.2501 ABBREVIATIONS

The following abbreviations are used throughout this subchapter:

1. EMS: Emergency Medical Services
2. OEMS: Office of Emergency Medical Services
3. PreMIS: Prehospital Medical Information System
4. MR: Medical Responder
5. EMT: Emergency Medical Technician
6. EMT-D: EMT Defibrillation
7. EMT-I: EMT Intermediate
8. EMT-P: EMT Paramedic
9. EMD: Emergency Medical Dispatcher
10. EMDPRS: Emergency Medical Dispatch Priority Reference System
11. EMS-NP: EMS Nurse Practitioner
12. EMS-PA: EMS Physician Assistant
13. MICN: Mobile Intensive Care Nurse
14. AHA: American Heart Association
15. CPR: cardiopulmonary resuscitation

History Note: Authority G.S. 143-508(b); Temporary Adoption Eff. January 1, 2002.

.2502 AIR MEDICAL AMBULANCE

“Air Medical Ambulance” means an aircraft specifically designed and equipped to transport patients by air. The patient care compartment of air medical ambulances shall be staffed by medical crewmembers approved for the mission by the medical director.

History Note: Authority G.S. 143-508(b); 143-508(d)(8); Temporary Adoption Eff. January 1, 2002.

.2503 AIR MEDICAL PROGRAM

“Air Medical Program” means a specialty care transport program designed and operated for transportation of patients by either fixed or rotary wing aircraft.
.2504 ASSISTANT MEDICAL DIRECTOR
“Assistant Medical Director” means a physician, EMS-PA, or EMS-NP who assists the medical director with the medical management of an EMS system or EMS specialty care transport program.

History Note: Authority G.S. 143-508(b); 143-508(d)(1);

.2505 CONVALESCENT AMBULANCE
“Convalescent Ambulance” means an ambulance used on a scheduled basis solely to transport patients having a known, non-emergency medical condition. Convalescent ambulances shall not be used in place of any other category of ambulance defined in this Subchapter.

History Note: Authority G.S. 143-508(b); 143-508(d)(8);

.2506 EDUCATIONAL MEDICAL ADVISOR
“Educational medical advisor” means the physician responsible for overseeing the medical components of approved EMS educational programs in basic and advanced EMS educational institutions.

History Note: Authority G.S. 143-508(b); 143-508(d)(3);

.2507 EMS EDUCATIONAL INSTITUTION
“EMS Educational Institution” means any agency credentialed by the OEMS to offer EMS educational programs.

History Note: Authority G.S. 143-508(b); 143-508(d)(4);

.2508 EMS INSTRUCTOR
“EMS Instructor” means a person who is credentialed by the OEMS as a Level I or II EMS Instructor or EMD Instructor and who is approved to instruct or coordinate EMS educational programs.

History Note: Authority G.S. 143-508(b); 143-508(d)(3); 143-508(d)(4);
.2509 EMS NONTRANSPORTING VEHICLE
“EMS nontransporting vehicle” means a motor vehicle dedicated and equipped to move medical equipment and EMS personnel functioning within the scope of practice of EMT-I or EMT-P to the scene of a request for assistance. EMS nontransporting vehicles shall not be used for the transportation of patients on the streets, highways, waterways, or airways of the state.

History Note: Authority G.S. 143-508(b); 143-508(d)(8);

.2510 EMS SYSTEM
“EMS System” means a coordinated arrangement of resources (including personnel, equipment and facilities) organized to respond to medical emergencies and integrated with other health care providers and networks including, but not limited to, public health, community health monitoring activities, and special needs populations.

History Note: Authority G.S. 143-508(b);

.2511 GROUND AMBULANCE
“Ground Ambulance” means an ambulance used to transport patients with traumatic or medical conditions or patients for whom the need for emergency medical care is anticipated either at the patient location or during transport. Ground ambulances may be used to transport all types of patients.

History Note: Authority G.S. 143-508(b); 143-508(d)(8);

.2512 MEDICAL CREWMEMBERS
“Medical Crew Member” means EMS personnel or other health care professionals who hold current North Carolina credentials and are affiliated with a specialty care transport program.

History Note: Authority G.S. 143-508(b); 143-508(d)(3);

.2513 MEDICAL DIRECTOR
“Medical director” means the physician responsible for the medical aspects of the management of an EMS system or EMS specialty care transport program.
.2514 MEDICAL OVERSIGHT
“Medical oversight” means the responsibility for the management and accountability of the medical care aspects of an EMS system. Medical oversight includes physician direction of the initial education and continuing education of EMS personnel; development and monitoring of both operational and treatment protocols; evaluation of the medical care rendered by EMS personnel; participation in system evaluation; and directing, by two-way voice communications, the medical care rendered by the EMS personnel.

History Note: Authority G.S. 143-508(b);

.2515 MODEL EMS SYSTEM
“Model EMS system” means an approved EMS system that chooses to meet the criteria for and receives this designation by the OEMS.

History Note: Authority G.S. 143-508(b);

.2516 OFFICE OF EMERGENCY MEDICAL SERVICES
“Office of Emergency Medical Services (OEMS)” means a section of the Division of Facility Services of the North Carolina Department of Health and Human Services located at 701 Barbour Drive, Raleigh, North Carolina 27603.

History Note: Authority G.S. 143-508(b);

.2517 OPERATIONAL PROTOCOLS
“Operational protocols” means the written administrative policies and procedures of an EMS system that provide guidance for the day-to-day operation of the system.

History Note: Authority G.S. 143-508(b);

.2518 PHYSICIAN
“Physician” means a medical or osteopathic doctor licensed by the NC Medical Board to practice medicine in the state of North Carolina.
.2519 QUALITY MANAGEMENT COMMITTEE
“Quality management committee” means a committee within an EMS system or specialty care transport program that is affiliated with a medical review committee as referenced in G.S. 143-518(a)(5) and is responsible for the continued monitoring and evaluation of medical and operational issues within the system and for improvement of the system.

.2520 SPECIALTY CARE TRANSPORT PROGRAM
“Specialty care Transport Program” means a program designed and operated for the provision of specialized medical care and transportation of critically ill or injured patients.

.2521 SPECIALTY CARE TRANSPORT PROGRAM CONTINUING EDUCATION COORDINATOR
“Specialty Care Transport Program Continuing Education Coordinator” means a Level I EMS Instructor within a specialty care transport program who is responsible for the coordination of EMS continuing education programs for EMS personnel within the program.

.2522 SYSTEM CONTINUING EDUCATION COORDINATOR
“System Continuing Education Coordinator” means a Level I EMS Instructor within a model EMS system who is responsible for the coordination of EMS continuing education programs.

.2523 TREATMENT PROTOCOLS
“Treatment protocols” means a written document approved by the medical directors of both the local EMS system or specialty care transport program and the OEMS specifying the diagnostic procedures, treatment procedures, medication administration, and patient care related policies that shall be completed by EMS personnel or medical crewmembers based upon the assessment of a patient.

History Note: Authority G.S. 143-508(b); 143-508(d)(6); 143-508(d)(7);

.2524 WATER AMBULANCE

“Water Ambulance” means a watercraft specifically designed and equipped to transport patients.

History Note: Authority G.S. 143-508(b); 143-508(d)(8);
.2601 EMS SYSTEM REQUIREMENTS

(a) County government shall establish EMS Systems. Each EMS System shall have:

(1) A defined geographical service area for the EMS System. The minimum service area for an EMS System shall be one county. There may be multiple EMS Provider service areas within the service area of an EMS System. The highest level of care offered within any EMS Provider service area must be available to the citizens within that service area 24 hours per day;

(2) A scope of practice within the parameters defined by the North Carolina Medical Board pursuant to G.S. 143-514;

(3) A written plan describing the dispatch and coordination of all responders that provide EMS care within the system;

(4) A minimum of one licensed EMS provider. For those systems with providers operating within the EMD, EMT-D, EMT-I or EMT-P scope of practice, there shall be a plan for medical oversight required by Section .2800 of this Subchapter;

(5) An identified number of permitted ambulances to provide coverage to the service area 24 hours per day;

(6) Personnel credentialed to perform within the scope of practice of the system to staff the ambulance vehicles as required by G.S. 131E-158. There shall be a written plan for the use of credentialed EMS personnel for all practice settings used within the system;

(7) A system to collect data that uses the basic data set and data dictionary as specified in “North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection”;

(8) A written infection control policy that addresses the cleansing and disinfecting of vehicles and equipment that are used to treat or transport patients;

(9) A written plan to provide orientation to personnel on EMS operations and related issues for hospitals routinely receiving patients from the EMS system;

(10) A listing of facilities that will provide online medical direction for systems with providers operating within the EMT-D, EMT-I or EMT-P scope of practice. To provide online medical direction, the facility shall have, at a minimum:

(A) Availability of a physician, Mobile Intensive Care Nurse, EMS-nurse practitioner, or EMS-physician assistant to provide online medical direction to EMS personnel during all hours of operation of the facility;
(B) A written plan to provide physician backup to the MICN, EMS-NP, or EMS-PA providing online medical direction to EMS personnel;

(C) A mechanism for persons providing online medical direction to provide feedback to the Quality Management system; and

(D) A plan to provide orientation and education regarding treatment protocols for those individuals providing online medical direction.

(11) A written plan to ensure that each facility that routinely receives patients and also provides clinical education for EMS personnel that is precepted by a nurse, has a nurse liaison as defined by the “North Carolina Board of Nursing: Guidelines for the Selection and Performance of the Emergency Medical Services Nurse Liaison”;

(12) A written plan for providing emergency vehicle operation education for system personnel who operate emergency vehicles;

(13) An EMS communication system that provides for:
   (A) Public access using the emergency telephone number 9-1-1 within the public dial telephone network as the primary method for the public to request emergency assistance. This number shall be connected to the emergency communications center or Public Safety Answering Point (PSAP) with immediate assistance available such that no caller will be instructed to hang up the telephone and dial another telephone number. A person calling for emergency assistance shall never be required to speak with more than two persons to request emergency medical assistance;
   (B) An emergency communications system operated by public safety telecommunicators with training in the management of calls for medical assistance available 24 hours per day;
   (C) Dispatch of the most appropriate emergency medical response unit or units to any caller’s request for assistance. The dispatch of all response vehicles shall be in accordance with an official written EMS system plan for the management and deployment of response vehicles including requests for mutual aid; and
   (D) Two-way radio voice communications from within the defined service area to the emergency communications center or PSAP and to facilities where patients are routinely transported. The emergency communications system shall maintain all Federal Communications Commission (FCC) radio licenses or authorizations required.

(14) A written plan addressing the use of specialty care transport programs within the system;

(15) A written continuing education plan for EMS Personnel that meets the requirements of the North Carolina Medical Board pursuant to G.S. 143-514.

(b) An application to establish an EMS System shall be submitted by the county to the OEMS for review. When the system is comprised of more than one county, only one application shall be submitted. The proposal shall demonstrate that the system meets the requirements in Section (a) of this Rule. System approval shall be granted for a period not to exceed six years. Systems shall apply to OEMS for reapproval.
(c) Counties shall have one year from the effective date of these rules to apply for initial system approval.

History Note:  Authority G.S. 143-508(b); (d)(1), (5), (9); G.S. 143-509(1); G.S. 143-517;

.2602  MODEL EMS SYSTEMS

(a)  Some EMS Systems may choose to move beyond the minimum requirements in Rule .2601 and receive designation from the OEMS as a Model EMS System. To receive this designation, an EMS System shall document that, in addition to the system requirements in Rule .2601 of this Section, the following criteria have been met:

1.  A uniform level of care throughout the system available 24 hours per day;

2.  A plan for medical oversight that meets the requirements found in Section .2800 of this subchapter. Specifically, Model EMS Systems shall meet the additional requirements for medical director and written treatment protocols as defined in Rules .2801(1)(b) and .2805(a)(2) of this Subchapter;

3.  A mechanism to collect and electronically submit to the OEMS data corresponding to the advanced data set and data dictionary as specified in “North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection”;

4.  A written plan to address management of the EMS system to include:
   (A)  Triage of patients to appropriate facilities;
   (B)  Transport of patients to facilities outside of the system;
   (C)  Arrangements for transporting patients to appropriate facilities when diversion or bypass plans are activated;
   (D)  A mechanism for reporting, monitoring, and establishing standards for system response times;
   (E)  A disaster plan; and
   (F)  A mass gathering plan.

5.  A written continuing education plan for EMS Personnel, under the direction of the System Continuing Education Coordinator, developed and modified based on feedback from system data, review and evaluation of patient outcomes, and quality management reviews;

6.  A written plan to assure participation in clinical and field internship educational components for all EMS personnel;

7.  Operational protocols for the management of equipment, supplies and medications. These protocols shall include a methodology:
   (A)  to assure that each vehicle contains the required equipment and supplies on each response;
   (B)  for cleaning and maintaining the equipment and vehicles; and
(C) to assure that supplies and medications are not used beyond the expiration date and stored in a temperature controlled atmosphere according to manufacturer’s specifications.

(8) A written plan for the systematic and periodic inspection, repair and maintenance of all vehicles used in the system;

(9) A written plan addressing the role of the EMS system in the areas of public education, injury prevention, and community health;

(10) Affiliation with a minimum of one trauma Regional Advisory Committee; and

(11) A system wide communication system which meets the requirements of Paragraph (a)(13) of Rule .2601 of this Section, and in addition:

(A) Operates an EMD program;

(B) Has an operational E-911 system.

(b) EMS Systems holding current accreditation by a national accreditation agency may use this as documentation of completion of the equivalent requirements outlined above.

(c) The county shall submit an application for designation as a Model EMS System to the OEMS for review. When the system is comprised of more than one county, only one application shall be submitted. The application shall demonstrate that the system meets the standards found in Paragraph (a) of this Rule. Designation as a Model EMS System shall be awarded for a period not to exceed six years, after which time, the system shall apply to OEMS for model system redesignation.

History Note: Authority G.S. 143-508(b); (d)(1), (5), (9); G.S. 143-509(1);

.2603 SPECIAL SITUATIONS

Upon application of interested citizens in North Carolina, the North Carolina Medical Care Commission may approve the furnishing and providing of programs within the scope of practice of EMD, EMT, EMT-D, EMT-I, or EMT-P in North Carolina by persons who have been approved to provide these services by an agency of a state or federal jurisdiction adjoining North Carolina. This approval may be granted where the North Carolina Medical Care Commission concludes that the requirements enumerated in Rule .2601 of this Subchapter cannot be reasonably obtained by reason of lack of geographical access.

History Note: Authority G.S. 143-508(b)

.2604 EMS PROVIDER LICENSE REQUIREMENTS

(a) Any firm, corporation, agency, organization or association that provides emergency medical services as its primary responsibility shall be licensed as an EMS Provider by meeting the following criteria:
(1) Be affiliated with an EMS System. Providers that apply for an initial EMS Provider license after January 1, 2002, shall have until December 31, 2002, to comply with this requirement;
(2) Present an application for a permit for any ambulances which will be in service as required by G.S. 131E-156;
(3) Submit a written plan detailing how the provider will furnish credentialed personnel;
(4) Where there is a franchise ordinance in effect which covers the proposed service area, be granted a current franchise to operate or present written documentation of impending receipt of a franchise from the county; and
(5) Present a written plan and method for recording systematic, periodic inspection repair, cleaning and routine maintenance of all EMS responding vehicles.

(b) Presenting documentation to the OEMS that the provider meets the criteria found in Paragraph (a) of this Rule may renew an EMS Provider License.

History Note: Authority G.S. 131E-155.1(c);

.2605 EMS PROVIDER LICENSE CONDITIONS
(a) Applications for an EMS Provider License shall be received by the OEMS at least 30 days prior to the date that the provider proposes to initiate service. Applications for renewal of an EMS Provider License shall be received by the OEMS at least 30 days prior to the expiration date of the current license.
(b) Only one license shall be issued to each EMS provider. The Department shall issue a license to the EMS provider following verification of compliance with applicable laws and rules.
(c) EMS Provider Licenses shall not be transferred.
(d) The license shall be posted in a prominent location accessible to public view at the primary business location of the EMS provider.
(e) In order to provide a transition time for implementation of these rules, EMS providers that have a current EMS Provider License as of December 31, 2001, with an expiration date in 2002, shall be issued a one-year extension to the current license from the current expiration date.

History Note: Authority G.S. 131E-155.1(c);

.2606 TERM OF EMS PROVIDER LICENSE
(a) EMS Provider Licenses shall remain in effect up to six years, unless any of the following occurs:
   (1) The Department imposes an administrative sanction which specifies license expiration;
   (2) The EMS provider closes or goes out of business;
   (3) The EMS provider changes name or ownership; or
(4) Substantial failure to comply with Rule .2604 of this Section.

(b) When the name or ownership of the EMS provider changes, an EMS Provider License application shall be submitted to the OEMS at least 30 days prior to the effective date of the change; and

(c) For EMS providers maintaining affiliation with a Model EMS System, licenses may be renewed without requirement for submission of an application.

History Note: Authority G.S. 131E-155.1(c);

.2607 GROUND AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS
To be permitted as a ground ambulance, a vehicle shall have:

(1) A patient compartment that meets the following minimum interior dimensions:
   (a) The length, measured on the floor from the back of the driver’s compartment, driver’s seat or partition to the inside edge of the rear loading doors, shall be at least 102 inches; and
   (b) The height shall be at least 48 inches over the patient area, measured from the approximate center of the floor, exclusive of cabinets or equipment.

(2) Patient care equipment and supplies as defined in the treatment protocols for the system. Vehicles used by EMS providers that are not required to have treatment protocols shall have patient care equipment and supplies as defined in the “North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection.” The equipment and supplies shall be clean, in working order and secured in the vehicle.

(3) Other equipment to include:
   (a) One fire extinguisher that shall be a dry chemical or all-purpose type with a pressure gauge mounted in a quick-release bracket; and
   (b) The availability of 1 pediatric restraint device to safely transport pediatric patients under 20 pounds in the patient compartment of the ambulance.

(4) The name of the ambulance provider permanently displayed on each side of the vehicle.

(5) Reflective tape affixed to the vehicle such that there is reflectivity on all sides of the vehicle.

(6) Emergency warning lights and audible warning devices mounted on the vehicle other than those required by Federal Motor Vehicle Safety Standards. All warning devices shall function properly.

(7) No structural or functional defects that may adversely affect the patient, the EMS personnel, or the safe operation of the vehicle.

(8) An operational two-way radio that shall:
   (a) be mounted to the ambulance and installed for safe operation and control by the ambulance driver;
(b) have sufficient range, radio frequencies and capabilities to establish and maintain two-way voice radio communication from within the defined service area of the EMS system to the emergency communications center or public safety answering point (PSAP) designated to direct or dispatch the deployment of the ambulance;

(c) be capable of establishing two-way voice radio communication from within the defined service area to the emergency department of the hospital(s) where patients are routinely transported and to facilities that provide on-line medical direction to EMS personnel;

(d) be equipped with a radio control device mounted in the patient compartment capable of operation by the patient attendant to receive on-line medical direction; and

(e) be licensed or authorized by the Federal Communications Commission (FCC).

(9) Ground ambulances shall not use a radiotelephone device such as a cellular telephone as the only source of two-way radio voice communication.

(10) Other communications instruments or devices such as data radio, facsimile, computer or telemetry radio shall be in addition to the mission dedicated dispatch radio and shall function independently from the mission dedicated radio.

History Note: Authority G.S. 131E-157(a); G.S. 143-508(d)(8);

.2608 CONVALESCENT AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS

To be permitted as a convalescent ambulance, a vehicle shall have:

(1) A patient compartment that meets the following minimum interior dimensions:
   (a) The length, measured on the floor from the back of the driver’s compartment, driver’s seat or partition to the inside edge of the rear loading doors, shall be at least 102 inches; and
   (b) The height shall be at least 48 inches over the patient area, measured from the approximate center of the floor, exclusive of cabinets or equipment.

(2) Patient care equipment and supplies as defined in the treatment protocols for the system. Vehicles used by EMS providers that are not required to have treatment protocols shall have patient care equipment and supplies as defined in the “North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection”. The equipment and supplies shall be clean, in working order and secured in the vehicle.

(3) Other equipment to include:
   (a) One fire extinguisher that shall be a dry chemical or all-purpose type with a pressure gauge mounted in a quick-release bracket; and
   (b) The availability of 1 pediatric restraint device to safely transport pediatric patients under 20 pounds in the patient compartment of the ambulance.

(4) Convalescent ambulances shall:
(a) not be equipped, permanently or temporarily, with any emergency warning devices, audible or visual, other than those required by Federal Motor Vehicle Safety Standards;
(b) have the name of the ambulance provider permanently displayed on each side of the vehicle;
(c) not have emergency medical symbols, such as the Star of Life, block design cross, or any other medical markings, symbols, or emblems, including the word “EMERGENCY,” on the vehicle;
(d) have the words “CONVALESCENT AMBULANCE” lettered on both sides and on the rear of the vehicle body; and
(e) have reflective tape affixed to the vehicle such that there is reflectivity on all sides of the vehicle.

(5) A two-way radio or radiotelephone device such as a cellular telephone shall be available to summon emergency assistance for a vehicle permitted as a convalescent ambulance.

(6) The convalescent ambulance shall not have structural or functional defects that may adversely affect the patient, the EMS personnel, or the safe operation of the vehicle.

History Note: Authority G.S. 131E-157(a); G.S. 143-508(d)(8); Temporary Adoption Eff. January 1, 2002.

.2609 AIR MEDICAL AMBULANCE: VEHICLE AND EQUIPMENT REQUIREMENTS
To be permitted as an air medical ambulance, an aircraft shall meet the following requirements:

(1) Configuration of the aircraft interior shall not compromise the ability to provide appropriate care or prevent providers from performing emergency procedures if necessary.
(2) Patient care equipment and supplies as defined in the treatment protocols for the program. Air Medical Ambulances used by EMS providers that are not required to have treatment protocols shall have patient care equipment and supplies as defined in the “North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection.” The equipment and supplies shall be clean, in working order and secured in the vehicle.
(3) Internal voice communication system to allow for communication between the medical crew and flight crew;
(4) Due to the different configurations and space limitations of air medical ambulances, the medical director shall designate the combination of medical equipment specified in Paragraph (b) of this Rule that is carried on a mission based on anticipated patient care needs.
(5) Air medical ambulances shall have the name of the organization permanently displayed on each side of the aircraft.
(6) Air medical ambulances shall be equipped with a two-way voice radio licensed by the Federal Communications Commission capable of operation on any frequency required to allow communications with public safety agencies such as fire departments, police departments,
ambulance and rescue units, hospitals and local government agencies within the defined service area.

(7) All rotary wing aircraft permitted as an air medical ambulance shall have the following flight equipment operational in the aircraft:
   (a) Two 360-channel VHF aircraft frequency transceivers;
   (b) One VHF omnidirectional ranging (VOR) receiver;
   (c) Attitude indicators;
   (d) One transponder with 4097 code, Mode C with altitude encoding;
   (e) Turn and slip indicator in the absence of three attitude indicators;
   (f) Current FAA approved navigational aids and charts for the area of operations;
   (g) Radar altimeter;
   (h) Satellite Global Navigational system;
   (i) Emergency Locator Transmitter (ELT);
   (j) A remote control external search light;
   (k) A light which illuminates the tail rotor;
   (l) A fire extinguisher; and
   (m) Survival gear appropriate for the service area and the number of occupants.

(8) Any fixed wing aircraft issued a permit to operate as an air medical ambulance shall have a current “Instrument Flight Rules” certification.

(9) The availability of 1 pediatric restraint device to safely transport pediatric patients under 20 pounds in the patient compartment of the air medical ambulance.

(10) The air medical ambulance shall not have structural or functional defects that may adversely affect the patient, the EMS personnel, or the safe operation of the aircraft.

History Note: Authority G.S. 131E-157(a); G.S. 143-508(d)(8);

.2610 WATER AMBULANCE: WATERCRAFT AND EQUIPMENT REQUIREMENTS
To be permitted as a water ambulance, a watercraft shall meet the following requirements:

(1) A patient care area which:
   (a) Provides access to the head, torso, and lower extremities of the patient while providing sufficient working space to render patient care;
   (b) Is covered to protect the patient and EMS personnel from the elements; and
   (c) Has an opening of sufficient size to permit the safe loading and unloading of a person occupying a litter.

(2) Patient care equipment and supplies as defined in the treatment protocols for the system. Water ambulances used by EMS providers that are not required to have treatment protocols shall have
patient care equipment and supplies as defined in the “North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection.” The equipment and supplies shall be clean, in working order and secured in the vehicle.

(3) Water ambulances shall have the name of the ambulance provider permanently displayed on each side of the watercraft.

(4) Water ambulances shall have a 360-degree beacon warning light in addition to warning devices required in Chapter 75A Article 1 of the North Carolina General Statutes.

(5) Water ambulances shall be equipped with:

(a) Two floatable rigid long backboards with proper accessories for securing infant, pediatric, and adult patients and stabilization of the head and neck;

(b) One floatable liter with patient restraining straps and capable of being secured to the watercraft.

(c) One fire extinguisher that shall be a dry chemical or all-purpose type with a pressure gauge mounted in a quick-release bracket.

(d) Lighted compass;

(e) Radio navigational aids such as ADF (automatic directional finder), Satellite Global Navigational system, navigational radar, or other comparable radio equipment suited for water navigation;

(f) Marine radio;

(g) One pediatric restraint device to safely transport pediatric patients under 20 pounds in the patient compartment of the ambulance;

(6) The water ambulance shall not have structural or functional defects that may adversely affect the patient, the EMS personnel, or the safe operation of the watercraft.

History Note: Authority G.S. 131E-157(a); G.S. 143-508(d)(8);
Temporary Adoption Eff. January 1, 2002

.2611 AMBULANCE PERMIT CONDITIONS

(a) An EMS provider shall apply to the OEMS for the appropriate ambulance permit prior to placing an ambulance in service.

(b) The Department shall issue a permit for an ambulance following verification of compliance with applicable laws and rules.

(c) Only one Ambulance Permit shall be issued for each ambulance.

(d) An ambulance shall be permitted in only one category.

(e) Ambulance Permits shall not be transferred except in the case of air medical ambulance replacement aircraft when the primary aircraft is out of service.

(f) The Ambulance Permit shall be posted as designated by the OEMS inspector.
(g) In order to provide a transition time for implementation of these rules, ambulances with a current ambulance permit as of December 31, 2001, shall be issued a one-year extension to the current ambulance permit from the current expiration date.

History Note: Authority G.S. 131E-157(a); G.S. 143-508(d)(8);

.2612 TERM OF AMBULANCE PERMIT
(a) Ambulance Permits shall remain in effect up to two years in an EMS system or four years in a Model EMS system, unless any of the following occurs:
   (1) The Department imposes an administrative sanction which specifies permit expiration;
   (2) The EMS provider closes or goes out of business;
   (3) The EMS provider changes name or ownership; or
   (4) Substantial failure to comply with the applicable paragraphs of Rules .2607, .2608, .2609, or .2610 of this Section.

(b) Ambulance Permits will be renewed without OEMS inspection for those ambulances currently operated within a Model EMS System.

History Note: Authority G.S. 131E-157(a); G.S. 143-508(d)(8);

.2613 EMS NONTRANSPORTING VEHICLE REQUIREMENTS
To be permitted as an EMS nontransporting vehicle, a vehicle shall have:
   (1) Patient care equipment and supplies as defined in the treatment protocols for the system. The equipment and supplies shall be clean, in working order and secured in the vehicle.
   (2) EMS nontransporting vehicles shall have the name of the organization permanently displayed on each side of the vehicle.
   (3) EMS nontransporting vehicles shall have reflective tape affixed to the vehicle such that there is reflectivity on all sides of the vehicle.
   (4) Emergency warning lights and audible warning devices mounted on the vehicle other than those required by Federal Motor Vehicle Safety Standards. All warning devices shall function properly.
   (5) The vehicle shall not have structural or functional defects that may adversely affect the EMS personnel or the safe operation of the vehicle.
   (6) One fire extinguisher that shall be a dry chemical or all-purpose type with a pressure gauge, mounted in a quick-release bracket.
   (7) An operational two-way radio that shall:
(a) be mounted to the EMS nontransporting vehicle and installed for safe operation and control by the driver;
(b) have sufficient range, radio frequencies and capabilities to establish and maintain two-way voice radio communication from within the defined service area of the EMS system to the emergency communications center or public safety answering point (PSAP) designated to direct or dispatch the deployment of the ambulance;
(c) be capable of establishing two-way voice radio communication from within the defined service area to facilities that provide on-line medical direction to EMS personnel; and
(d) be licensed or authorized by the Federal Communications Commission (FCC).

(8) EMS nontransporting vehicles shall not use a radiotelephone device such as a cellular telephone as the only source of two-way radio voice communication.

(9) Other communications instruments or devices such as data radio, facsimile, computer or telemetry radio shall be in addition to the mission dedicated dispatch radio and shall function independently from the mission dedicated radio.

History Note: Authority G.S. 131E-157(a); G.S. 143-508(d)(8); Temporary Adoption Eff. January 1, 2002.

.2614 EMS NONTRANSPORTING VEHICLE PERMIT CONDITIONS

(a) An EMS provider shall apply to the OEMS for an EMS nontransporting vehicle permit prior to placing such a vehicle in service.
(b) The Department shall issue a permit for a vehicle following verification of compliance with applicable laws and rules.
(c) Only one EMS nontransporting vehicle permit shall be issued for each vehicle.
(d) EMS nontransporting vehicle permits shall not be transferred.
(e) The EMS nontransporting vehicle permit shall be posted as designated by the OEMS inspector.
(f) In order to provide a transition time for implementation of these rules, EMS nontransporting vehicles with a current permit as of December 31, 2001, shall be issued a one-year extension to the current permit from the current expiration date.

History Note: Authority G.S. 131E-157(a); G.S. 143-508(d)(8); Temporary Adoption Eff. January 1, 2002.

.2615 TERM OF EMS NONTRANSPORTING VEHICLE PERMIT

(a) EMS nontransporting vehicle permits shall remain in effect up to two years in an EMS system or four years in a model EMS system, unless any of the following occurs:

(1) The Department imposes an administrative sanction that specifies permit expiration;
(2) The EMS provider closes or goes out of business;
(3) The EMS provider changes name or ownership; or
(4) Substantial failure to comply with Rule .2613 of this Section.

(b) EMS nontransporting vehicle permits will be renewed without OEMS inspection for those vehicles currently operated within a Model EMS System.

History Note: Authority G.S. 131E-157(a); G.S. 143-508(d)(8);

.2616 WEAPONS AND EXPLOSIVES FORBIDDEN

(a) Weapons, as defined by the local county district attorney’s office, and explosives shall not be worn or carried aboard an ambulance or EMS nontransporting vehicle within the State of North Carolina when the vehicle is operating in any patient treatment or transport capacity or is available for such function.

(b) This Rule shall apply whether or not such weapons and explosives are concealed or visible.

(c) This Rule shall not apply to duly appointed law enforcement officers.

(d) Safety flares are authorized for use on an ambulance with the following restrictions:

(1) These devices are not stored inside the patient compartment of the ambulance; and
(2) These devices shall be packaged and stored so as to prevent accidental discharge or ignition.

History Note: Authority G.S. 131E-157(a); G.S. 143-508(d)(8);
.2701 PROGRAM CRITERIA
(a) Programs seeking designation to provide specialty care transports shall submit an application for program approval to the OEMS at least 60 days prior to field implementation. The application shall document that the program has:

(1) A defined service area;
(2) A medical oversight plan meeting the requirements of Section .2800;
(3) Service continuously available on a 24 hour per day basis.
(4) The capability to provide the following patient care skills and procedures:
   (A) Advanced airway techniques including rapid sequence induction, cricothyrotomy, and ventilator management, including continuous monitoring of the patient’s oxygenation;
   (B) Insertion of femoral lines;
   (C) Maintaining invasive monitoring devices to include central venous pressure lines, arterial and venous catheters, arterial lines, intra-ventricular catheters, and epidural catheters; and
   (D) Interpreting 12-lead electrocardiograms.
(5) A written continuing education plan for EMS Personnel, under the direction of the Specialty Care Transport Program Continuing Education Coordinator, developed and modified based on feedback from program data, review and evaluation of patient outcomes, and quality management reviews.

(b) Applications for specialty care transport program approval shall document that the applicant meets the requirements for the specific program type or types applied for as specified in Rules .2702, .2703 or .2704 of this Section.

(c) Specialty care transport program approval shall be valid for a period to coincide with the EMS Provider License, not to exceed six years. Programs shall apply to the OEMS for reapproval.

History Note: Authority G.S. 143-508(d)(1); (8); (9)

.2702 AIR MEDICAL SPECIALTY CARE TRANSPORT PROGRAM
(a) In addition to the general requirements of specialty care transport programs in Rule .2701 of this section, air medical programs shall document that the program has:

(1) medical crewmembers that have all completed training regarding:
   (A) altitude physiology;
   (B) the operation of the EMS communications system used in the program;
(C) in-flight emergencies specific to the aircraft used in the program;
(D) aircraft safety. This training shall be conducted every six months.

(2) a Certificate of Need obtained from the Department when applicable;
(3) a written plan for transporting patients to appropriate facilities when diversion or bypass plans are activated.
(4) a written plan for providing emergency vehicle operation education for program personnel who operate ground emergency vehicles;
(5) a written plan specifying how EMS systems will request ground support ambulances operated by the program.

(b) Air medical programs based outside of North Carolina that provide specialty care transports may be granted approval by the OEMS to operate in North Carolina by submitting an application for program approval. The application shall document that the program meets all criteria specified in Rules .2604 and .2701 of this Subchapter and Paragraph (a) of this Rule.

History Note: Authority G.S. 143-508(d)(1);

.2703 GROUND SPECIALTY CARE TRANSPORT PROGRAMS

(a) When transporting patients that have a medical need for one or more of the skills or procedures as defined for specialty care transport programs .2701(a)(4), staffing for the vehicle used in the ground specialty care transport program shall be at a level to ensure the capability to provide in the patient compartment, when the patient condition requires, two of the following personnel approved by the medical director as medical crew members:

(1) EMT-Paramedic
(2) Nurse practitioner
(3) Physician
(4) Physician assistant
(5) Registered nurse
(6) Respiratory therapist

(b) When transporting patients that do not require specialty care transport skills or procedures, staffing for the vehicles used in the ground specialty care transport program shall be at a level to ensure compliance with G.S. 131E-158 (a).

(c) In addition to the general requirements of specialty care transport programs in Rule .2701 of this section, ground programs providing specialty care transports shall document that the program has:

(1) a communication system that will provide, at a minimum, two-way voice communications to medical crewmembers anywhere in the service area of the program. The medical director shall verify that the communications system is satisfactory for on-line medical direction.
(2) medical crewmembers that have all completed training regarding:
(A) operation of the EMS communications system used in the program; and
(B) the medical and safety equipment specific to the vehicles used in the program. This
training shall be conducted every six months.

(3) Operational protocols for the management of equipment, supplies and medications. These
protocols shall include:
(A) A standard equipment and supply listing for all ambulance vehicles used in the program.
This listing shall meet or exceed the requirements for each category of ambulance used in
the program as found in Rules .2607, .2608, .2609, and .2610 of this Subchapter;
(B) A standard listing of medications for all ambulance and EMS nontransporting vehicles
used in the system. This listing shall be based on the local treatment protocols and be
approved by the medical director;
(C) A methodology to assure that each vehicle contains the required equipment and supplies
on each response;
(D) A methodology for cleaning and maintaining the equipment and vehicles; and
(E) A methodology for assuring that supplies and medications are not used beyond the expiration
date and stored in a temperature controlled atmosphere according to manufacturer’s
specifications.

(4) A written plan for providing emergency vehicle operation education for program personnel who
operate emergency vehicles;

(5) A written plan specifying how EMS systems will request ambulances operated by the program.

(d) Ground Specialty Care Transport programs based outside of North Carolina may be granted approval by the
OEMS to operate in North Carolina by submitting an application for program approval. The application shall
document that the program meets all criteria specified in Rules .2604 and .2701 of this Subchapter and Paragraphs
(a) and (b) of this Rule.

History Note:  Authority G.S. 143-508(d)(1); (8); (9);

.2704 HOSPITAL AFFILIATED GROUND SPECIALTY CARE TRANSPORT PROGRAMS USED FOR
INPATIENT TRANSPORTS

(a) Patients transported by this type specialty care transport program shall:

(1) have a medical need for one or more of the skills or procedures as defined for specialty care
transport programs as defined in .2701(a)(4); or

(2) be a patient of the hospital administering the program, or be scheduled for admission to or
discharge from the hospital administering the program;

(b) In addition to the general requirements of specialty care transport programs in Rule .2701 of this section,
hospital affiliated ground programs providing specialty care transports shall document that the program has:
(1) a communication system that will provide, at a minimum, two-way voice communications to medical crewmembers anywhere in the service area of the program. The medical director shall verify that the communications system is satisfactory for on-line medical direction.

(2) medical crewmembers that have all completed training regarding:
   
   (A) operation of the EMS communications system used in the program; and
   (B) the medical and safety equipment specific to the vehicles used in the program. This training shall be conducted every six months.

(3) staffing at a level to ensure the capability to provide in the patient compartment, when the patient condition requires, two of the following personnel approved by the medical director as medical crew members:

   (A) EMT-Paramedic
   (B) Nurse practitioner
   (C) Physician
   (D) Physician assistant
   (E) Registered nurse
   (F) Respiratory therapist

(4) Operational protocols for the management of equipment, supplies and medications. These protocols shall include:

   (A) A standard equipment and supply listing for all ambulance vehicles used in the program. This listing shall meet or exceed the requirements for each category of ambulance used in the program as found in Rules .2607, .2608, .2609, and .2610 of this Subchapter;

   (B) A standard listing of medications for all ambulance and EMS nontransporting vehicles used in the program. This listing shall be based on the local treatment protocols and be approved by the medical director;

   (C) A methodology to assure that each vehicle contains the required equipment and supplies on each response;

   (D) A methodology for cleaning and maintaining the equipment and vehicles; and

   (E) A methodology for assuring that supplies and medications are not used beyond the expiration date and stored in a temperature controlled atmosphere according to manufacturer’s specifications.

(5) A written plan for providing emergency vehicle operation education for program personnel who operate emergency vehicles.

(6) A written plan specifying how EMS systems will request ambulances operated by the program.

(c) Hospital Affiliated Specialty Care Transport programs based outside of North Carolina may be granted approval by the OEMS to operate in North Carolina by submitting an application for program approval. The application shall document that the program meets all criteria specified in Rules .2604 and .2701 of this Subchapter and Paragraphs (a) and (b) of this Rule.
History Note: Authority G.S. 143-508(d)(1); (8); (9);
.2801 COMPONENTS OF MEDICAL OVERSIGHT FOR EMS SYSTEMS

Each EMS System operating within the scope of practice for EMD, EMT-D, EMT-I or EMT-P or seeking designation as a Model EMS System shall have the following components in place to assure medical oversight of the system:

1. A medical director appointed, either directly or by clearly documented delegation, by the county responsible for establishing the EMS system. Systems may elect to appoint one or more assistant medical directors;
   a. For EMS Systems, the medical director and assistant medical directors shall meet the criteria as defined in the “North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection”;
   b. For Model EMS Systems, the medical director and assistant medical directors shall also meet the additional criteria for medical directors of Model EMS Systems as defined in the “North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection”;

2. Written treatment protocols for use by EMS personnel;

3. For systems providing EMD service, an EMDPRS approved by the medical director;

4. A quality management committee; and

5. Written procedures for use by EMS personnel to obtain on-line medical direction. On-line medical direction shall:
   a. Be restricted to medical orders that fall within the scope of practice of the EMS personnel and within the scope of approved system treatment protocols;
   b. Be provided only by physicians, EMS-physician assistants, EMS-nurse practitioners, or mobile intensive care nurses. Only physicians may deviate from written treatment protocols; and
   c. Be provided by a system of two-way voice communication that can be maintained throughout the treatment and disposition of the patient.

History Note: Authority G.S. 143-508(b); 143-509(12);

.2802 COMPONENTS OF MEDICAL OVERSIGHT FOR SPECIALTY CARE TRANSPORT PROGRAMS
Each specialty care transport program shall have the following components in place to assure medical oversight of the system:

1. A medical director. The administration of the specialty care transport program shall appoint a medical director following the criteria for medical directors of specialty care transport programs as defined by the “North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection”. The program administration may elect to appoint one or more assistant medical directors;

2. Treatment protocols for use by medical crewmembers;

3. A quality management committee; and

4. A written protocol for use by medical crewmembers to obtain on-line medical direction. On-line medical direction shall:
   a. Be restricted to medical orders that fall within the scope of practice of the medical crewmembers and within the scope of approved program treatment protocols;
   b. Be provided only by physicians, EMS-physician assistants, EMS-nurse practitioners, or mobile intensive care nurses. Only physicians may deviate from written treatment protocols; and
   c. Be obtained via a system of two-way voice communication that can be maintained throughout the treatment and disposition of the patient.

**History Note:** Authority G.S. 143-508(b); 143-509(12); Temporary Adoption Eff. January 1, 2002.

.2803 RESPONSIBILITIES OF THE MEDICAL DIRECTOR FOR EMS SYSTEMS

(a) The medical director for an EMS system shall be responsible for the following:

1. Ensure that medical control is available 24 hours a day;

2. The establishment, approval and annual updating of treatment protocols;

3. For EMD programs, the establishment, approval, and annual updating of the EMDPRS;

4. Medical supervision of the selection, system orientation, continuing education and performance of EMS personnel;

5. Medical supervision of a scope of practice performance evaluation for all EMS personnel in the system based on the treatment protocols for the system;

6. The medical review of the care provided to patients; and

7. Providing guidance regarding decisions about the equipment, medical supplies, and medications that will be carried on ambulances or EMS nontransporting vehicles within the scope of practice of EMT-D, EMT-I, or EMT-P.

8. Keeping the care provided up to date with current medical practice
(b) Any tasks related to paragraph (a) of this rule may be completed, through clearly established written delegation, by assisting physicians, physician assistants, nurse practitioners, registered nurses, EMD’s, or EMT-P’s.

(c) The medical director shall have the authority to suspend temporarily, pending due process review, any EMS personnel from further participation in the EMS system when it is determined the activities or medical care rendered by such personnel may be detrimental to the care of the patient, constitute unprofessional behavior, or result in non-compliance with credentialing requirements.

History Note: Authority G.S. 143-508(b); 143-509(12); Temporary Adoption Eff. January 1, 2002.

.2804 RESPONSIBILITIES OF THE MEDICAL DIRECTOR FOR SPECIALTY CARE TRANSPORT PROGRAMS

(a) The medical director for a specialty care transport program shall be responsible for the following:

1. The establishment, approval and periodic updating of treatment protocols
2. Medical supervision of the selection, program orientation, continuing education and performance of medical crewmembers;
3. Medical supervision of a scope of practice performance evaluation for all medical crewmembers in the program based on the treatment protocols for the program;
4. The medical review of the care provided to patients;
5. Keeping the care provided up to date with current medical practice; and
6. In air medical programs, determination and specification of the medical equipment required in Paragraph (2) of Rule .2609 of this Subchapter that is carried on a mission based on anticipated patient care needs.

(b) Any tasks related to paragraph (a) of this rule may be completed, through clearly established written delegation, by assisting physicians, physician assistants, nurse practitioners, registered nurses, or medical crewmembers.

(c) The medical director shall have the authority to suspend temporarily, pending due process review, any medical crewmembers from further participation in the specialty care transport program when it is determined the activities or medical care rendered by such personnel may be detrimental to the care of the patient, constitute unprofessional behavior, or result in non-compliance with credentialing requirements.

History Note: Authority G.S. 143-508(b); 143-509(12); Temporary Adoption Eff. January 1, 2002.

.2805 REQUIREMENTS FOR TREATMENT PROTOCOLS FOR EMS SYSTEMS

(a) Written treatment protocols:
(1) used in EMS Systems shall meet the minimum standard treatment protocols as defined in the “North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection”;

(2) used in Model EMS Systems shall also meet the minimum standard treatment protocols for Model EMS Systems as defined in the “North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection”;

(3) shall not contain medical procedures, medications, or intravenous fluids which exceed the scope of practice defined by the North Carolina Medical Board pursuant to G.S. 143-514 for the level of care offered in the EMS system or any other applicable health care licensing board;

(b) Treatment protocols developed locally shall, at a minimum, meet the requirements of paragraph (a) of this Rule, shall be reviewed annually and any change in the treatment protocols shall be submitted to the OEMS medical director for review and approval at least 30 days prior to the implementation of the change.

History Note: Authority G.S. 143-508(b); 143-509(12); Temporary Adoption Eff. January 1, 2002.

.2806 REQUIREMENTS FOR TREATMENT PROTOCOLS FOR SPECIALTY CARE TRANSPORT PROGRAMS

(a) Treatment protocols used by medical crewmembers within a specialty care transport program shall:

(1) Incorporate all skills, medications, equipment, and supplies for specialty care transport programs as defined by the “North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection” and shall be approved by the OEMS medical director; and

(2) Not contain medical procedures, medications, or intravenous fluids that exceed the scope of practice of the medical crewmembers;

(b) Treatment protocols shall be reviewed annually and any change in the treatment protocols shall be submitted to the OEMS medical director for review and approval at least 30 days prior to the implementation of the change.

History Note: Authority G.S. 143-508(b); 143-509(12); Temporary Adoption Eff. January 1, 2002.

.2807 REQUIREMENTS FOR EMERGENCY MEDICAL DISPATCH PRIORITY REFERENCE SYSTEM (EMDPRS)

(a) EMDPRS used by EMD’s within an approved EMD program shall:

(1) Meet or exceed the statewide standard for EMDPRS as defined by the “North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection” and shall be approved by the OEMS medical director; and

(2) Not exceed the EMD scope of practice;
(b) An EMDPRS developed locally shall be reviewed and updated annually and submitted to the OEMS medical director for approval. Any change in the EMDPRS shall be submitted to the OEMS medical director for review and approval at least 30 days prior to the implementation of the change.

History Note: Authority G.S. 143-508(b); 143-509(12); Temporary Adoption Eff. January 1, 2002.

.2808 QUALITY MANAGEMENT COMMITTEE FOR EMS SYSTEMS

(a) The quality management committee for an EMS system shall:

(1) Be composed of at least one voting representative from each of the following components of the system:
   (A) physicians;
   (B) nurses;
   (C) medical facility personnel such as pharmacists or respiratory therapists;
   (D) EMS educators;
   (E) county government officials; and
   (F) EMS providers;

(2) Appoint a physician as chairperson;

(3) Meet at a minimum on a quarterly basis;

(4) Ensure that a medical review committee as referenced in G.S. 143-518(a)(5), or sub-committee thereof, analyzes system data to evaluate the ongoing quality of patient care and medical direction within the system;

(5) Use information gained from system data analysis to make recommendations regarding the content of educational programs for EMS personnel;

(6) Review treatment protocols of the EMS system and make recommendations to the medical director for changes;

(7) Establish a written procedure to guarantee reviews for EMS personnel temporarily suspended by the medical director; and

(8) Maintain minutes of committee meetings throughout the approval period of the EMS System.

(b) The quality management committee shall adopt written guidelines, which address at a minimum:

(1) Structure of committee membership;

(2) Appointment of committee officers;

(3) Appointment of committee members;

(4) Length of terms of committee members;

(5) Frequency of attendance of committee members;

(6) Establishment of a quorum for conducting business; and

(7) Confidentiality of medical records and personnel issues.
.2809 QUALITY MANAGEMENT COMMITTEE FOR SPECIALTY CARE TRANSPORT PROGRAMS

(a) The quality management committee for a specialty care transport program shall:

1. Be composed of at least one voting representative from each of the following components of the program:
   A. physicians;
   B. nurses;
   C. medical facility personnel such as pharmacists or respiratory therapists;
   D. educators; and
   E. medical crewmembers;

2. Appoint a physician as chairperson;

3. Meet at a minimum on a quarterly basis;

4. Ensure that a medical review committee as referenced in G.S. 143-518(a)(5), or sub-committee thereof, analyzes system data to evaluate the ongoing quality of patient care and medical direction within the program;

5. Use information gained from program data analysis to make recommendations regarding the content of educational programs for medical crewmembers;

6. Review treatment protocols of the specialty care transport programs and make recommendations to the medical director for changes;

7. Establish a written procedure to guarantee reviews for medical crewmembers temporarily suspended by the medical director; and

8. Maintain minutes of committee meetings throughout the approval period of the specialty care transport program.

(b) Each quality management committee shall adopt written guidelines, which address at a minimum:

1. Structure of committee membership;

2. Appointment of committee officers;

3. Appointment of committee members;

4. Length of terms of committee members;

5. Frequency of attendance of committee members;

6. Establishment of a quorum for conducting business; and

7. Confidentiality of medical records and personnel issues.

History Note: Authority G.S. 143-508(b); 143-509(12);
.2901 EDUCATIONAL PROGRAMS

(a) An educational program approved to qualify EMS personnel to perform within their scope of practice shall be offered by an EMS Educational Institution.

(b) Educational programs approved to qualify EMS personnel or EMS Instructors for credentialing or renewal of credentials shall meet the requirements of the North Carolina Medical Board pursuant to G.S. 143-514.

History Note: Authority G.S. 143-508(d)(3), (4); 143-514;

.2902 INITIAL CREDENTIALING REQUIREMENTS FOR EMS PERSONNEL

(a) EMS personnel applicants shall meet the following criteria within one year of the completion date of the approved educational program for their level of application. If the educational program was completed over one year prior to application, applicants shall submit evidence of completion of continuing education during the past year. This continuing education shall be consistent with their level of application and approved by the OEMS.

   (1) Be at least 18 years of age;

   (2) Successfully complete a scope of practice performance evaluation, approved by the OEMS, for the level of application;

       (A) For MR and EMT credentialing, this evaluation shall be conducted under the direction of a Level II EMS Instructor credentialed at or above the level of application or other person approved by the OEMS.

       (B) For EMT-D, EMT-I, EMT-P, EMD, MICN, EMS-PA, and EMS-NP credentialing, this evaluation shall be conducted under the direction of the educational medical advisor, a Level II EMS Instructor credentialed at or above the level of application and designated by the educational medical advisor, or other person approved by the OEMS.

   (3) Successfully complete a written examination approved or administered by the OEMS. Applicants who fail the written EMT examination but achieve a minimum score of 70% on the medical responder subset contained within the examination may be credentialed as medical responders.

(b) EMD applicants shall successfully complete, within one year prior to application, an AHA CPR course or equivalent, including infant, pediatric and adult CPR, in addition to paragraphs (a)(1), (a)(2)(B) and (a)(3) of this rule;
(c) MICN applicants shall currently be a registered nurse who is licensed to practice nursing in North Carolina and have two years emergency or critical care experience, or a combination of this experience in addition to paragraphs (a)(1) and (a)(2)(B) of this rule;

(d) EMS-NP applicants shall currently be a registered nurse who is licensed to practice nursing in North Carolina and approved as a nurse practitioner by the North Carolina Board of Nursing and the North Carolina Medical Board and have two years emergency or critical care experience, or a combination of this experience in addition to paragraphs (a)(1) and (a)(2)(B) of this rule; and

(e) EMS-PA applicants shall currently be a physician assistant licensed by the North Carolina Medical Board and have two years emergency or critical care experience, or a combination of this experience in addition to paragraphs (a)(1) and (a)(2)(B) of this rule.

History Note: Authority G.S. 143-508(d)(3); 131E-159 (a), (b);

.2903 CREDENTIALING REQUIREMENTS LEGAL RECOGNITION APPLICANTS

(a) Applicants holding current credentials with the National Registry of Emergency Medical Technicians, a national credentialing agency approved by the OEMS, or another state where the education and credentialing requirements are approved for legal recognition by the OEMS may be eligible for credentialing at their level of application without examination.

(b) Persons who live in a state that borders North Carolina may continue to obtain a North Carolina credential through legal recognition if they continue to renew their credentials in the state in which they reside.

(c) Persons who live in North Carolina and have a current credential in another state that borders North Carolina may renew their North Carolina credential through legal recognition if they continue to meet the credentialing requirements in the state in which they are credentialed.

(d) Persons who were previously credentialed in North Carolina and are currently credentialed in another state, the National Registry of Emergency Medical Technicians, or a national credentialing agency approved by the OEMS may be eligible for credentialing at their level of application without examination.

History Note: Authority G.S. 143-508(d)(3), (4); 131E-159 (a), (b), (c), (d);

.2904 TERM OF CREDENTIALS FOR EMS PERSONNEL

(a) Credentials for EMS personnel shall be valid for the period stated on the credential issued to the applicant. This period shall not exceed four years.

(b) Credentials obtained through legal recognition shall be valid for four years or the unexpired term of the credential that was used to obtain a credential in this state, whichever is shorter.
.2905 RENEWAL OF CREDENTIALS FOR EMS PERSONNEL AND EMS INSTRUCTORS

Persons shall renew credentials by presenting documentation to the OEMS that they have successfully completed the requirements for their level of application as defined by the North Carolina Medical Board pursuant to G.S. 143-514.

History Note: Authority G.S. 131E-159 (a, (c), (d); Temporary Adoption Eff. January 1, 2002.

.2906 SCOPE OF PRACTICE FOR EMS PERSONNEL

EMS Personnel educated in approved programs, credentialed by the OEMS, and affiliated with an approved EMS system may perform acts and administer intravenous fluids and medications as allowed by the North Carolina Medical Board pursuant to G.S. 143-514.

History Note: Authority G.S. 131-159 (a); 143-508 (d)(3); Temporary Adoption Eff. January 1, 2002.

.2907 PRACTICE SETTINGS FOR EMS PERSONNEL

EMS Personnel may function in the following practice settings in accordance with the protocols approved by the medical director of the EMS System or Specialty Care Transport Program with which they are affiliated, and by the OEMS:

1. at the location of a physiological or psychological illness or injury including transportation to an appropriate treatment facility if required;
2. at public or community health facilities in conjunction with public and community health initiatives;
3. in hospitals and clinics;
4. in residences, facilities, or other locations as part of wellness or injury prevention initiatives within the community and the public health system; and
5. at mass gatherings or special events.

History Note: Authority G.S. 143-508(d)(6); G.S. 143-514; Temporary Adoption Eff. January 1, 2002.

.2908 CREDENTIALING REQUIREMENTS FOR LEVEL I EMS INSTRUCTORS

(a) Applicants for credentialing as a Level I EMS instructor shall meet the following:
(1) Be currently credentialed by the OEMS as an EMT, EMT-D, EMT-I, or EMT-P;
(2) Three years equivalent experience at the scope of practice for the level of application;
(3) Within one year prior to application, successfully complete a scope of practice performance evaluation, approved by the OEMS, for the level of EMS personnel application;
   (A) For a credential to teach at the EMT level this evaluation shall be conducted under the direction of a Level II EMS Instructor credentialed at or above the level of application or other person approved by the OEMS.
   (B) For a credential to teach at the EMT-D, EMT-I, or EMT-P levels, this evaluation shall be conducted under the direction of the educational medical advisor, a Level II EMS Instructor credentialed at or above the level of application and designated by the educational medical advisor, or other person approved by the OEMS.
(4) 100 hours of formal teaching experience in an approved EMS educational program or equivalent;
(5) Successful completion of a Level I EMS Instructor methodology course as defined by the North Carolina Medical Board pursuant to G.S. 143-514;
(6) Attendance at a Level I EMS Instructor workshop approved by the OEMS; and
(7) A high school diploma or General Education Development certificate.

(b) Persons who have a current EMT Instructor Certification as of December 31, 2001, shall be issued a Level I EMS Instructor credential consistent with the term of their EMT Instructor Certification.

(c) The credential of a Level I EMS Instructor shall remain in effect up to four years, unless any of the following occurs:
   (1) The OEMS imposes an administrative action against the instructor credential;
   (2) The instructor fails to maintain a current EMS Personnel credential at the highest level that the instructor is approved to teach.

_History Note:_ Authority G.S. 143-508(d)(3);

**.2909 CREDENTIALING REQUIREMENTS FOR LEVEL II EMS INSTRUCTORS**

(a) Applicants for credentialing as a Level II EMS instructor shall meet the following:
   (1) Be currently credentialed by the OEMS as an EMT, EMT-D, EMT-I, or EMT-P;
   (2) Completion of post-secondary level education equal to or exceeding an Associate Degree. Persons who have a current EMT Instructor Certification as of December 31, 2001, and apply for Level II EMS Instructor credentials by December 31, 2003, are exempt from this requirement;
   (3) Within one year prior to application, successfully complete a scope of practice performance evaluation, approved by the OEMS, for the level of EMS personnel application;
(A) For EMT instructor credentialing, this evaluation shall be conducted under the direction of a Level II EMS Instructor credentialed at or above the level of application or other person approved by the OEMS.

(B) For EMT-D, EMT-I, and EMT-P instructor credentialing, this evaluation shall be conducted under the direction of the educational medical advisor, a Level II EMS Instructor credentialed at or above the level of application and designated by the educational medical advisor, or other person approved by the OEMS.

(4) Two years teaching experience as a Level I EMS Instructor or equivalent;

(5) Successful completion of an EMS Education Administration Course as defined by the North Carolina Medical Board pursuant to G.S. 143-514;

(6) Current approval by the OEMS as an EMS evaluator; and

(7) Attendance at a Level II EMS Instructor workshop approved by the OEMS;

(b) The credential of a Level II EMS Instructor shall remain in effect up to four years, unless any of the following occurs:

(1) The OEMS imposes an administrative action against the instructor credential;

(2) The instructor fails to maintain a current EMS Personnel credential at the highest level that the instructor is approved to teach.

History Note: Authority G.S. 143-508(d)(3);

.2910 CREDENTIALING REQUIREMENTS FOR EMD INSTRUCTORS

(a) Applicants for credentialing as an EMD instructor shall meet the following:

(1) Be currently credentialed by the OEMS as an EMD;

(2) Three years experience as an EMD;

(3) 100 hours of classroom teaching experience in EMS or telecommunications subjects;

(4) Successful completion of an EMD Instructor Course approved by the OEMS;

(5) Within one year prior to application, successfully complete a scope of practice performance evaluation approved by the OEMS, for EMD credentialing. This evaluation shall be conducted under the direction of the educational medical advisor, an EMD Instructor designated by the educational medical advisor, or other person approved by the OEMS;

(6) A high school diploma or General Education Development certificate; and

(7) Attendance at a Level I EMS Instructor workshop approved by the OEMS.

(b) Persons currently approved by the OEMS as EMD Instructors shall be issued an EMD Instructor credential valid through December 31, 2003.

(c) The credential of an EMD Instructor shall remain in effect up to four years, unless any of the following occurs:

(1) The OEMS imposes an administrative action against the EMD instructor credential;
(2) The instructor fails to maintain a current EMD credential.

History Note: Authority G.S. 143-508(d)(3);

.2911 CREDENTIALING OF INDIVIDUALS TO ADMINISTER LIFESAVING TREATMENT TO PERSONS SUFFERING AN ADVERSE REACTION TO INSECT STINGS

(a) To become credentialed by the North Carolina Medical Care Commission to administer epinephrine to persons who suffer adverse reactions to insect stings, a person shall meet the following:

(1) Be 18 years of age or older; and

(2) Successfully complete an educational program taught by a physician licensed to practice medicine in North Carolina or designee of the physician. The educational program shall instruct individuals in the appropriate use of procedures for the administration of epinephrine to pediatric and adult victims who suffer adverse reactions to insect stings and shall include at a minimum the following:

(A) Definition of anaphylaxis;

(B) Agents which might cause anaphylaxis and the distinction between them, including drugs, insects, foods, and inhalants;

(C) Recognition of symptoms of anaphylaxis for both pediatric and adult victims;

(D) Appropriate emergency treatment of anaphylaxis as a result of insect stings;

(E) Availability and design of packages containing equipment for administering epinephrine to victims suffering from anaphylaxis as a result of insect stings;

(F) Pharmacology of epinephrine including indications, contraindications, and side effects;

(G) Discussion of legal implications of rendering aid; and

(H) Instruction that treatment is to be utilized only in the absence of the availability of physicians or other practitioners who are authorized to administer the treatment.

(b) A credential to administer epinephrine to persons who suffer adverse reactions to insect stings may be issued by the North Carolina Medical Care Commission upon receipt of a completed application signed by the applicant and the physician who taught or was responsible for the educational program. All credentials shall be valid for the period stated on the credential issued to the applicant and this period shall not exceed four years.

History Note: Authority G.S. 143-508(d)(11);
.3001 CONTINUING EDUCATION EMS EDUCATIONAL INSTITUTION REQUIREMENTS

(a) Continuing Education EMS Educational Institutions shall be credentialed by the OEMS to provide EMS continuing education programs.

(b) Continuing Education EMS Educational Institutions shall have, at a minimum;

(1) a Level I credentialed instructor as program coordinator. The program coordinator shall hold a Level I instructor credentialed at a level equal to or greater than the highest level of continuing education program offered in the system. Educational institutions offering only EMD continuing education programs may meet this requirement with a credentialed EMD instructor;

(2) a continuing education program consistent with the system continuing education plan for EMS personnel;

(A) In an EMS System, the continuing education programs for EMD, EMT-D, EMT-I and EMT-P shall be reviewed and approved by the medical director of the EMS System;

(B) In a Model EMS System, the continuing education program shall be reviewed and approved by the system continuing education coordinator and medical director.

(C) In a specialty care transport program, the continuing education program shall be reviewed and approved by Specialty Care Transport Program Continuing Education Coordinator and the medical director.

(3) instructional supplies and equipment, a record-keeping system detailing student attendance and performance, and facilities as defined by the North Carolina Medical Board pursuant to G.S. 143-514;

(4) educational programs offered in accordance with Rule .2901 of this Subchapter

(c) An application for credentialing as a Continuing Education EMS Educational Institution shall be submitted to the OEMS for review. The application shall demonstrate that the applicant meets the requirements in Paragraph (b) of this Rule.

(d) Continuing Education EMS Educational Institution credentials shall be valid for a period not to exceed four years.

(e) For Continuing Education EMS Educational Institutions maintaining affiliation with a Model EMS System, credentials may be renewed without requirement for submission of an application

History Note: Authority G.S. 143-508(d)(4);
Temporary Adoption Eff. January 1, 2002
.3002 BASIC EMS EDUCATIONAL INSTITUTION REQUIREMENTS

(a) Basic EMS Educational Institutions may offer MR, EMT, EMT-D, EMD, EMS-NP, EMS-PA, and MICN courses for which they have been credentialed by the OEMS.

(b) For initial courses, Basic EMS Educational Institutions shall have, at a minimum;

1. a Level I EMS Instructor as lead course instructor for MR, EMT, and EMT-D courses;
2. an EMD Instructor as lead course instructor for EMD courses;
3. instructors for EMS-NP, EMS-PA and MICN appointed by the EMS educational program coordinator and approved by the educational medical advisor;
4. a lead EMS educational program coordinator. This individual may be either a Level II EMS Instructor credentialed at or above the highest level of course offered by the institution, or a combination of staff who cumulatively meet the requirements of the Level II EMS Instructor referenced in this paragraph. These individuals may share the responsibilities of the lead EMS educational coordinator. The details of this option shall be defined in the educational plan required in paragraph (b)(6) of this rule. Basic EMS Educational Institutions offering only EMD courses may meet this requirement with a credentialed EMD instructor;
5. an Educational Medical Advisor that meets the criteria as defined in the “North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection”;
6. an educational plan approved by the OEMS addressing program components as defined by the North Carolina Medical Board pursuant to G.S. 143-514; and
7. instructional supplies and equipment, a record-keeping system detailing student attendance and performance, and facilities as defined by the North Carolina Medical Board pursuant to G.S. 143-514.

(c) For EMS continuing education programs, Basic EMS Educational Institutions shall meet the requirements defined in paragraphs (a) and (b) of Rule .3001 of this Section.

(d) An application for credentialing as a Basic EMS Educational Institution shall be submitted to the OEMS for review. The proposal shall demonstrate that the applicant meets the requirements in Paragraphs (b) and (c) of this Rule.

(e) Basic EMS Educational Institution credentials shall be valid for a period not to exceed four years.

(f) For Basic EMS Educational Institutions maintaining affiliation with a Model EMS System, credentials may be renewed without requirement for submission of an application.

History Note: Authority G.S. 143-508(d)(4);
Temporary Adoption Eff. January 1, 2002

.3003 ADVANCED EMS EDUCATIONAL INSTITUTION REQUIREMENTS

(a) Advanced EMS Educational Institutions may offer all EMS educational programs for which they have been credentialed by the OEMS.
(b) For initial courses, Advanced EMS Educational Institutions shall have, at a minimum;
   (1) a Level I EMS Instructor as lead course instructor for MR, EMT and EMT-D courses;
   (2) an EMD Instructor as lead course instructor for EMD courses;
   (3) instructors for EMS-NP, EMS-PA and MICN appointed by the EMS educational program
       coordinator and approved by the educational medical advisor;
   (4) a Level II EMS Instructor as lead instructor for EMT-I and EMT-P courses;
   (5) a lead EMS educational program coordinator. This individual may be either a Level II EMS
       Instructor credentialed at or above the highest level of course offered by the institution, or a
       combination of staff who cumulatively meet the requirements of the Level II EMS Instructor
       referenced in this paragraph. These individuals may share the responsibilities of the lead EMS
       educational coordinator. The details of this option shall be defined in the educational plan required
       in paragraph (b)(7) of this rule;
   (6) an Educational Medical Advisor that meets the criteria as defined in the “North Carolina College
       of Emergency Physicians: Standards for Medical Oversight and Data Collection”;
   (7) an educational plan approved by OEMS addressing program components as defined by the North
       Carolina Medical Board pursuant to G.S. 143-514; and
   (8) instructional supplies and equipment, a record-keeping system detailing student attendance and
       performance, and facilities as defined by the North Carolina Medical Board pursuant to G.S. 143-
       514.

(c) For EMS continuing education programs, Advanced EMS Educational Institutions shall meet the requirements
defined in paragraphs (a) and (b) of Rule .3001 of this Section.

(d) An application for credentialing as an Advanced EMS Educational Institution shall be submitted to the OEMS
for review. The application shall demonstrate that the applicant meets the requirements in Paragraphs (b) and (c) of
this Rule. Advanced EMS Educational Institutions holding current accreditation by a national EMS educational
accreditation agency that has been recognized by OEMS may use this accreditation as documentation toward
meeting the requirements of Paragraphs (b) and (c) of this Rule.

(e) Advanced Educational Institution credentials shall be valid for a period not to exceed four years.

(f) For Advanced EMS Educational Institutions maintaining affiliation with a Model EMS System, credentials may
be renewed without requirement for submission of an application.

History Note: Authority G.S. 143-508(d)(4);

.3004 TRANSITION FOR APPROVED TEACHING INSTITUTIONS
Approved Teaching Institutions under contract with the OEMS as of December 31, 2001 shall be credentialed as an
EMS Educational Institution consistent with the existing level of approval through December 31, 2002. These
institutions may continue to offer courses currently allowed under the contract while preparing for credentialing under these rules.

_History Note:_ Authority G.S. 143-508(b);

_Temporary Adoption Eff. January 1, 2002._
.3101 DENIAL, SUSPENSION, AMENDMENT OR REVOCATION

(a) The Department may deny, suspend, or revoke the permit of an ambulance or EMS nontransporting vehicle if the EMS provider:

(1) fails to substantially comply with the requirements of Section .2600 of this Subchapter;
(2) obtains or attempts to obtain a permit through fraud or misrepresentation; or
(3) fails to provide emergency medical care within the defined EMS service area in a timely and professional manner.

(b) In lieu of suspension or revocation, the Department may issue a temporary permit for an ambulance or EMS nontransporting vehicle whenever the Department finds that:

(1) the EMS provider to which that vehicle is assigned has substantially failed to comply with the provisions of G.S. 131E, Article 7 and the rules adopted under that article; and
(2) there is a reasonable probability that the EMS provider can remedy the permit deficiencies within a length of time determined by the department; and
(3) there is a reasonable probability that the EMS provider will be willing and able to remain in compliance with the rules regarding vehicle permits for the foreseeable future.

(c) The Department shall give the EMS provider written notice of the temporary permit. This notice shall be given personally or by certified mail and shall set forth:

(1) the duration of the temporary permit not to exceed 60 days;
(2) a copy of the vehicle inspection form;
(3) the statutes or rules alleged to be violated; and
(4) notice to the EMS provider’s right to a contested case hearing on the temporary permit.

(d) The temporary permit shall be effective immediately upon its receipt by the EMS provider and shall remain in effect until the Department:

(1) restores the vehicle to full permitted status; or
(2) suspends or revokes the vehicle’s permit

(e) The Department may deny, suspend, or revoke the credentials of EMS personnel or EMS instructors for any of the following reasons:

(1) failure to comply with the applicable performance and credentialing requirements as found in this Subchapter;
(2) immoral conduct;
(3) making false statements or representations to the OEMS or willfully concealing information in connection with an application for credentials;
being unable to perform as a professional with reasonable skill and safety to patients and the public by reason of illness, use of alcohol, drugs, chemicals, or any other type of material or by reason of any physical or mental abnormality;

(5) unprofessional conduct, including but not limited to a failure to comply with the rules relating to the proper function of credentialed EMS personnel or EMS instructors contained in this Subchapter or the performance of or attempt to perform a procedure which is detrimental to the health and safety of any person or which is beyond the scope of practice of credentialed EMS personnel or EMS instructors;

(6) conviction in any court of a crime involving moral turpitude, a conviction of a felony, or conviction of a crime involving the function of credentialed EMS personnel or EMS instructors;

(7) by false representations obtaining or attempting to obtain money or anything of value from a patient;

(8) adjudication of mental incompetence;

(9) lack of professional competence to practice with a reasonable degree of skill and safety for patients including but not limited to a failure to perform a prescribed procedure, failure to perform a prescribed procedure competently or performance of a procedure which is not within the scope of practice of credentialed EMS personnel or EMS instructors;

(10) making false statements or representations, willfully concealing information, or failing to respond within a reasonable period of time and in a reasonable manner to inquiries from the OEMS;

(11) testing positive for any substance, legal or illegal, which could impair the physical or psychological ability of the credentialed EMS personnel or EMS instructor to perform all required or expected functions while on duty;

(12) representing or allowing others to represent that the credentialed EMS personnel or EMS instructor has a credential that the credentialed EMS personnel or EMS instructor does not in fact have; or

(13) inappropriate use or disclosure of records or data associated with EMS Systems, Specialty Care Transport Programs, or patients.

(f) The Department may amend any EMS provider license by reducing it from a full license to a provisional license whenever the Department finds that:

(1) the licensee has substantially failed to comply with the provisions of G.S. 131E, Article 7 and the rules adopted under that article; and

(2) there is a reasonable probability that the licensee can remedy the licensure deficiencies within a reasonable length of time; and

(3) there is a reasonable probability that the licensee will be able thereafter to remain in compliance with the licensure rules for the foreseeable future.

(g) The Department shall give the licensee written notice of the amendment to the EMS provider License. This notice shall be given personally or by certified mail and shall set forth:
(1) the length of the provisional EMS provider license;
(2) the factual allegations;
(3) the statutes or rules alleged to be violated; and
(4) notice to the EMS provider’s right to a contested case hearing on the amendment of the EMS provider license.

(h) The provisional EMS provider license shall be effective immediately upon its receipt by the licensee and shall be posted in a prominent location at the primary business location of the EMS provider, accessible to public view, in lieu of the full license. The provisional license shall remain in effect until the Department:

(1) restores the licensee to full licensure status; or
(2) revokes the licensee’s license.

(i) The Department may revoke or suspend an EMS provider license whenever the Department finds that the licensee:

(1) has substantially failed to comply with the provisions of G.S. 131E, Article 7 and the rules adopted under that article and it is not reasonably probable that the licensee can remedy the licensure deficiencies within a reasonable length of time;
(2) has substantially failed to comply with the provisions of G.S. 131E, Article 7 and the rules adopted under that article and, although the licensee may be able to remedy the deficiencies within a reasonable period of time, it is not reasonably probable that the licensee will be able to remain in compliance with licensure rules for the foreseeable future;
(3) has failed to comply with the provision of G.S. 131E, Article 7 and the rules adopted under that article that endanger the health, safety or welfare of the patients cared for or transported by the licensee; or
(4) obtained or attempted to obtain an ambulance permit, EMS nontransporting vehicle permit, or EMS provider license through fraud or misrepresentation.

(j) The issuance of a provisional EMS provider license is not a procedural prerequisite to the revocation or suspension of a license pursuant to Paragraph (i) of this Rule.

(k) The Department may amend, deny, suspend, or revoke the credential of an EMS educational institution for any of the following reasons:

(1) failure to substantially comply with the requirements of Section .3000 of this Subchapter; or
(2) obtaining or attempting to obtain a credential through fraud or misrepresentation.

(l) The Department may amend, deny, suspend, or revoke the approval of an EMS System or designation of a Model EMS System for any of the following reasons:

(1) failure to substantially comply with the requirements of Section .2600 of this Subchapter; or
(2) obtaining or attempting to obtain designation through fraud or misrepresentation.

(m) The Department may amend, deny, suspend, or revoke the designation of a Specialty Care Transport Program for any of the following reasons:

(1) failure to substantially comply with the requirements of Section .2700 of this Subchapter; or
(2) obtaining or attempting to obtain designation through fraud or misrepresentation.

History Note: Authority G.S. 131E-155.1(d); 131E-157(c); 131E-159(a); 143-508(d)(10); Temporary Adoption Eff. January 1, 2002.

.3102 PROCEDURES FOR DENIAL, SUSPENSION, AMENDMENT, OR REVOCATION

Denial, suspension, amendment or revocation of credentials, licenses, permits, approvals, or designations shall follow the law regarding contested cases found in G.S. 150B.

History Note: Authority G.S. 143-508(d)(10)
.3201 TRAUMA SYSTEM DEFINITIONS
The following definitions apply throughout this Subchapter:

(1) “Advanced Trauma Life Support (ATLS)” refers to the course sponsored by the American College of Surgeons.

(2) “ACS” stands for the American College of Surgeons.

(3) “Affiliated Hospital” means a non-trauma center hospital that is owned by the trauma center such that a contract or other agreement exists between these facilities to allow for the diversion or transfer of the trauma center’s patient population to this non-trauma center hospital.

(4) “Bypass” means the transport of an Emergency Medical Services patient past an Emergency Medical Services receiving facility for the purposes of accessing a designated trauma center or a higher-level trauma center.

(5) “Contingencies” are conditions placed on a trauma center’s designation, which if unmet, can result in the loss or amendment of a hospital’s designation.

(6) “Trauma Performance Improvement Program (TPIP)” means a system in which outcome data is used to modify the process of patient care and prevent repetition of adverse events.

(7) “Deficiency” is the failure to meet essential criteria for a trauma center’s designation as specified in Section .3300 of this Subchapter, which can serve as the basis for a focused review or denial of a trauma center designation.

(8) “Department” means the North Carolina Department of Health and Human Services.

(9) “Diversion” means that a hospital of its own volition reroutes a trauma patient to a trauma center.

(10) “E-Code” is a numeric identifier that defines the cause of injury, taken from the International Classification of Diseases (ICD).

(11) “Focused Review” is an evaluation of the trauma center’s corrective actions to remove contingencies (as the result of deficiencies) placed upon it following a renewal site visit.

(12) “Hospital” means a licensed facility as defined in G.S. 131E-176.

(13) “Immediately available” implies the physical presence of the health professional in an appropriate location at the time of need by the trauma patient.

(14) “Lead RAC Agency” is the agency (comprised of 1 or more Level I or II trauma centers) that provides staff support and serves as the coordinating entity for trauma planning in a region.

(15) “Level I Trauma Center” is a regional resource trauma center that has the capability of providing leadership, research and total care for every aspect of injury from prevention to rehabilitation.
“Level II Trauma Center” is a hospital that provides definitive trauma care regardless of the severity of the injury, but may not be able to provide the same comprehensive care as a Level I trauma center, and does not have trauma research as a primary objective.

“Level III Trauma Center” is a hospital that provides prompt assessment, resuscitation, emergency operations, and stabilization and arranges for hospital transfer as needed to a Level I or II trauma center.

“OEMS” means Office of Emergency Medical Services.

“Post Graduate Year Four (PGY4)” means any surgery resident having complete three clinical years of general surgical training. A pure laboratory year will not constitute a clinical year.

“Promptly available” implies the physical presence of health professionals in an appropriate location within a short period of time, which is defined by the trauma system (director) and continuously monitored by the performance improvement program.

“RAC” stands for “Regional Advisory Committee ” which is comprised of a Lead RAC Agency and a group representing trauma care providers and the community, for the purpose of regional trauma planning, establishing, and maintaining a coordinated trauma system.

“RFP” stands for “Request for Proposal” and is a standardized state document that must be completed by each hospital seeking initial or renewal trauma center designation.

“Revocation” means the removal of a trauma center designation, for concerns related to patient morbidity/mortality and/or failure to meet essential criteria and/or recurrent contingencies.

“Transfer Agreement” means a formal written agreement between two agencies specifying the appropriate transfer of patient populations delineating the conditions and methods of transfer.

“Trauma Center” is a hospital facility designated by the State of North Carolina and distinguished by its ability to immediately manage, on a 24-hour basis, the severely injured patient or those at risk for severe injury.

“Trauma Center Criteria” means essential or desirable characteristics to define Level I, II or III trauma centers.

“Trauma Center Designation” means a formalized process of approval in which a hospital voluntarily seeks to have its trauma care capabilities and performance evaluated by experienced on-site reviewers.

“Trauma Minimum Data Set” means the basic data required of all hospitals for submission to the trauma statewide database.

“Trauma Patient” is any patient with an ICD-9-CM discharge diagnosis 800.00-959.9 excluding 905-909 (late effects of injury), 9100-924 (blisters, contusions, abrasions, and insect bites), and 930-939 (foreign bodies).

“Trauma Program” means an administrative entity that includes the trauma service and coordinates other trauma related activities. It must also include, at a minimum, the trauma medical director, trauma program manager/trauma coordinator and trauma registrar. This program’s reporting
structure must give it the ability to interact with at least equal authority with other departments providing patient care.

(31) “Trauma Protocols” are standards for practice in a variety of situations within the trauma system.

(32) “Trauma Guidelines” are suggested standards for practice in a variety of situations within the trauma system.

(33) “Trauma Registry” is an OEMS maintained database to provide information for analysis and evaluation of the quality of patient care, including epidemiological and demographic characteristics of trauma patients.

(34) “Trauma Service” means a clinical service established by the medical staff that has oversight of and responsibility for the care of the trauma patient.

(35) “Trauma System” means an integrated network that ensures that acutely injured patients are expeditiously taken to hospitals appropriate for their level of injury.

(36) “Trauma Team” means a group of health care professionals organized to provide coordinated and timely care to the trauma patient.

(37) “Triage” is a predetermined schematic for patient distribution based upon established medical needs.

_History Note:_ Authority G.S. 131E-162;

_Temporary Adoption Eff. January 1, 2002._
.3301 LEVEL I TRAUMA CENTER CRITERIA
To receive designation as a Level I Trauma Center, a hospital shall have the following:

(1) a trauma program and a trauma service which have been operational for at least six months prior to application for designation;

(2) membership in and inclusion of all trauma patient records in the North Carolina Trauma Registry for at least six months prior to submitting a Request for Proposal;

(3) trauma medical director who is a board-certified general surgeon. The trauma medical director must:
   (a) have a minimum of three years clinical experience on a trauma service or trauma fellowship training;
   (b) serve on the center’s trauma service;
   (c) participate in providing care to patients with life-threatening or urgent injuries;
   (d) participate in the North Carolina Chapter of the ACS Committee on Trauma as well as other regional and national trauma organizations;
   (e) remain a current provider in the ACS’ Advanced Trauma Life Support Course and in the provision of trauma related instruction to other health care personnel; and
   (f) be involved with trauma research and the publication of results and presentations.

(4) a full-time trauma nurse coordinator (TNC)/program manager (TPM) who is a registered nurse, licensed by the North Carolina Board of Nursing;

(5) a full-time trauma registrar (TR) who has a working knowledge of medical terminology, is able to operate a personal computer, and has demonstrated the ability to extract data from the medical record;

(6) a hospital department/division/section for general surgery, neurological surgery, emergency medicine, anesthesiology, and orthopaedic surgery, with designated chair or physician liaison to the trauma program for each;

(7) clinical capabilities in general surgery with two separate posted call schedules. One shall be for trauma, one for general surgery. In those instances where a physician may simultaneously be listed on both schedules, there must be a defined back-up surgeon listed on the schedule to allow the trauma surgeon to provide care for the trauma patient. The trauma service director shall specify, in writing, the specific credentials that each back-up surgeon must have. These, at a minimum, must state that the back-up surgeon has surgical privileges at the trauma center and is boarded or eligible in general surgery (with board certification in general surgery within five years of completing other qualifications).
residency). If a trauma surgeon is simultaneously on call at more than one hospital, there shall be a defined, posted trauma surgery back-up call schedule composed of surgeons credentialed to serve on the trauma panel.

(8) response of a trauma team to provide evaluation and treatment of a trauma patient 24-hours-per-day that includes:

(a) an in-house Post Graduate Year 4 or senior general surgical resident, at a minimum, who is a member of that hospital’s surgical residency program and responds within 20 minutes of notification;

(b) a trauma attending whose presence at the patient’s bedside within 20 minutes of notification is documented and who participates in therapeutic decisions and is present at all operative procedures;

(c) an emergency physician who is present in the emergency department 24-hours-per-day who is either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine). Emergency physicians caring only for pediatric patients may, as an alternative, be boarded in pediatric emergency medicine. These physicians must be board-certified within five years after successful completion of a residency and serve as a designated member of the trauma team until the arrival of the trauma surgeon;

(d) neurosurgery and orthopaedic surgery specialists who are never simultaneously on-call at another Level II or higher trauma center, who are promptly available, if requested by the trauma team leader, unless there is either an in-house attending neurosurgeon/orthopaedic surgeon, a Post Graduate Year 2 or high in-house neurosurgery/orthopaedic surgery resident or an in-house trauma surgeon or emergency physician as long as the institution can document management guidelines and annual continuing medical education for neurosurgical/orthopaedic emergencies. There must be a specified written back-up on the call schedule whenever the neurosurgical/orthopaedist is simultaneously on-call at a hospital other than the trauma center;

(e) an in-house anesthesiologist or a clinical anesthesiology year 3 (CA3) resident as long as an anesthesiologist on-call is advised and promptly available if requested by the trauma team leader and;

(f) Registered nursing personnel trained in the care of trauma patients.

(9) a written credentialing process established by the department of surgery to approve attending general surgeons covering the trauma service. The surgeons must have a minimum of board certification in general surgery within five years of completing residency;

(10) standard written protocols relating to trauma management must be formulated and routinely updated;
criteria to ensure team activation prior to arrival of trauma/burn patients, to include at a minimum, the following:
(a) shock;
(b) respiratory distress;
(c) airway compromise;
(d) unresponsiveness (Glasgow Coma Scale less than 8) with potential for multiple injuries; and
(e) gunshot wound to head, neck or torso.

prompt surgical evaluation shall be considered based upon the following criteria:
(a) proximal amputations;
(b) burns meeting institutional transfer criteria;
(c) vascular compromise;
(d) crush to chest or pelvis;
(e) two or more proximal long bone fractures; and
(f) spinal cord injury.

prompt surgical consults shall be considered based upon the following criteria:
(a) falls greater than 20 feet;
(b) pedestrian struck by motor vehicle;
(c) motor vehicle crash with;
   (i) ejection (includes motorcycle);
   (ii) rollover;
   (iii) speed greater than 40 mph; or
   (iv) death at the scene
(d) extremes of age, < 5 or > 70 years

clinical capabilities (promptly available if requested by the trauma team leader, with a posted on-call schedule), to include individuals credentialed in the following:
(a) cardiac surgery;
(b) critical care;
(c) hand surgery;
(d) microvascular/replant surgery;
(e) neurosurgery (The neurosurgeon must be dedicated to one hospital or a back-up call schedule must be available. If fewer than 25 emergency neurosurgical trauma operations are done in a year, and the neurosurgeon is dedicated only to that hospital, then a published back-up call list is not necessary.)
(f) obstetrics/gynecologic surgery;
(g) ophthalmic surgery;
(h) oral/maxillofacial surgery;
(i) orthopaedics (dedicated to one hospital or a back-up call schedule must be available);
(j) pediatric surgery;
(k) plastic surgery;
(l) radiology;
(m) thoracic surgery; and
(n) urologic surgery.

(15) an emergency department which has at a minimum;
(a) a designated physician director who is board-certified or board prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine);
(b) 24-hour-per-day staffing by physicians physically present in the Emergency Department such that:
   (i) at least one physician on every shift in the Emergency Department is either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine) to serve as the designated member of the trauma team at least until the arrival of the trauma surgeon. Emergency physicians caring only for pediatric patients may, as an alternative, be boarded in pediatric emergency medicine. All these physicians must be board-certified within five years after successful completion of a residency;
   (ii) all remaining emergency physicians, if not board-certified or prepared in emergency medicine as outlined in (15)(b)(i) above, are board-certified or eligible by the American Board of Surgery, American Board of Family Practice, or American Board of Internal Medicine, with each being board-certified within five years after successful completion of a residency; and
   (iii) all emergency physicians practice emergency medicine as their primary specialty.
(c) nursing personnel with experience in trauma care who continually monitor the trauma patient from hospital arrival to disposition to an intensive care unit, operating room, or patient care unit;
(d) equipment for patients of all ages to include:
   (i) airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators, pocket masks, and oxygen);
   (ii) pulse oximetry;
   (iii) end-tidal carbon dioxide determination equipment;
   (iv) suction devices;
   (v) electrocardiograph-oscilloscope-defibrillator with internal paddles;
(vi) apparatus to establish central venous pressure monitoring;
(vii) intravenous fluids and administration devices to include larger bore catheters and intraosseous infusion devices;
(viii) sterile surgical sets for airway control/cricothyrotomy, thoracotomy, vascular access, and thoracostomy, peritoneal lavage, and central line insertion;
(ix) apparatus for gastric decompression;
(x) 24-hour-per-day x-ray capability;
(xi) two-way communication equipment for communication with the emergency transport system;
(xii) skeletal traction devices, including capability for cervical traction;
(xiii) arterial catheters;
(xiv) thermal control equipment for patients;
(xv) thermal control equipment for blood and fluids;
(xvi) rapid infuser system;
(xvii) Broselow tape;
(xviii) sonography; and
(xix) doppler

(16) an operating suite which is immediately available 24-hours-per-day and has at a minimum:
  (a) 24-hour-per-day immediate availability on in-house staffing;
  (b) equipment for patients of all ages to include:
      (i) cardiopulmonary bypass capability;
      (ii) operating microscope;
      (iii) thermal control equipment for patients
      (iv) thermal control equipment for blood and fluids;
      (v) 24-hour-per-day x-ray capability including c-arm image intensifier;
      (vi) endoscopes and bronchoscopes;
      (vii) craniotomy instruments;
      (viii) capability of fixation of long-bone and pelvic fractures; and
      (ix) rapid infuser system.

(17) a postanesthetic recovery room or surgical intensive care unit which has at a minimum:
  (a) 24-hour-per-day in-house staffing by registered nurses;
  (b) equipment for patients of all ages to include:
      (i) capability for resuscitation and continuous monitoring of temperature, hemodynamics, and gas exchange;
      (ii) capability for continuous monitoring of intracranial pressure;
      (iii) pulse oximetry;
      (iv) end-tidal carbon dioxide determination capability;
(v) thermal control equipment for patients; and
(vi) thermal control equipment for blood and fluids.

(18) an intensive care unit for trauma patients which has at a minimum:

(a) a designated surgical director for trauma patients;
(b) a physician on duty in the intensive care unit 24-hours-per-day or immediately available from within the hospital as long as this physician is not the sole physician on-call for the emergency department;
(c) ratio of one nurse per two patients on each shift;
(d) equipment for patients for all ages to include:
   (i) airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators, and pocket masks);
   (ii) oxygen source with concentration controls;
   (iii) cardiac emergency cart;
   (iv) temporary, transvenous pacemaker;
   (v) electrocardiograph-oscilloscope-defibrillator with internal paddles;
   (vi) cardiac output monitoring capability;
   (vii) electronic pressure monitoring capability;
   (viii) mechanical ventilator;
   (ix) patient weighing devices;
   (x) pulmonary function measuring devices;
   (xi) temperature control devices; and
   (xii) intracranial pressure monitoring devices.
(e) within 30 minutes of request, be able to perform blood gas measurements, hematocrit level, and chest x-ray studies;

(19) acute hemodialysis capability;

(20) physician-directed burn center staffed by nursing personnel trained in burn care or a written transfer agreement with a burn center;

(21) acute spinal cord management capability or written transfer agreement with a hospital capable of caring for a spinal cord injured patient;

(22) radiological capabilities which has at a minimum:
   (a) 24-hour-per-day in-house radiology technologist;
   (b) 24-hour-per-day in-house computerized tomography technologist;
   (c) sonography;
   (d) computed tomography;
   (e) angiography;
   (f) magnetic resonance imaging; and
   (g) resuscitation equipment to include: airway management, and IV therapy.
respiratory therapy services available in-house 24-hours-per-day;

24-hour-per-day clinical laboratory service, which must include at a minimum:

(a) standard analysis of blood, urine, and other body fluids, including micro-sampling when appropriate;
(b) blood typing and cross-matching;
(c) coagulation studies;
(d) comprehensive blood bank or access to community central blood bank with storage facilities;
(e) blood gases and pH determination; and
(f) microbiology.

a rehabilitation service which provides at a minimum:

(a) a professional staff trained in rehabilitation care of critically injured patients;
(b) for major trauma patients, functional assessment and recommendations regarding short and long term rehabilitation needs within one week of the patient’s admission to the hospital or as soon as hemodynamically stable;
(c) full in-house rehabilitation service or a written transfer agreement with a rehabilitation facility accredited by the Commission on Accreditation of Rehabilitation Facilities;
(d) physical, occupational, speech therapies, and social services; and
(e) substance evaluation and counseling capability.

a performance improvement program, as outlined in the document “Performance Improvement Guidelines for North Carolina Trauma Centers”, dated January 1, 2002, which is incorporated by reference and includes:

(a) a state approved trauma registry whose data is submitted to the OEMS at least quarterly, which includes all trauma patients seen at the trauma center itself or those that are routinely diverted or transferred to its affiliated hospital;
(b) morbidity and mortality reviews to include all trauma deaths;
(c) trauma performance committee that meets at least quarterly, to include physicians, nurses, pre-hospital personnel, and a variety of other healthcare providers which reviews policies, procedures, and system issues and whose members or designee attend at least 50% of the regular meetings;
(d) multidisciplinary peer review committee that meets at least quarterly and includes physicians from trauma, neurosurgery, orthopaedics, emergency medicine, anesthesiology, and other specialty physicians as needed specific to the case, and the trauma nurse coordinator/program manager and whose members or designee attend at least 50% of the regular meetings;
(e) identification of discretionary and non-discretionary audit filters;
(f) documentation and review of times and reasons for trauma related diversion of patients;
(g) documentation and review of response times for trauma surgeons (who must demonstrate 80% compliance), neurosurgeons, anesthesiologists or airway managers, and orthopaedists;

(h) appropriate trauma team notification;

(i) review of pre-hospital trauma care to include dead on arrivals; and

(j) review of times and reasons for transfer of injured patients.

(27) an outreach program to include:

(a) written transfer agreements to address the transfer and receipt of trauma patients;

(b) programs for physicians within the community and within the referral area (to include telephone and on-site consultations) about how to access the trauma center resources and refer patients within the system;

(c) development of a Regional Advisory Committee (RAC) as specified in Rule .3502 of this Subchapter;

(d) development of regional criteria for coordination of trauma care;

(e) assessment of trauma system operations at the regional level; and

(f) ATLS.

(28) a program of injury prevention and public education to include:

(a) epidemiology research to include studies in injury control, collaboration with other institutions on research, monitoring progress of prevention programs, and consultation with qualified researchers on evaluation measures;

(b) surveillance methods to include trauma registry data, special Emergency Department and field collection projects;

(c) designation of an injury prevention coordinator; and

(d) outreach activities, program development, information resources and collaboration with existing national, regional, and state trauma programs.

(29) a trauma research program designed to produce new knowledge applicable to the care of injured patients to include:

(a) identifiable institutional review board process,

(b) extramural educational presentations which must include 12 education/outreach presentations over a three-year period; and

(c) ten peer-reviewed publications over a three-year period that could come from any aspect of the trauma program.

(30) a documented continuing education program for staff physicians, nurses, allied health personnel, and community physicians to include:

(a) a general surgery residency program;

(b) current board certification for neurosurgeons and orthopaedics;
(c) 20 hours of category I or II trauma related continuing medical education every two years for all attending general surgeons on the trauma service, orthopaedists, and neurosurgeons, with at least 50% of this being extramural;

(d) 20 hours of category I or II trauma related continuing medical education every two years for all emergency physicians, with at least 50% of this being extramural;

(e) Advanced Trauma Life Support (ATLS) completion for general surgeons on the trauma service and emergency physicians. Emergency physicians, if not boarded in emergency medicine, must be current in ATLS;

(f) 20 hours of category I trauma related continuing medical education (beyond in-house in-services) every two years for the trauma nurse coordinator/program manager;

(g) sixteen hours of trauma registry related or trauma related continuing education every two years, as deemed appropriate by the trauma nurse coordinator/program manager for the trauma registrar;

(h) at least an 80% compliance rate for 16 hours of trauma related continuing education (as approved by the trauma nurse coordinator/program manager) every two years related to trauma care for RN’s and LPN’s in transport programs, emergency departments, primary intensive care units, primary trauma floors, and other areas deemed appropriate by the trauma nurse coordinator/program manager; and

(i) sixteen hours of trauma registry related or trauma related continuing education every two years for physician assistants and mid-level practitioners routinely caring for trauma patients.

History Note: Authority G.S. 131E-162; Temporary Adoption Eff. January 1, 2002.

.3302 LEVEL II TRAUMA CENTER CRITERIA

To receive designation as a Level II Trauma Center, a hospital shall have the following:

(1) a trauma program and a trauma service which have been operational for at least six months prior to application for designation;

(2) membership in and inclusion of all trauma patient records in the North Carolina Trauma Registry for at least six months prior to submitting a Request for Proposal;

(3) a trauma medical director who is a board-certified general surgeon. The trauma medical director must:

(a) have a minimum of three years clinical experience on a trauma service and/or trauma fellowship training;

(b) serve on the center’s trauma service;

(c) participate in providing care to patients with life-threatening urgent injuries;
(d) participate in the North Carolina Chapter of the ACS’ Committee on Trauma as well as other regional and national trauma organizations;

(e) remain a current provider in the ACS’ Advanced Trauma Life Support Course and in the provision of trauma related instruction to other health care personnel; and

(4) a full-time trauma nurse coordinator (TNC)/program manager (TPM) who is a registered nurse, licensed by the North Carolina Board of Nursing;

(5) a full-time trauma registrar (TR) who has a working knowledge of medical terminology, is able to operate a personal computer, and has demonstrated the ability to extract data from the medical record;

(6) a hospital department/division/section for general surgery, neurological surgery, emergency medicine, anesthesiology, and orthopaedic surgery, with designated chair or physician liaison to the trauma program for each;

(7) clinical capabilities in general surgery with two separate posted call schedules. One shall be for trauma, one for general surgery. In those instances where a physician may simultaneously be listed on both schedules, there must be a defined back-up surgeon listed on the schedule to allow the trauma surgeon to provide care for the trauma patient. The trauma service director shall specify, in writing, the specific credentials that each back-up surgeon must have. These, at a minimum, must state that the back-up surgeon has surgical privileges at the trauma center and is boarded or eligible in general surgery (with board certification in general surgery within five years of completing residency). If a trauma surgeon is simultaneously on call at more than one hospital, there shall be a defined, posted trauma surgery back-up call schedule composed of surgeons credentialed to serve on the trauma panel.

(8) response of a trauma team to provide evaluation and treatment of a trauma patient 24-hours-per-day that includes:

(a) a trauma attending whose presence at the patient’s bedside within 20 minutes of notification is documented and who participates in therapeutic decisions and is present at all operative procedures;

(b) an emergency physician who is present in the emergency department 24-hours-per-day who is either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine) or board-certified or eligible by the American Board of Surgery, American Board of Family Practice, or American Board of Internal Medicine and practices emergency medicine as his primary specialty. This physician must be board-certified within five years after successful completion of a residency and serves as a designated member of the trauma team until the arrival of the trauma surgeon;

(c) neurosurgery and orthopaedic surgery specialists who are never simultaneously on-call at another Level II or higher trauma center, who are promptly available, if requested by the
trauma team leader, as long as there is either an in-house attending neurosurgeon/orthopaedic surgeon; a Post Graduate Year 2 or higher in-house neurosurgery/orthopaedic surgery resident; or in-house emergency physician or the on-call trauma surgeon as long as the institution can document management guidelines and annual continuing medical education for neurosurgical/orthopaedic emergencies. There must be a specified written back-up on the call schedule whenever the neurosurgeon/orthopaedic surgeon is simultaneously on-call at a hospital other than the trauma center; and

(d) an in-house anesthesiologist or a clinical anesthesiology year 3(CA3) resident unless an anesthesiologist on-call is advised and promptly available after notification or an in-house CRNA under physician supervision, practicing in accordance with G.S. 90-171.20(7)e., pending the arrival of the anesthesiologist.

(9) a written credentialing process established by the department of surgery to approve attending general surgeons covering trauma service. The surgeons must have a minimum of board certification in general surgery within five years of completing residency;

(10) standard written protocols relating to trauma care management must be formulated and routinely updated;

(11) criteria to ensure team activation prior to arrival of trauma/burn patients, to include at a minimum, the following:

(a) shock;
(b) respiratory distress;
(c) airway compromise;
(d) unresponsiveness (Glasgow Coma Scale less than 8) with potential for multiple injuries; and
(e) gunshot wound to head, neck or torso.

(12) prompt surgical evaluation shall be considered based upon the following criteria:

(a) proximal amputations;
(b) burns meeting institutional transfer criteria;
(c) vascular compromise;
(d) crush to chest or pelvis;
(e) two or more proximal long bone fractures; and
(f) spinal cord injury.

(13) prompt surgical consults shall be considered based upon the following criteria:

(a) falls greater than 20 feet;
(b) pedestrian struck by motor vehicle;
(c) motor vehicle crash with;
   (i) ejection (includes motorcycle);
(ii) rollover;
(iii) speed greater than 40 mph; or
(iv) death at the scene

(d) extremes of age, < 5 or > 70 years

(14) clinical capabilities (promptly available if requested by the trauma team leader, with a posted on-call schedule), to include individuals credentialed in the following:

(a) critical care;
(b) hand surgery;
(c) neurosurgery (The neurosurgeon must be dedicated to one hospital or a back-up call schedule must be available. If fewer than 25 emergency neurosurgical trauma operations are done in a year, and the neurosurgeon is dedicated only to that hospital, then a published back-up call list is not necessary.)
(d) obstetrics/gynecologic surgery;
(e) ophthalmic surgery;
(f) oral maxillofacial surgery;
(g) orthopaedics (dedicated to one hospital or a back-up call schedule must be available);
(h) plastic surgery;
(i) radiology;
(j) thoracic surgery; and
(k) urologic surgery.

(15) an emergency department which has at a minimum:

(a) a designated physician director who is board-certified or board prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine);
(b) 24-hour-per-day staffing by physicians physically present in the Emergency Department who:
   (i) are either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine or board-certified or eligible by the American Board of Surgery, American Board of Family Practice, or American Board of Internal Medicine). This physician must be board-certified within five years after successful completion of a residency;
   (ii) are designated members of the trauma team; and
   (iii) practice emergency medicine as their primary specialty.
(c) nursing personnel with experience in trauma care who continually monitor the trauma patient from hospital arrival to disposition to an intensive care unit, operating room, or patient care unit;
equipment for patients of all ages to include:

(i) airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators, pocket masks, and oxygen);

(ii) pulse oximetry;

(iii) end-tidal carbon dioxide determination equipment;

(iv) suction devices;

(v) electrocardiograph-oscilloscope-defibrillator with internal paddles;

(vi) apparatus to establish central venous pressure monitoring;

(vii) intravenous fluids and administration devices to include large bore catheters and intravenous infusion devices;

(viii) sterile surgical sets for airway control/cricothyrotomy, thoracotomy, vascular access, and thoracostomy, peritoneal lavage, and central line insertion;

(ix) apparatus for gastric decompression;

(x) 24-hour-per-day x-ray capability;

(xi) two-way communication equipment for communication with the emergency transport system;

(xii) skeletal traction devices, including capability for cervical traction;

(xiii) arterial catheters;

(xiv) thermal control equipment for patients; and

(xx) thermal control equipment for blood and fluids;

(xxi) rapid infuser system;

(xxii) Broselow tape;

(xxiii) sonography; and

(xxiv) doppler.

(16) an operating suite which is immediately available 24-hours-per-day and which has at a minimum:

(a) 24-hour-per-day immediate availability of in-house staffing;

(b) equipment for patients of all ages to include:

(i) thermal control equipment for patients;

(ii) thermal control equipment for blood and fluids;

(iii) 24-hour-per-day x-ray capability, including c-arm image intensifier;

(iv) endoscopes and bronchoscopes;

(v) craniotomy instruments; and

(vi) capability of fixation of long-bone and pelvic fractures;

(vii) rapid infuser system.

(17) a postanesthetic recovery room or surgical intensive care unit which has at a minimum:

(a) 24-hour-per-day in-house staffing by registered nurses;

(b) equipment for patients of all ages to include:
(i) capability for resuscitation and continuous monitoring of temperature, hemodynamics, and gas exchange;

(ii) capability for continuous monitoring of intracranial pressure;

(iii) pulse oximetry;

(iv) end-tidal carbon dioxide determination capability;

(v) thermal control equipment for patients; and

(vi) thermal control equipment for blood and fluids.

(18) an intensive care unit for trauma patients which has at a minimum:

(a) a designated surgical director of trauma patients;

(b) a physician on duty in the intensive care unit 24-hours-per-day or immediately from within the hospital as long as this physician is not the sole physician on-call for the emergency department;

(c) ratio of one nurse per two patients on each shift;

(d) equipment for patients of all ages to include:

(i) airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators, and pocket masks);

(ii) oxygen source with concentration controls;

(iii) cardiac emergency cart;

(iv) temporary transvenous pacemaker;

(v) electrocardiograph-oscilloscope-defibrillator with internal paddles;

(vi) cardiac output monitoring capability;

(vii) electronic pressure monitoring capability;

(viii) mechanical ventilator;

(ix) patient weighing devices;

(x) pulmonary function measuring devices;

(xi) temperature control devices; and

(xii) intracranial pressure monitoring devices.

(e) within 30 minutes of request, be able to perform blood gas measurements, hematocrit level, and chest x-ray studies.

(19) acute hemodialysis capability or utilization of a written transfer agreement;

(20) physician-directed burn center staffed by nursing personnel trained in burn care or a written transfer agreement with a burn center;

(21) acute spinal cord management capability or written transfer agreement with a hospital capable of caring for a spinal cord injured patient;

(22) radiological capabilities which has at a minimum:

(a) 24-hour-per-day in-house radiology technologist;

(b) 24-hour-per-day in-house computerized tomography technologist
(c) sonography;
(d) computed tomography;
(e) angiography; and
(f) resuscitation equipment to include: airway management and IV therapy.

(23) respiratory therapy services available in-house 24-hours-per-day;

(24) 24-hour-per-day clinical laboratory service which must include at a minimum:
(a) standard analysis of blood, urine, and other body fluids, including micro-sampling when appropriate;
(b) blood typing and cross-matching;
(c) coagulation studies;
(d) comprehensive blood bank or access to a community central blood bank with storage facilities;
(e) blood gases and pH determination; and
(f) microbiology.

(25) a rehabilitation service which provides at a minimum:
(a) a professional staff trained in rehabilitation care of critically injured patients;
(b) for major trauma patients, functional assessment and recommendation regarding short and long term rehabilitation needs within one week of the patients’ admission to the hospital or as soon as hemodynamically stable;
(c) full in-house rehabilitation service or a written transfer agreement with a rehabilitation facility accredited by the Commission on Accreditation of Rehabilitation Facilities;
(d) physical, occupational, speech therapies, and social services; and
(e) substance abuse evaluation and counseling capability.

(26) a performance improvement program, as outlined in the document “Performance Improvement Guidelines for North Carolina Trauma Centers,” dated January 1, 2002, which is incorporated by reference and includes:
(a) a state approved trauma registry whose data is submitted to the OEMS at least quarterly, which includes all trauma patients seen at the trauma center itself or those that are routinely diverted or transferred to its affiliated hospital;
(b) morbidity and mortality reviews to include all trauma deaths;
(c) trauma performance committee that meets at least quarterly, to include physicians, nurses, pre-hospital personnel, and a variety of other healthcare providers which reviews policies, procedures, and system issues and whose members or designee attend at least 50% of the regular meetings;
(d) multidisciplinary peer review committee that meets at least quarterly and includes physicians from trauma, neurosurgery, orthopaedics, emergency medicine, anesthesiology, and other specialty physicians as needed specific to the case, and the
trauma nurse coordinator/program manager and whose members or designee attend at least 50% of the regular meetings;

(e) identification of discretionary and non-discretionary audit filters;

(f) documentation and review of times and reasons for trauma related diversion of patients;

(g) documentation and review of response times for trauma surgeons (who must demonstrate 80% compliance), neurosurgeons, anesthesiologist or airway managers, and orthopaedists;

(h) appropriate trauma team notification;

(i) review of pre-hospital trauma care to include dead on arrivals; and

(j) review of times and reasons for transfer of injured patients.

(27) an outreach program to include:

(a) written transfer agreements to address the transfer and receipt of trauma patients;

(b) programs for physicians within the community and within the referral area (to include telephone and on-site consultations) about how to access the trauma center resources and refer patients within the system;

(c) development of a Regional Advisory Committee (RAC) as specified in Rule .3502 of this Subchapter;

(d) development of regional criteria for coordination of trauma care; and

(e) assessment of trauma system operations at the regional level.

(28) a program of injury prevention and public education to include:

(a) designation of a injury prevention coordinator; and

(b) outreach activities, program development, information resources and collaboration with existing national, regional, and state trauma programs.

(29) a documented continuing education program for staff physicians, nurses, allied health personnel, and community physicians to include:

(a) current board certification for neurosurgeons and orthopaedists;

(b) 20 hours of category I or II trauma related continuing medical education every two years for all attending general surgeons on the trauma service, orthopaedics, and neurosurgeons, with at least 50% of this being extramural;

(c) 20 hours of category I or II trauma related continuing medical education every two years for all emergency physicians, with at least 50% of this being extramural;

(d) Advanced Trauma Life Support (ATLS) completion for general surgeons on the trauma service and emergency physicians. Emergency physicians, if not boarded in emergency medicine, must be current in ATLS.

(e) 20 hours of category I trauma related continuing medical education (beyond in-house in-services) every two years for the trauma nurse coordinator/program manager;
(f) sixteen hours of trauma registry related or trauma related continuing education every two years, as deemed appropriate by the trauma nurse coordinator/program manager, for the trauma registrar;

(g) at least 80% compliance rate for 16 hours of trauma related continuing education (as approved by the trauma nurse coordinator/program manager) every two years related to trauma care for RN’s and LPN’s in transport programs, emergency departments, primary intensive care units, primary trauma floors, and other areas deemed appropriate by the trauma nurse coordinator/program manager; and

(h) sixteen contact hours of trauma related continuing education every two years for physician assistants and mid-level practitioners routinely caring for trauma patients.

**History Note:** Authority G.S. 131E-162;

### .3303 LEVEL III TRAUMA CENTER CRITERIA

To receive designation as a Level III Trauma Center, a hospital shall have the following:

1. a trauma program and a trauma service which have been operational for at least six months prior to application for designation;
2. membership in and inclusion of all trauma patient records in the North Carolina Trauma Registry for at least six months prior to submitting a Request for Proposal application;
3. a trauma medical director who is a board-certified general surgeon. The trauma medical director must:
   a. serve on the center’s trauma service;
   b. participate in providing care to patients with life-threatening or urgent injuries;
   c. participate in the North Carolina Chapter of the ACS’ Committee on Trauma;
   d. remain a current provider in the ACS’ Advanced Trauma Life Support Course in the provision of trauma related instruction to other health care personnel.
4. a designated trauma nurse coordinator (TNC)/program manager (TPM) who is a registered nurse, licensed by the North Carolina Board of Nursing;
5. a trauma registrar (TR) who has a working knowledge of medical terminology, is able to operate a personal computer, and has demonstrated the ability to extract data from the medical record;
6. a hospital department/division/section for general surgery, emergency medicine, anesthesiology, and orthopaedic surgery, with designated chair or physician liaison to the trauma program for each;
7. clinical capabilities in general surgery with a written posted call schedule that indicates who is on call for both trauma and general surgery. If a trauma surgeon is simultaneously on call at more
than one hospital, there must be a defined, posted trauma surgery back-up call schedule composed of surgeons credentialed to serve on the trauma panel. The trauma service director shall specify, in writing, the specific credentials that each back-up surgeon must have. These, at a minimum, must state that the back-up surgeon has surgical privileges at the trauma center and is boarded or eligible in general surgery (with board certification in general surgery within five years of completing residency).

(8) response of a trauma team to provide evaluation and treatment of a trauma patient 24-hours-per-day that includes:

(a) a trauma attending whose presence at the patient’s bedside within 30 minutes of notification is documented and who participates in therapeutic decisions and is present at all operative procedures;
(b) an emergency physician who is present in the emergency department 24-hours-per-day who is either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine) or board-certified or eligible by the American Board of Surgery, American Board of Family Practice, or American Board of Internal Medicine and practices emergency medicine as his primary specialty. This physician must be board-certified within five years after successful completion of a residency and serves as a designated member of the trauma team until the arrival of the trauma surgeon;
(c) an anesthesiologist who is on-call and promptly available after notification by the trauma team leader or an in-house CRNA under physician supervision, practicing in accordance with G.S. 90-171.20(7)e., pending the arrival of the anesthesiologist within 20 minutes of notification.

(9) a written credentialing process established by the department of surgery to approve attending general surgeons covering the trauma service. These surgeons must have a minimum of board certification in general surgery within five years of completing residency;

(10) standard written protocols relating to trauma care management must be formulated and routinely updated;

(11) Criteria to ensure team activation prior to arrival of trauma/burn patients, to include at a minimum, the following:

(a) shock;
(b) respiratory distress;
(c) airway compromise;
(d) unresponsiveness (Glasgow Coma Scale less than 8) with potential for multiple injuries; and
(e) gunshot wound to head, neck or torso.

(12) prompt surgical evaluation shall be considered based upon the following criteria:
(a) proximal amputations;
(b) burns meeting institutional transfer criteria;
(c) vascular compromise;
(d) crush to chest or pelvis;
(e) two or more proximal long bone fractures; and
(f) spinal cord injury.

(13) prompt surgical consults shall be considered based upon the following criteria:
(a) falls greater than 20 feet;
(b) pedestrian struck by motor vehicle;
(c) motor vehicle crash with;
   (i) ejection (includes motorcycle);
   (ii) rollover;
   (iii) speed greater than 40 mph; or
   (iv) death at the scene
(d) extremes of age, < 5 or > 70 years

(14) clinical capabilities (promptly available within 30 minutes if requested by the trauma team leader, with a posted on-call schedule) to include individuals credentialed in the following:
(a) orthopaedics; and
(b) radiology;

(15) an emergency department which has at a minimum;
(a) a designated physician director who is board-certified or board prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine);
(b) 24-hour-per-day staffing by physicians physically present in the Emergency Department who:
   (i) are either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine) or board-certified or eligible by the American Board of Surgery, American Board of Family Practice, or American Board of Internal Medicine. This physician must be board-certified within five years after successful completion of a residency;
   (ii) are designated members of a trauma team; and
   (iii) practice emergency medicine as their primary specialty.
(c) nursing personnel with experience in trauma care who continually monitor the trauma patient from hospital arrival to disposition to an intensive care unit, operating room, or patient care unit;
(d) resuscitation equipment for patients of all ages to include:
(i) airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators, pocket masks, and oxygen);
(ii) pulse oximetry;
(iii) end-tidal carbon dioxide determination equipment;
(iv) suction devices;
(v) electrocardiograph-oscilloscope-defibrillator with internal paddles;
(vi) apparatus to establish central venous pressure monitoring;
(vii) intravenous fluids and administration devices to include large bore catheters and intraosseous infusion devices;
(viii) sterile surgical sets for airway control/cricothyrotomy, thoracotomy, vascular access, and thoracostomy, peritoneal lavage, and central line insertion;
(ix) apparatus for gastric decompression;
(x) 24-hour-per-day x-ray capability;
(xi) two-way communication equipment for communication with the emergency transport system;
(xii) skeletal traction devices;
(xiii) thermal control equipment for patients; and
(xiv) thermal control equipment for blood and fluids;
(xv) rapid infuser system;
(xvi) Broselow tape; and
(xvii) doppler.

16 an operating suite which has at a minimum:
   (a) personnel available 24-hours-a-day, on-call and available within 30 minutes of notification unless in-house;
   (b) age specific equipment to include:
      (i) thermal control equipment for patients;
      (ii) thermal control equipment for blood and fluids;
      (iii) 24-hour-per-day x-ray capability, including c-arm image intensifier;
      (iv) endoscopes and bronchoscopes;
      (v) equipment for long bone and pelvic fixation; and
      (vi) rapid infuser system.

17 a postanesthetic recovery room or surgical intensive care unit which has at a minimum:
   (a) 24-hour-per-day availability of registered nurses within 30 minutes from inside or outside the hospital;
   (b) equipment for patients of all ages to include:
      (i) capability for resuscitation and continuous monitoring of temperature, hemodynamics, and gas exchange;
(ii) pulse oximetry;
(iii) end-tidal carbon dioxide determination;
(iv) thermal control equipment for patients; and
(v) thermal control equipment for blood and fluids.

(18) an intensive care unit for trauma patients which has at a minimum:

(a) a designated surgical director of trauma patients;
(b) a physician on duty in the intensive care unit 24-hours-per-day or immediately available from within the hospital (which may be a physician who is the sole physician on-call for the Emergency Department);
(c) equipment for patients of all ages to include:
   (i) airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators and pocket masks);
   (ii) oxygen source with concentration controls;
   (iii) cardiac emergency cart;
   (iv) temporary transvenous pacemaker;
   (v) electrocardiograph-oscilloscope-defibrillator;
   (vi) cardiac output monitoring capability;
   (vii) electronic pressure monitoring capability;
   (viii) mechanical ventilator;
   (ix) patient weighing devices;
   (x) pulmonary function measuring devices; and
   (xi) temperature control devices.
(d) within 30 minutes of request, be able to perform blood gas measurements, hematocrit level, and chest x-ray studies;

(19) physician-directed burn center staffed by nursing personnel trained in burn care or a written transfer agreement with a burn center;

(20) acute spinal cord management capability or written transfer agreement with a hospital capable of caring for a spinal cord injured patient;

(21) acute head injury management capability or written transfer agreement with a hospital capable of caring for a head injury;

(22) radiological capabilities which have at a minimum:

(a) radiology technologist available within 30 minutes of notification or documentation that procedures are available within 30 minutes;
(b) if the capability of computed tomography exists in the hospital, the computed tomography technologist must be available within 30 minutes of notification;
(c) sonography; and
(d) resuscitation equipment to include: airway management and IV therapy.
(23) respiratory therapy services on-call 24-hours-per-day;

(24) 24-hour-per-day clinical laboratory service which must include at a minimum:

(a) standard analysis of blood, urine, and other body fluids, including micro-sampling when appropriate;

(b) blood-typing and cross-matching;

(c) coagulation studies;

(d) comprehensive blood bank or access to a community central blood bank with storage facilities;

(e) blood gases and pH determination; and

(f) microbiology.

(25) full in-house rehabilitation service or written transfer agreement with a rehabilitation facility accredited by the Commission on Accreditation of Rehabilitation Facilities;

(26) physical therapy and social services.

(27) a performance improvement program, as outlined in the document “Performance Improvement Guidelines for North Carolina Trauma Centers”, dated January 1, 2002, which is incorporated by reference and includes:

(a) a state approved trauma registry whose data is submitted to the OEMS at least quarterly, which includes all trauma patients seen at the trauma center itself or those that are routinely diverted or transferred to its affiliated hospital;

(b) morbidity and mortality reviews to include all trauma deaths;

(c) trauma performance committee that meets at least quarterly, to include physicians, nurses, pre-hospital personnel, and a variety of other healthcare providers which reviews policies, procedures, and system issues and whose members or designee attend at least 50% of the regular meetings;

(d) multidisciplinary peer review committee that meets at least quarterly and includes physicians from trauma, emergency medicine, and other specialty physicians as needed specific to the case, and the trauma nurse coordinator/program manager and whose members or designee attend at least 50% of the regular meetings;

(e) identification of discretionary and non-discretionary audit filters;

(f) documentation and review of times and reasons for trauma related diversion of patients;

(g) documentation and review of response times for trauma surgeons (who must demonstrate 80% compliance) and orthopaedists;

(h) appropriate trauma team notification;

(i) documentation (unless in-house) and review of emergency department response times for anesthesiologists or airway managers and computerized tomography technologist;

(j) documentation of availability of the surgeon on-call for trauma, such that compliance is 90% or greater where there is no trauma surgeon back-up call schedule;
(k) trauma performance and multidisciplinary peer review committees may be incorporated together or included in other staff meetings as appropriate for the facility performance improvement rules;

(l) review of pre-hospital trauma care to include dead on arrivals; and

(m) review of times and reasons for transfer of injured patients.

(28) an outreach program to include:

(a) written transfer agreements to address the transfer and receipt of trauma patients;

(b) participation in a Regional Advisory Committee (RAC).

(29) coordination and/or participation in community prevention activities;

(30) a documented continuing education program for staff physicians, nurses, allied health personnel, and community physicians to include:

(a) 20 hours of category I or II trauma related continuing medical education every two years for all attending general surgeons on the trauma service, with at least 50% of this being extramural;

(b) 20 hours of category I or II trauma related continuing medical education every two years for all emergency physicians, with at least 50% of this being extramural;

(c) Advanced Trauma Life Support (ATLS) completion for general surgeons on the trauma service and emergency physicians. Emergency physicians, if not boarded in emergency medicine, must be current in ATLS;

(d) 20 hours of category I trauma related continuing medical education (beyond in-house in-services) every two years for the trauma nurse coordinator/program manager;

(e) sixteen hours of trauma registry related or trauma related continuing education every two years, as deemed appropriate by the trauma nurse coordinator/program manager, for the trauma registrar;

(f) at least an 80% compliance rate for 16 hours of trauma related continuing education (as approved by the trauma nurse coordinator/program manager) every two years related to trauma care for RN’s and LPN’s in transport programs, emergency departments, primary intensive care units, primary trauma floors, and other areas deemed appropriate by the trauma nurse coordinator/program manager; and

(g) sixteen hours of trauma registry related or trauma related continuing education every two years for physician assistants and mid-level practitioners routinely caring for trauma patients.

History Note: Authority G.S. 131E-162;
(a) For initial trauma center designation, the hospital shall request a consult visit by OEMS and have the consult within one year prior to submission of the RFP.

(b) A hospital interested in pursuing trauma center designation shall submit a letter of intent 180 days prior to the submission of an RFP to the OEMS. The letter shall also define the hospital’s primary trauma catchment area. Simultaneously, Level I or II applicants shall also demonstrate the need for the trauma center designation by submitting one original and three copies of documents which include, at a minimum:

1. the population to be served and the extent to which the population is under served for trauma care with the methodology used to reach this conclusion;

2. geographic considerations to include trauma primary and secondary catchment area and distance from other trauma centers; and

3. trauma patient volume and severity of injury for the facility for the 24-month period of time preceding the application. The trauma center shall show that its trauma service will be taking care of at least 200 trauma patients with an Injury Severity Score (ISS) greater than or equal to 15 during the first two-year period of its designation. This criteria shall be met without compromising the quality of care or cost effectiveness of any other designated Level I or II trauma center sharing all or part of its catchment area or by jeopardizing the existing trauma center’s ability to meet this same 200 patient minimum.

(c) Following receipt of the letter of intent by OEMS, any designated Level I or II trauma center(s) sharing all or part of the applicant’s catchment area must provide to OEMS a trauma registry download for the same two-year period used by the applicant. This download shall be provided within 30 days of the request of OEMS.

(d) OEMS shall review the regional data, from both the applicant and the existing trauma center(s), and ascertain the applicant’s ability to satisfy the justification of need information required in Paragraph (b) (1-3) of this Rule. Simultaneously, the applicant’s primary RAC shall be notified of the application and be provided the regional data as required in Paragraph (b) (1-3) of this Rule submitted by the applicant for review and comment. The RAC shall be given a minimum of 30 days to submit any concerns in writing for OEMS’ consideration. If no comments are received, OEMS shall proceed.

(e) OEMS shall notify the hospital in writing of its decision to allow submission of an RFP. The RAC shall also be notified so that any necessary changes in protocols can be considered.

(f) OEMS shall also notify the respective Board of County Commissioners in the applicant’s trauma primary catchment area of the request for initial designation to allow for comment.

(g) Hospitals desiring to be considered for initial trauma center designation shall complete and submit an original and five copies of bound, page-numbered RFP to the OEMS at least 90 days prior to the proposed site visit date.

(h) For Level I, II, and III applicants, the RFP shall demonstrate that the hospital meets the standards for the designation level applied for as found in Rule .3301, .3302, or .3303 of this Section and shall include information which supports compliance with the criteria contained in “North Carolina’s Trauma Center Criteria,” dated January 1, 2002, which is incorporated by reference.
(i) If OEMS does not recommend a site visit, the reasons shall be forwarded to the hospital in writing within 30 days of the decision. The hospital may reapply for designation within six months following the submission of an updated RFP. If the hospital fails to respond within six months, the hospital shall reapply following the process outlined in Paragraphs (a) – (h) of this Rule.

(j) If the OEMS recommends the hospital for a site visit, the hospital shall be notified within 30 days and the site visit shall be conducted within six months of the recommendation. The site visit shall be scheduled on a date mutually agreeable to the hospital and the OEMS.

(k) Any in-state reviewer for a Level I or II visit (except the OEMS representatives) shall be from outside the planning region in which the hospital is located. The composition of a Level I or II state site survey team shall be as follows:

1. one out-of-state Fellow of the ACS, experienced as a site surveyor, who shall be designated the primary reviewer.
2. one emergency physician who currently works in a designated trauma center, is a member of the North Carolina College of Emergency Physicians, and is boarded in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine),
3. one in-state trauma surgeon who is a member of the North Carolina Committee on Trauma;
4. one out-of-state trauma nurse coordinator/program manager;
5. the medical director of the OEMS; and
6. the Hospitals Specialist of the OEMS.

(l) All site team members for a Level III visit shall be from in state, and all (except for the OEMS representatives) shall be from outside the planning region in which the hospital is located. The composition of a Level III state site survey team shall be as follows:

1. one Fellow of the ACS, who is a member of the North Carolina Committee on Trauma and shall be designated the primary reviewer;
2. one emergency physician who currently works in a designated trauma center, is a member of the North Carolina College of Emergency Physicians, and is boarded in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine).
3. a trauma nurse coordinator/program manager;
4. the medical director of the OEMS; and
5. the Hospitals Specialist of the OEMS.

(m) On the day of the site visit, the hospital shall make available all required patient medical charts.

(n) A post conference report based on the consensus of the site review team will be given verbally during a summary conference. A written consensus report will be completed, to include a peer review report, by the primary reviewer and submitted to OEMS within 30 days of the site visit.
(o) The report of the site survey team and the staff recommendations shall be reviewed by the State Emergency Medical Services Advisory Council at its next regularly scheduled meeting which is more than 45 days following the site visit. Based upon the site visit report and the staff recommendation, the State Emergency Medical Services Advisory Council shall recommend to the OEMS that the request for trauma center designation be approved or denied.

(p) All criteria defined in Rule .3301, .3302 or .3303 of this Section shall be met for initial designation at the level requested. Initial designation shall not be granted if deficiencies exist.

(q) Hospitals with a deficiency(ies) may be given up to 12 months to demonstrate compliance. Satisfaction of deficiency(ies) may require an additional site visit. If compliance is not demonstrated within the time period, to be defined by OEMS, the hospital shall be required to submit a new application and updated RFP and follow the process outlined in Paragraphs (a) – (h) of this Rule.

(r) The final decision regarding trauma center designation shall be rendered by the OEMS.

(s) The hospital shall be notified, in writing, of the State Emergency Medical Services Advisory Council’s and OEMS’ final recommendation within 30 days of the Advisory Council meeting.

(t) If a trauma center changes its trauma program administrative structure (such that the trauma service, trauma medical director, trauma nurse coordinator/program manager and/or trauma registrar are relocated on the hospital’s organizational chart) at any time, it shall notify OEMS of this change in writing within 30 days of the occurrence.

(u) Initial designation as a trauma center is valid for a period of three years.

History Note: Authority G.S. 131E-162; 143-509(3); Temporary Adoption Eff. January 1, 2002.

.3305 RENEWAL DESIGNATION PROCESS

(a) One of two options may be utilized to achieve trauma center renewal:

(1) Undergo a site visit conducted by OEMS to obtain a four-year renewal designation; or

(2) Undergo a verification visit arranged by the ACS, in conjunction with OEMS, to obtain a three year renewal designation;

(b) For hospitals choosing option number (a)(1) of this Rule:

(1) Prior to the end of the designation period, the OEMS shall forward to the hospital an RFP for completion. The hospital shall, within 10 days of receipt of the RFP, define for OEMS the trauma center’s trauma primary catchment area. Upon this notification, OEMS shall notify the respective Board of County Commissioners in the applicant’s trauma primary catchment area of the request for renewal to allow for comment.

(2) Hospitals seeking a renewal of trauma center designation shall complete and submit an original and five copies of a bound, page-numbered RFP as directed by the OEMS to the OEMS and the specified site surveyors at least 30 days prior to the site visit. The RFP shall include information
that supports compliance with the criteria contained in Rule .3301, .3302, or .3303 of this Section as relates to the trauma center’s level of designation.

(3) All criteria defined in Rule .3301, .3302 or .3303 of this Section, as relates to the trauma center’s level of designation, shall be met for renewal designation.

(4) A site visit shall be conducted within 120 days prior to the end of the designation period. The site visit shall be scheduled on a date mutually agreeable to the hospital and the OEMS.

(5) The composition of a Level I or II site survey team shall be the same as that specified in Rule .3304(k) of this Section.

(6) The composition of a Level III site survey team shall be the same as that specified in Rule .3304(l) of this Section.

(7) On the day of the site visit, the hospital shall make available all required patient medical charts.

(8) A post conference report based on consensus of the site review team will be given verbally during the summary conference. A written consensus report will be completed, to include a peer review report, by the primary reviewer and submitted to OEMS within 30 days of the site visit.

(9) The report of the site survey team and a staff recommendation shall be reviewed by the State Emergency Medical Services Advisory Council at its next regularly scheduled meeting which is more than 45 days following the site visit. Based upon the site visit report and the staff recommendation, the State Emergency Medical Services Advisory Council shall recommend to the OEMS that the request for trauma center renewal be approved or denied.

(10) Hospitals with a deficiency(ies) have two weeks to provide documentation to demonstrate compliance. If the hospital has a deficiency that cannot be corrected in two weeks, the hospital, instead of a renewal, may be given a time period (up to 12 months) to demonstrate compliance and undergo a focused review, which may require an additional site visit. If compliance is not demonstrated within the time period, as specified by OEMS, the trauma center designation shall not be renewed. To become redesignated, the hospital shall be required to submit an updated RFP and follow the initial applicant process outlined in Rule .3304 of this Section.

(11) The final decision regarding trauma center renewal shall be rendered by the OEMS.

(12) The hospital shall be notified in writing of the State Emergency Medical Services Advisory Council’s and OEMS’ final recommendation within 30 days of the Advisory Council meeting.

(13) The four-year renewal date that may be eventually granted will not be extended due to the focused review period.

(14) Hospitals in the process of satisfying contingencies placed on them prior to December 31, 2001, shall be evaluated based on the rules that were in effect at the time of their renewal visit.

(c) For hospitals choosing option number (a)(2) of this Rule:

(1) At least six months prior to the end of the trauma center’s designation period, the trauma center must notify the OEMS of its intent to undergo an ACS verification visit. It must simultaneously define in writing to the OEMS its trauma primary catchment area. Trauma centers choosing this
option must then comply with all the ACS’ verification procedures, as well as any additional state
criteria as outlined in Rule .3301, .3302 or .3303, as apply to their level of designation.

(2) If a trauma center currently using the ACS’ verification process chooses not to renew using this
process, it must notify the OEMS at least six months prior to the end of its state trauma center
designation period of its intention to exercise option (a)(1) of this Rule.

(3) When completing the ACS’ documentation for verification, the trauma center must simultaneously
submit two identical copies to OEMS. The trauma center must simultaneously complete
documents supplied by OEMS to verify compliance with additional North Carolina criteria (i.e.
criteria that exceed the ACS criteria) and forward these to OEMS and the ACS.

(4) The OEMS shall notify the Board of County Commissioners within the trauma center’s trauma
primary catchment area of the trauma center’s request for renewal to allow for comments.

(5) The trauma center must make sure the site visit is scheduled to ensure that the ACS’ final written
report, accompanying medical record reviews and cover letter are received by OEMS at least 30
days prior to a regularly scheduled State Emergency Medical Services Advisory Council meeting
to ensure that the trauma center’s state designation period does not terminate without
consideration by the State Emergency Medical Services Advisory Council.

(6) The composition of the Level I and Level II site team must be as specified in Rule .3304(k) of this
Section, except that both the required trauma surgeons and the emergency physician may be from
out-of-state. Neither North Carolina Committee on Trauma nor North Carolina College of
Emergency Physician membership will be required of the surgeons or emergency physician,
respectively, if from out-of-state.

(7) The composition of the Level III site team must be as specified in Rule .3304(l) of this Section,
except that the trauma surgeon, emergency physician, and trauma nurse coordinator/program
manager may be from out-of-state. Neither North Carolina Committee on Trauma nor North
Carolina College of Emergency Physician membership will be required of the surgeon or
emergency physician, respectively, if from out-of-state.

(8) All state trauma center criteria must be met as defined in Rule .3301, .3302, and 3303, for renewal
of state designation. An ACS’ verification is not required for state designation. An ACS’
verification does not ensure a state designation.

(9) The final written report issued by the ACS’ verification review committee, the accompanying
medical record reviews (from which all identifiers may be removed) and cover letter must be
forwarded to OEMS within 10 working days of its receipt by the trauma center seeking renewal.

(10) The written reports from the ACS and the OEMS staff recommendation shall be reviewed by the
State Emergency Medical Services Advisory Council at its next regularly scheduled meeting. The
State EMS Advisory Council shall recommend to OEMS that the request for trauma center
renewal be approved or denied.
(11) The hospital shall be notified in writing of the State Emergency Medical Services Advisory Council’s and OEMS’ final recommendation within 30 days of the Advisory Council meeting.

(12) Hospitals with contingencies, as the result of a deficiency(ies), as determined by OEMS, may undergo a focused review (to be conducted by the OEMS) whereby the trauma center may be given up to 12 months to demonstrate compliance. Satisfaction of contingency(ies) may require an additional site visit. If compliance is not demonstrated within the time period, as specified by OEMS, the trauma center designation shall not be renewed. To become redesignated, the hospital shall be required to submit a new RFP and follow the initial applicant process outlined in Rule .3304 of this Section.

History Note: Authority G.S. 131E-162; 143-509(3);
.3401 DENIAL, FOCUSED REVIEW, VOLUNTARY WITHDRAWAL, OR REVOCATION OF TRAUMA CENTER DESIGNATION
(a) The OEMS may deny the initial or renewal designation (without first allowing a focused review) of a trauma center for any of the following reasons:
   (1) failure to comply with G.S. 131E-162 and the rules adopted under that article; or
   (2) attempting to obtain a trauma center designation through fraud or misrepresentation; or
   (3) failure to comply with G.S. 131E-162 and the rules adopted under that article endangers the health, safety or welfare of patients cared for in the hospital; or
   (4) repetition of contingencies placed on the trauma center in previous site visits.
(b) When a trauma center is required to have a focused review, an option only for a trauma center seeking renewal, it must be able to demonstrate compliance with the provisions of G.S.131E-162 and the rules adopted under that article within one year or less as required and delineated in writing by OEMS.
(c) The OEMS may revoke a trauma center designation at any time or deny a request for renewal of designation, whenever the OEMS finds that the trauma center has failed to comply with the provisions of G.S. 131E-162 and the rules adopted under that article; and
   (1) it is not probable that the trauma center can remedy the deficiencies within one year or less; or
   (2) although the trauma center may be able to remedy the deficiencies within a reasonable period of time, it is not probable that the trauma center shall be able to remain in compliance with designation rules for the foreseeable future; or
   (3) the trauma center fails to meet the requirements of a focused review; or
   (4) failure to comply endangers the health, safety or welfare of patients cared for in the trauma center.
(d) The OEMS shall give the trauma center written notice of revocation. This notice shall be given personally or by certified mail and shall set forth:
   (1) the factual allegations;
   (2) the statutes or rules alleged to be violated; and
   (3) notice of the hospital’s right to a contested case hearing on the amendment of the designation.
(e) Focused review is not a procedural prerequisite to the revocation of a designation pursuant to Subparagraph (d) of this Rule.
(f) With the OEMS’ approval, a trauma center may voluntarily withdraw its designation for a maximum of one year by submitting a written request. This request shall include the reasons for withdrawal and a plan for resolution of the issues. To reactivate the designation, the facility shall provide written documentation of compliance that is acceptable to the OEMS. Voluntary withdrawal shall not affect the original expiration date of the trauma center’s designation.
(g) If the trauma center fails to resolve the issues which resulted in a voluntary withdrawal within the specified time period for resolution, the OEMS may revoke the trauma center designation.

(h) In the event of a revocation or voluntary withdrawal, the OEMS shall provide written notification to all hospitals and Emergency Medical Services providers within the trauma center’s defined trauma primary catchment area. The OEMS shall provide written notification to same if, and when, the voluntary withdrawal reactivates to full designation.

History Note: Authority G.S. 131E-162;

.3402 PROCEDURES FOR APPEAL OF DENIAL, FOCUSED REVIEW OR REVOCATION

Appeal of denial or revocation of a trauma center designation shall follow the law regarding contested cases found in G.S. 150B.

History Note: Authority G.S. 131E-162;

.3403 MISREPRESENTATION OF DESIGNATION

(a) Hospitals shall not represent themselves as a trauma center unless they are currently designated by the Department pursuant to Section .3300 of this Subchapter.

(b) Designation applies only to the hospital that submitted the RFP and underwent the formal site survey and does not extend to its satellite facilities or affiliates.

History Note: Authority G.S. 131E-162;
.3501 STATE TRAUMA SYSTEM
(a) The state trauma system consists of regional plans, policies, guidelines and performance improvement initiatives by the RACs and monitored by the OEMS.
(b) The OEMS shall require that each hospital select a Regional Advisory Committee (RAC). If a hospital does not exist in a given county, the EMS system for the county shall select the RAC. Each RAC shall include at least one Level I or II trauma center. Any hospital changing its affiliation shall report the change in writing to the OEMS within 30 days of the date of the change.
(c) The OEMS shall notify each RAC of its hospital and county membership.

History Note: Authority G.S. 131E-162;

.3502 REGIONAL TRAUMA SYSTEM PLAN
(a) A Level I and/or II trauma center shall facilitate development of and provide RAC staff support which shall include, at a minimum, the following:
   (1) the trauma medical director(s) from the Lead RAC Agency;
   (2) trauma nurse coordinator(s) or program manager(s) from the Lead RAC Agency;
(b) The RAC membership shall include, at a minimum, the following:
   (1) the trauma medical director(s) and the trauma nurse coordinator(s) or program manager(s) from the Lead RAC Agency;
   (2) if on staff, an outreach coordinator(s) or designee(s), as well as an identified RAC registrar or designee(s) from the Lead RAC Agency;
   (3) a senior level hospital administrator;
   (4) an emergency physician;
   (5) an Emergency Medical Services representative
   (6) a representative from each hospital participating in the RAC;
   (7) community representatives;
   (8) an EMS System physician involved in medical oversight.
(c) The RAC shall develop and submit a plan, within one year of notification of the RAC membership, or for existing RACs within six months of the implementation date of this rule, to the OEMS containing at a minimum:
   (1) organizational structure to include the roles of the members of the system;
   (2) goals and objectives to include the orientation of the providers to the regional system;
(3) RAC membership list, rules of order, terms of office, meeting schedule (held at a minimum of two times per year);
(4) copies of documents and information required by the OEMS as defined in Rule .3503 of this Section;
(5) system evaluation tools to be utilized;
(6) written documentation of regional support for the plan; and
(7) performance improvement activities to include the RAC Registry.

d) The RAC shall submit to the OEMS an annual progress report that assesses compliance with the regional trauma system plan and specifies any updates to the plan.

e) Upon OEMS receipt of a letter of intent for initial Level I or II trauma center designation pursuant to Rule .3304 (b) of this Subchapter, the applicant’s RAC shall be provided the applicant’s data from OEMS to review and comment. This data which should demonstrate the need for the trauma center designation must include, at a minimum:

   (1) the population to be served and the extent to which the population is under served for trauma care with the methodology used to reach this conclusion;
   (2) geographic considerations to include trauma primary and secondary catchment area and distance from other trauma centers; and
   (3) trauma patient volume and severity of injury for the facility for the twenty-four month period of time preceding the application. The trauma center shall show that its trauma service will be taking care of at least 200 trauma patients with an Injury Severity Score (ISS) greater than or equal to 15 during the first two-year period of its designation. This criteria shall be met without compromising the quality of care or cost effectiveness of any other designated Level I or II trauma center sharing all or part of its catchment area or by jeopardizing the existing trauma center’s ability to meet this same 200 patient minimum.

(f) The RAC has 30 days to comment on the request for initial designation.

(g) The RAC shall also be notified of the OEMS approval to submit an RFP so that necessary changes in protocols can be considered.

History Note: Authority G.S. 131E-162; Temporary Adoption Eff. January 1, 2002.

.3503 REGIONAL TRAUMA SYSTEM POLICY DEVELOPMENT

The RAC shall oversee the development, implementation, and evaluation of the regional trauma system to include:

(1) public information and education programs to include system access and injury prevention;
(2) written trauma systems guidelines to address the following:
   (A) regional communications;
   (B) triage;
(C) treatment at the scene and in the pre-hospital, inter-hospital, and emergency department
treatment to and shall include: guidelines to facilitate the rapid assessment and initial
resuscitation of the severely injured patient, including primary and secondary survey.
Criteria addressing management during transport should include continued assessment
and management of airway, cervical spine, breathing, circulation, neurologic and
secondary parameters, communication and documentation.

(D) transport to determine the appropriate the appropriate mode of transport and level of care
required to transport, considering patient condition, requirement for trauma center
resources, family requests and capability of transferring entity.

(E) bypass procedures which define:
   (i) circumstances and criteria for bypass decisions;
   (ii) time and distance criteria; and
   (iii) mode of transport which bypasses closer facilities.

(F) scene and inter-hospital diversion procedures which shall include delineation of specific
factors such as hospital census and/or acuity, physician availability, staffing issues,
disaster status, or transportation which would require routing of a patient to an other
trauma center.

(3) transfer agreements (to include those with other hospitals, as well as specialty care facilities such as
burn, pediatrics, spinal cord and rehabilitation) which shall outline mutual understandings between
facilities to transfer/accept certain patients. These shall specify responsible parties, documentation
requirements and minimum care requirements.

(4) a performance improvement plan which includes:
   (A) a performance improvement committee of the RAC;
       (i) whose membership only includes health care professionals, as defined and protected
           by G.S. 131E-95 or in G.S. 90-21.222A;and
           (ii)continuously evaluates the regional trauma system through structured review of
                process of care and outcomes.
   (B) a RAC registry database, once operational, that reports quarterly or as requested by the
       OEMS.

\textit{History Note:Authority G.S. 131E-162;}

\textit{Temporary Adoption Eff. January 1, 2002.}
.3601 INCORPORATION BY REFERENCE
The following documents contain information and guidelines required for the development and function of EMS Systems and are incorporated herein by reference including subsequent amendments and editions. Copies of these are available free of charge from the North Carolina Office of Emergency Medical Services, Division of Facility Services, Department of Health and Human Services, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, telephone (919) 733-2285. Documents may also be downloaded free of charge at www.ncems.org.

(1) “North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection”;
(2) “North Carolina Board of Nursing: Guidelines for the Selection and Performance of the Emergency Medical Services Nurse Liaison”; and
(3) “Performance Improvement Guidelines for North Carolina Trauma Centers”

History Note: Authority G.S. 131E-155.1(b); 131E-156(b); 131E-159(a); 131E-162; 143-508(b);