TITLE 10 – DEPARTMENT OF HEALTH AND HUMAN SERVICES

CHAPTER 3 – FACILITY SERVICES

SUBCHAPTER 3D – OFFICE OF EMERGENCY MEDICAL SERVICES REGULATIONS

SECTION .3200 – TRAUMA SYSTEM DEFINITIONS

.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.

(16) "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.

(17) "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.

(18) "OEMS" means Office of Emergency Medical Services.

(19) "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.

(20) "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.

(21) "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.

(22) "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.

(23) "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.

(24) "Transfer Agreement" means a formal written agreement between two agencies specifying the appropriate transfer of patient populations delineating the conditions and methods of transfer.

(25) "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.

(26) "Trauma Center Criteria" means essential or desirable characteristics to define Level I, II or III trauma centers.

(27) "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.

(28) "Trauma Minimum Data Set" means the basic data required of all hospitals for submission to the trauma statewide database.

(29) "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).

(30) "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.

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TITLE 10 – DEPARTMENT OF HEALTH AND HUMAN SERVICES

CHAPTER 3 – FACILITY SERVICES

SUBCHAPTER 3D – OFFICE OF EMERGENCY MEDICAL SERVICES REGULATIONS

SECTION .3300 – TRAUMA CENTER STANDARDS AND APPROVAL

.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

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;

(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) 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) opthalmic 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.

(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 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 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.

(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, 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 a 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) opthalmic 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;

(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 large bore catheters and introsseous 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;

(xix) 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;*
Temporary Adoption Eff. January 1, 2002.

.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 specifiy, 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 rubes, 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;*
Temporary Adoption Eff. January 1, 2002.

.3304 INITIAL DESIGNATION PROCESS

(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 emegency 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);*
Temporary Adoption Eff. January 1, 2002.

TITLE 10 – DEPARTMENT OF HEALTH AND HUMAN SERVICES

CHAPTER 3 – FACILITY SERVICES

SUBCHAPTER 3D – OFFICE OF EMERGENCY MEDICAL SERVICES REGULATIONS

SECTION .3400 – TRAUMA CENTER DESIGNATION ENFORCEMENT

.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;*
Temporary Adoption Eff. January 1, 2002.

.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;*
Temporary Adoption Eff. January 1, 2002.

.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;*
Temporary Adoption Eff. January 1, 2002.

TITLE 10 – DEPARTMENT OF HEALTH AND HUMAN SERVICES

CHAPTER 3 – FACILITY SERVICES

SUBCHAPTER 3D – OFFICE OF EMERGENCY MEDICAL SERVICES REGULATIONS

SECTION .3500 – TRAUMA SYSTEM DESIGN

.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;*
Temporary Adoption Eff. January 1, 2002.

.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.

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

TITLE 10 – DEPARTMENT OF HEALTH AND HUMAN SERVICES

CHAPTER 3 – FACILITY SERVICES

SUBCHAPTER 3D – OFFICE OF EMERGENCY MEDICAL SERVICES REGULATIONS

SECTION .3600 - FORMS

.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);
Temporary Rules Eff. January 1, 2002.