depression and arrest;
(5) Angina pectoris;
(6) Myocardial infarction;
(7) Hypertension/Hypotension;
(8) Allergic reactions;
(9) Convulsions;
(10) Syncope;
(11) Bradycardia;
(12) Insulin shock; and
(13) Cardiac arrest.

d) A dentist administering moderate parenteral conscious sedation or moderate pediatric conscious sedation shall ensure that the facility is staffed with sufficient auxiliary personnel for each procedure performed who shall document annual successful completion of basic life support training and be capable of assisting with procedures, problems, and emergency incidents that may occur as a result of the sedation or secondary to an unexpected medical complication.

(e) Upon request, the holder of an anesthesia or moderate pediatric conscious sedation permit may travel to the office of a licensed dentist who does not hold such a permit and provide minimal sedation, moderate parenteral and enteral conscious sedation or moderate pediatric conscious sedation services for the patients of that dentist who are undergoing dental procedures. The permit holder is solely responsible for providing that the facility in which the parenteral or enteral conscious sedation is administered meets the requirements established by the Board, that the required drugs and equipment are present, and that the permit holder utilizes sufficient auxiliary personnel for each procedure performed who shall document annual successful completion of basic life support training and be capable of assisting with procedures, problems, and emergency incidents that may occur as a result of the parenteral conscious sedation or secondary to an unexpected medical complication.

21 NCAC 16Q .0303 is proposed for amendment as follows:

**21 NCAC 16Q .0303  TEMPORARY APPROVAL PRIOR TO SITE INSPECTION**

(a) If a dentist meets the requirements of Paragraphs (a), (b), (c), (d), and (f) of Rule .0301 of this Section, he/she shall be granted temporary approval to administer moderate parenteral conscious sedation or moderate pediatric conscious sedation until a permit can be issued. Temporary approval may be granted based solely on credentials until all processing and investigation has been completed. Temporary approval may not exceed three months. An on-site evaluation of the facilities, equipment, procedures, and personnel shall be required. The evaluation shall be conducted in accordance with Rules .0204 -.0205 of this Subchapter, except that evaluations of dentists applying for moderate parenteral conscious sedation permits may be conducted by dentists who have been issued parenteral moderate conscious sedation permits by the Board and who have administered parenteral moderate conscious sedation for at least three years. Fees required by Rule .0204 of this Subchapter shall apply.

(b) An inspection may be made upon renewal of the permit or for cause.

(c) Temporary approval shall not be granted to a provisional licensee.

21 NCAC 16Q .0401 is proposed for amendment as follows:

21 NCAC 16Q .0401 ENTERAL MINIMAL CONSCIOUS SEDATION CREDENTIALS AND PERMIT

(a) Before a dentist licensed to practice in North Carolina may administer or supervise a certified registered nurse anesthetist to administer enteral minimal conscious sedation, he or she shall obtain either a parenteral conscious sedation permit issued by the Board, a general anesthesia permit issued by the Board, or an enteral conscious sedation permit issued by the Board. The dentist shall obtain a minimal conscious sedation permit issued by the Board, a moderate conscious sedation permit issued by the Board or a general anesthesia permit issued by the Board. A permit is not required for prescription administration of DEA controlled drugs prescribed for postoperative pain control intended for home use. A dentist may obtain an enteral a minimal conscious sedation permit from the Board by completing submitting the appropriate information on an application form provided by the Board and paying a fee of fifty dollars ($50.00). Such permit must be renewed annually and shall be displayed with the current renewal at all times in a conspicuous place in the office of the permit holder.

(b) A dentist who holds only an enteral conscious sedation permit shall not administer deep sedation or general anesthesia. Only a dentist who holds a general anesthesia license may administer deep sedation or general anesthesia.

(c) Application:

(1) An enteral a minimal conscious sedation permit may be obtained by completing an application form provided by Board, a copy of which may be obtained from the Board office, and meeting the requirements of Section .0400 of this Subchapter.

(2) The application form must be filled out completely and appropriate fees paid.

(3) Prior to issuance of an enteral a minimal conscious sedation permit the applicant shall undergo a facility inspection. The Board shall direct an evaluator to perform this inspection. The applicant shall be notified in writing that an inspection is required and provided with the name of the evaluator who shall perform the inspection. The applicant shall be responsible for successful completion of inspection of his or her facility within three months of notification. An extension of no more than 90 days shall be granted if the designated evaluator or applicant requests one.

(4) During an inspection or evaluation, the applicant or permit holder shall demonstrate competency in the following areas:

(A) Monitoring of blood pressure, pulse, and respiration;

(B) Drug dosage and administration (by verbal demonstration);

(C) Treatment of untoward reactions including respiratory or cardiac depression (by verbal demonstration);

(D) Sterilization;

(E) Use of CPR certified personnel;
Monitoring of patient during recovery (by verbal demonstration); and
Sufficiency of patient recovery time (by verbal demonstration).

During an inspection or evaluation, the applicant or permit holder shall verbally demonstrate competency to the evaluator in the treatment of the following clinical emergencies:

- Laryngospasm;
- Bronchospasm;
- Emesis and aspiration;
- Respiratory depression and arrest;
- Angina pectoris;
- Myocardial infarction;
- Hypertension/Hypotension;
- Syncope;
- Allergic reactions;
- Convulsions;
- Bradycardia;
- Insulin shock; and
- Cardiac arrest.

An applicant for a minimal enteral conscious sedation permit shall be licensed and in good standing with the Board in order to be approved. For purposes of these rules “good standing” means that a licensee is not suspended, whether or not the suspended licensee is on probation. Applications from licensees who are not in good standing shall not be approved.

The dentist applying for a minimal enteral conscious sedation permit shall meet one of the following criteria:

1. Successful completion of training consistent with that described in Part I or Part III of the American Dental Association (ADA) Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry, and have documented administration of minimal enteral conscious sedation in a minimum of five cases;
2. Successful completion of an ADA accredited post-doctoral training program which affords comprehensive training necessary to administer and manage minimal enteral conscious sedation;
3. Successful completion of an 18-hour eighteen hour enteral minimal conscious sedation course which must be approved by the Board based on whether it affords comprehensive training necessary to administer and manage enteral minimal conscious sedation;
(4) (D) successful completion of an ADA accredited postgraduate program in pediatric dentistry; or

(5) (E) is a North Carolina licensed dentist in good standing who has been utilizing enteral minimal conscious sedation in a competent manner for the five years preceding January 1, 2002, at least one year immediately preceding the effective date of this Rule and his or her office facility has passed an on-site inspection by a Board evaluator as required in Paragraph (c) (b) (3) of this Rule. Competency shall be determined by presentation of successful administration of enteral minimal conscious sedation in a minimum of five clinical cases.

(2) Prior to administering enteral conscious sedation to children under the age of 13, a dentist who qualifies only for an enteral conscious sedation permit shall also successfully complete a six hour course in pediatric enteral conscious sedation developed by the Pediatric Dentistry Department at the University of North Carolina or an equivalent course and submit documentation showing successful completion of such course to the Board. The requirements of this paragraph shall not apply to Pediatric Dentists who meet the requirements of Paragraph (c)(1)(D) of this Rule nor to those dentists who otherwise meet the requirements of Paragraph (c)(1)(E) of this Rule and in addition have administered enteral conscious sedation to children under the age of 13 in a competent manner for the five years preceding January 1, 2002. Competency shall be determined by presentation of successful administration of enteral conscious sedation in a minimum of five clinical cases.

History Note: Authority G.S. 90-28; 90-30.1;
Temporary Adoption Eff. March 13, 2003; December 11, 2002;
21 NCAC 16Q.0402 is proposed for amendment as follows:

**21 NCAC 16Q.0402 PERMIT REQUIREMENTS, CLINICAL PROVISIONS AND EQUIPMENT**

(a) Enteral **Minimal** conscious sedation is indicated for use only for conscious sedation as defined in Rule 0101(9), 0101(15) of this Subchapter (relating to Definitions). Enteral **Minimal** conscious sedation is not indicated for use to achieve deep sedation.

(b) A **minimal** An enteral conscious sedation permit is not required for minor psychosedatives used for anxiolysis prescribed for administration outside of the dental office when pre-procedure instructions are likely to be followed. Medication administered for the purpose of **minimal** enteral conscious sedation shall not exceed the maximum doses recommended by the drug manufacturer, sedation textbooks, or juried sedation journals. **When medications for enteral conscious sedation are used in combination, the total sedation dose shall not exceed recommended dosages for medications used in combination.** Drugs in combination are not permitted for minimal conscious sedation. During longer periods of **enteral minimal** conscious sedation, in which the amount of time of the procedures exceeds the effective duration of the sedative effect of the **drug(s)** drug used, the incremental doses of the **sedative sedative(s)** shall not exceed total safe dosage levels based on the effective half-life of the **drug** drug used.

(c) Each dentist shall:

1. **(1)** adhere to the clinical requirements as detailed in paragraph (e) of this Rule;
2. **(2)** maintain under continuous direct supervision any auxiliary personnel, who shall be capable of assisting in procedures, problems, and emergencies incident to the use of **enteral minimal** conscious sedation or secondary to an unexpected medical complication;
3. **(3)** utilize sufficient auxiliary personnel for each procedure performed who shall document annual successful completion of basic life support training; and
4. **(4)** **not allow an enteral a minimal** conscious sedation procedure to be performed in his or her office by a Certified Registered Nurse Anesthetist (CRNA) unless the dentist holds a permit issued by the Board for the procedure being performed. This provision addresses dentists and is not intended to address the scope of practice of persons licensed by any other agency.

(d) Each dentist shall meet the following requirements:

1. **(1)** Patient Evaluation. Patients who are administered **enteral minimal** conscious sedation must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals Physical Status I, II (ASA I, II, as defined by the American Society of Anesthesiologists). A patient receiving minimal conscious sedation must be healthy or medically stable (ASA I, or ASA II as defined by the American Society of Anesthesiologists). An evaluation is a review of the patient’s current medical history and medication use. However, with **for** individuals who are not medically stable or who have
a significant health disability Physical Status III (ASA III, as defined by the American
Society of Anesthesiologists) a consultation with their primary care physician or
consulting medical specialist regarding potential procedure risk is required.

Pre-procedure preparation, informed consent:

(A) The patient or guardian must be advised of the procedure associated
with the delivery of the minimal enteral-conscious sedation.

(B) Equipment must be evaluated and maintained for proper operation.

(C) Baseline vital signs shall be obtained at the
discretion of the operator depending on the medical status of the patient
and the nature of the procedure to be performed.

(D) Dentists administering minimal enteral conscious sedation shall use
sedative agents that he/she is competent to administer and shall
administer such agents in a manner that is within the standard of care.

Patient monitoring:

(1) Patients who have been administered enteral minimal conscious sedation shall be
monitored during waiting periods prior to operative procedures. An adult who has
accepted responsibility for the patient and been given written pre-procedural instruction
may provide such monitoring. The patient shall be monitored for alertness,
responsiveness, breathing and skin coloration.

(2) Dentists administering enteral minimal conscious sedation shall maintain direct
supervision of the patient during the operative procedure and for such a period of time
necessary to establish pharmacologic and physiologic vital sign stability.

(A) Oxygenation. Color of mucosa, skin or blood shall be continually
evaluated. Oxygen saturation shall be evaluated continuously by pulse
oximetry, except as provided in Paragraph (e)(4) of this Rule.

(B) Ventilation. Shall perform observation Observation of chest excursions
or auscultation of breath sounds or both—both shall be performed.

(C) Circulation. Shall take and record an initial An initial blood pressure
and pulse shall be performed and thereafter as appropriate except as
provided in Paragraph (e)(4) of this Rule.

(3) An appropriate time oriented anesthetic record of vital signs shall be maintained in the
permanent record including documentation of individual individual(s) administering the
drug(s) and showing the name(s) of drug(s) and dosage(s) used. drug and showing the
name of drug, strength and dosage used.

(4) If the dentist responsible for administering enteral minimal conscious sedation must
deviate from the requirements set out in this Rule, he or she shall document the
occurrence of such deviation and the reasons for such deviation.
(f) Post-operative procedures:

(1) Following the operative procedure, positive pressure oxygen and suction equipment shall be immediately available in the recovery area or operatory.

(2) Vital signs shall be continuously monitored when the sedation is no longer being administered and the patient shall have direct continuous supervision until oxygenation and circulation are stable and the patient is sufficiently responsive for discharge from the office.

(3) Patients who have adverse reactions to enteral minimal conscious sedation shall be assisted and monitored either in an operatory chair or recovery area until stable for discharge.

(4) Recovery from enteral minimal conscious sedation shall include:

   (A) cardiovascular function stable;
   (B) airway patency uncompromised;
   (C) patient easily arousable and protective reflexes intact;
   (D) state of hydration within normal limits;
   (E) patient can talk, if applicable;
   (F) patient can sit unaided, if applicable;
   (G) patient can ambulate, if applicable, with minimal assistance; and
   (H) for the child who is very young or disabled, and incapable of the usually expected responses, the pre-sedation level of responsiveness or the level as close as possible for that child shall be achieved.

(5) Prior to allowing the patient to leave the office, the dentist shall determine that the patient has met the recovery criteria set out in Paragraph (f)(4) of this Rule and the following discharge criteria:

   (A) oxygenation, circulation, activity, skin color and level of consciousness are sufficient and stable and have been documented;
   (B) explanation and documentation of written postoperative instructions have been provided to the patient or a responsible adult at time of discharge;
   (C) responsible individual is available for the patient to transport the patient after discharge;
   (D) for a patient who must use a child restraint system designed for use in a motor vehicle, a vested adult is available to transport the patient after discharge and an additional responsible individual is available to attend to the patient.
(g) The dentist, personnel and facility shall be prepared to treat emergencies that may arise from the administration of minimal conscious sedation, and shall have the ability to provide positive pressure ventilation with 100% oxygen with an age appropriate device.

History Note: Authority G.S. 90-28; 90-30.1;
Temporary Adoption Eff. December 11, 2002;
21 NCAC 16Q .0403 is proposed for amendment as follows:

21 NCAC 16Q .0403  TEMPORARY APPROVAL PRIOR TO SITE INSPECTION

(a) If a dentist meets the requirements of Rule .0401 of this Section, he or she shall be granted temporary approval to administer minimal enteral conscious sedation until a permit can be issued. Temporary approval may be granted based solely on credentials until all processing and investigation has been completed. Temporary approval may not exceed three months.

(b) Temporary approval shall not be granted to a provisional licensee.

History Note:  Authority G.S. 90-28; 90-30.1.
Temporary Adoption Eff. December 11, 2002;
21 NCAC 16Q .0404 is proposed for adoption as follows:

**21 NCAC 16Q .0404  PROCEDURE FOR EVALUATION OR INSPECTION FOR MINIMAL CONSCIOUS SEDATION**

(a) When an evaluation or on-site inspection is required, the Board will designate one or more persons, each of whom is qualified to administer minimal conscious sedation and has so administered such for a minimum of one year preceding the inspection, exclusive of minimal conscious sedation training.

(b) Any dentist-member of the Board may observe or consult in any evaluation. When an on-site inspection involves only a facility and equipment check and not an evaluation of the dentist, such inspection may be accomplished by one or more evaluators.

(c) The inspection team shall determine compliance with the requirements of the Rules in this Subchapter, as applicable, by assigning a grade of "pass" or "fail".

(d) Each evaluator shall report his/her recommendation to the Board, setting forth the details supporting his/her conclusion. The Board is not bound by these recommendations. The Board shall make the final determination as to whether or not the applicant has passed the evaluation/inspection and shall so notify the applicant, in writing.

(e) At least a 15-day notice shall be given prior to an evaluation or inspection.

_History Note:_ Authority G.S. 90-28; 90-30.1; _Eff. October 10, 2007._
21 NCAC 16Q .0501 is proposed for amendment as follows:

21 NCAC 16Q .0501  ANNUAL RENEWAL REQUIRED

(a) All sedation permits General anesthesia, parenteral conscious sedation, and enteral conscious sedation permits shall be renewed by the Board on an annual basis. Such renewal shall be accomplished in conjunction with the license renewal process, and applications for permits shall be made at the same time as applications for renewal of licenses.

(b) All sedation permits Anesthesia, parenteral conscious sedation, and enteral conscious sedation permits shall be subject to the same renewal deadlines as are dental practice licenses, in accordance with G.S. 90-31. If the permit renewal application is not received by the date specified in G.S. 90-31, continued administration of general anesthesia or any level of conscious sedation anesthesia, parenteral conscious sedation, or enteral conscious sedation shall be unlawful and shall subject the dentist to the penalties prescribed by Section .0700 of this Subchapter.

(c) As a condition for renewal of the general anesthesia permit, the permit holder shall meet ensure that the requirements of 21 NCAC 16Q .0202 are met and document current, successful completion of advanced cardiac life support (ACLS) training, or its age-specific equivalent or other equivalent course, and auxiliary personnel shall document annual, successful completion of basic life support (BLS) training.

(d) As a condition for renewal of the parenteral moderate conscious sedation permit or moderate pediatric conscious sedation permit, the permit holder shall meet ensure that meet the requirements of 21 NCAC 16Q .0302 are met and also meet one of the following criteria:

(1) document current, successful completion of advanced cardiac life support (ACLS) ACLS training or its age-specific equivalent, or other equivalent course; or

(2) document annual, successful completion of basic life support (BLS) BLS training and obtain three hours of continuing education each year in one or more of the following areas, which may be counted toward fulfillment of the continuing education required each calendar year for license renewal:

(A) sedation;

(B) medical emergencies;

(C) monitoring IV sedation and the use of monitoring equipment;

(D) pharmacology of drugs and agents used in IV sedation;

(E) physical evaluation, risk assessment, or behavioral management; or

(F) audit ACLS/PALS courses. Moderate pediatric conscious sedation permit holders must have current Pediatric Advanced Life Support (PALS) at all times.

(e) As a condition for renewal of the enteral minimal conscious sedation permit, the permit holder shall meet ensure that the requirements of 16Q .0402 are met and shall document annual, successful completion of basic life support (BLS) BLS training and obtain six hours of continuing education every two years in one or more of the following areas, which may be counted toward fulfillment of the continuing education required each calendar year for license renewal:
(1) pediatric or adult sedation;
(2) medical emergencies;
(3) monitoring sedation and the use of monitoring equipment;
(4) pharmacology of drugs and agents used in sedation;
(5) physical evaluation, risk assessment, or behavioral management; or
(6) audit ACLS/PALS courses.

History Note: Statutory authority G.S. 90-28; 90-30.1; 90-48;
Eff. February 1, 1990;
Amended Eff. August 1, 2002;
Transferred and Recodified from 16Q .0401 to 16Q .0501;
Temporary Amendment Eff. December 11, 2002;