10A NCAC 13P .0904 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 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 that include:

(1) The population to be served and the extent to which the population is underserved 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) Evidence the Trauma Center will admit at least 1200 trauma patients yearly or show that its trauma service will be taking care of at least 240 trauma patients with an Injury Severity Score (ISS) greater than or equal to 15 yearly. 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 240-patient minimum.

(c) The hospital must be actively participating in the state Trauma Registry and submit data to the OEMS at least weekly and include all the Trauma Center's trauma patients as defined in Rule .0102(68) of this Subchapter who are either diverted to an affiliated hospital, admitted to the Trauma Center for greater than 24 hours from an ED or hospital, die in the ED, are DOA or are transferred from the ED to the OR, ICU, or another hospital (including transfer to any affiliated hospital) a minimum of 12 months prior to application.

(d) OEMS shall review the regional Trauma Registry 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 Subparagraphs (b)(1) through (3) of this Rule. Simultaneously, the applicant's primary RAC shall be notified by the OEMS of the application and be provided the regional data as required in Subparagraphs (b)(1) through (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 by the OEMS so that any necessary changes in protocols can be considered.

(f) OEMS shall 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 one paper copy with signatures and an electronic copy of the 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 Rules .0901, .0902, or .0903 of this Section.

(i) If OEMS does not recommend a site visit based upon failure to comply with Rules .0901, .0902, or .0903, 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) through (h) of this Rule.

(j) If the OEMS recommends the hospital for a site visit, the OEMS shall notify the hospital within 30 days and the site visit shall be conducted within six months of the recommendation. The site visit date shall be 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 works in a trauma center, is a member of the American 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 and one in-state trauma nurse coordinator/program manager; and

(5) OEMS Staff.

(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; and

(4) OEMS Staff.

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

(n) The lead researcher of the site review team shall give a verbal post-conference report representing a consensus of the site review team at the summary conference. A written consensus report shall 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 .0901, .0902, or .0903 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) shall 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 submit a new application and updated RFP and follow the process outlined in Paragraphs (a) through (h) of this Rule.

(r) The final decision regarding Trauma Center designation shall be rendered by the OEMS.

(s) The OEMS shall notify the hospital 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 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);*
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Eff. April 1, 2003;
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