

1 10A NCAC 13P .0904 is proposed for amendment as follows:

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3 **10A NCAC 13P .0904 INITIAL DESIGNATION PROCESS**

4 (a) For initial Trauma Center designation, the hospital shall request a consult visit by OEMS and the consult shall
5 occur within one year prior to submission of the RFP.

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

- 10 (1) the population to be served and the extent that the population is underserved for trauma care with
11 the methodology used to reach this conclusion;
- 12 (2) geographic considerations, to include trauma primary and secondary catchment area and distance
13 from other Trauma Centers; and
- 14 (3) evidence the Trauma Center will admit at least 1200 trauma patients ~~yearly~~ annually or show that
15 its trauma service will be taking care of at least 240 trauma patients with an ISS greater than or equal
16 to 15 yearly. These criteria shall be met without compromising the quality of care or cost
17 effectiveness of any other designated Level I or II Trauma Center sharing all or part of its catchment
18 area or by jeopardizing the existing Trauma Center's ability to meet this same 240-patient minimum.

19 (c) The hospital shall be participating in the State Trauma Registry as defined in Rule ~~.0102(61)~~ .0102 of this
20 Subchapter, and submit data to the OEMS weekly a minimum of 12 months prior to application that includes all the
21 Trauma Center's trauma patients as defined in Rule ~~.0102(59)~~ .0102 of this Subchapter who are:

- 22 (1) diverted to an affiliated hospital;
- 23 (2) admitted to the Trauma Center for greater than 24 hours from an ED or hospital;
- 24 (3) die in the ED;
- 25 (4) are DOA; or
- 26 (5) are transferred from the ED to the OR, ICU, or another hospital (including transfer to any affiliated
27 hospital).

28 (d) OEMS shall review the regional Trauma Registry data from both the applicant and the existing trauma center(s),
29 and ascertain the applicant's ability to satisfy the justification of need information required in ~~Subparagraphs (b)(1)~~
30 ~~through (3)~~ Paragraph (b) of this Rule. The OEMS shall notify the applicant's primary RAC of the application and
31 provide the regional data submitted by the applicant in ~~Subparagraphs (b)(1) through (3)~~ Paragraph (b) of this Rule
32 for review and comment. The RAC shall be given 30 days to submit written comments to the OEMS.

33 (e) OEMS shall notify the respective Board of County Commissioners in the applicant's primary catchment area of
34 the request for initial designation to allow for comment during the same 30 day comment period.

35 (f) OEMS shall notify the hospital in writing of its decision to allow submission of an RFP. If approved, the RAC
36 and Board of County Commissioners in the applicant's primary catchment area shall also be notified by the OEMS
37 that an RFP will be submitted.

1 (g) Once the hospital is notified that an RFP will be accepted, the hospital shall complete and submit an electronic
2 copy of the completed RFP with signatures to the OEMS at least 45 days prior to the proposed site visit date.

3 (h) The RFP shall demonstrate that the hospital meets the standards for the designation level applied for as found in
4 Rule .0901 of this Section.

5 (i) If OEMS does not recommend a site visit based upon failure to comply with Rule .0901 of this Section, the OEMS
6 shall send the written reasons to the hospital within 30 days of the decision. The hospital may reapply for designation
7 within six months following the submission of an updated RFP. If the hospital fails to respond within six months, the
8 hospital shall reapply following the process outlined in Paragraphs (a) through (h) of this Rule.

9 (j) If after review of the RFP, the OEMS recommends the hospital for a site visit, the OEMS shall notify the hospital
10 within 30 days and the site visit shall be conducted within six months of the recommendation. The hospital and the
11 OEMS shall agree on the date of the site visit.

12 (k) Except for OEMS representatives, any in-state reviewer for a Level I or II visit shall be from outside the local or
13 adjacent RAC, unless mutually agreed upon by the OEMS and the trauma center seeking designation where the
14 hospital is located. The composition of a Level I or II state site survey team shall be as follows:

15 (1) one out-of-state trauma surgeon who is a Fellow of the ACS, experienced as a site surveyor, who
16 shall be the primary reviewer;

17 (2) one in-state emergency physician who currently works in a designated trauma center, is a member
18 of the American College of Emergency Physicians or American Academy of Emergency Medicine,
19 and is boarded in emergency medicine by the American Board of Emergency Medicine or the
20 American Osteopathic Board of Emergency Medicine;

21 (3) one in-state trauma surgeon who is a member of the North Carolina Committee on Trauma;

22 (4) for Level I designation, one out-of-state trauma program manager with an equivalent license from
23 another state;

24 (5) for Level II designation, one in-state program manager who is licensed to practice ~~professional~~
25 nursing in North Carolina in accordance with the Nursing Practice Act, Article 9A, Chapter 90 of
26 the North Carolina General Statutes; and

27 (6) OEMS Staff.

28 (l) All site team members for a Level III visit shall be from in-state, and, except for the OEMS representatives, shall
29 be from outside the local or adjacent RAC where the hospital is located. The composition of a Level III state site
30 survey team shall be as follows:

31 (1) one trauma surgeon who is a Fellow of the ACS, who is a member of the North Carolina Committee
32 on Trauma and shall be the primary reviewer;

33 (2) one emergency physician who currently works in a designated trauma center, is a member of the
34 North Carolina College of Emergency Physicians or American Academy of Emergency Medicine,
35 and is boarded in emergency medicine by the American Board of Emergency Medicine or the
36 American Osteopathic Board of Emergency Medicine;

1 (3) one trauma program manager who is licensed to practice ~~professional~~ nursing in North Carolina in
 2 accordance with the Nursing Practice Act, Article 9A, Chapter 90 of the North Carolina General
 3 Statutes; and

4 (4) OEMS Staff.

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

6 (n) The primary reviewer of the site review team shall give a verbal post-conference report representing a consensus
 7 of the site review team. The primary reviewer shall complete and submit to the OEMS a written consensus report
 8 within 30 days of the site visit.

9 (o) The report of the site survey team and the staff recommendations shall be reviewed by the State Emergency
 10 Medical Services Advisory Council at its next regularly scheduled meeting following the site visit. Based upon the
 11 site visit report and the staff recommendation, the State Emergency Medical Services Advisory Council shall
 12 recommend to the OEMS that the request for Trauma Center designation be approved or denied.

13 (p) All criteria defined in Rule .0901 of this Section shall be met for initial designation at the level requested.

14 (q) Hospitals with a deficiency(ies) resulting from the site visit shall be given up to 12 months to demonstrate
 15 compliance. Satisfaction of deficiency(ies) may require an additional site visit. The need for an additional site visit ~~is~~
 16 shall be determined on a case-by-case basis based on the type of deficiency. If compliance is not demonstrated within
 17 the time period set by OEMS, the hospital shall submit a new application and updated RFP and follow the process
 18 outlined in Paragraphs (a) through (h) of this Rule.

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

20 (s) The OEMS shall notify the hospital in writing of the State Emergency Medical Services Advisory Council's and
 21 OEMS' final recommendation within 30 days of the Advisory Council meeting.

22 (t) If a trauma center changes its trauma program administrative structure such that the trauma service, trauma Medical
 23 Director, trauma program manager, or trauma registrar are relocated on the hospital's organizational chart at any time,
 24 it shall notify OEMS of this change in writing within 30 days of the occurrence.

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

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 27 *History Note: Authority G.S. 131E-162; 143-508(d)(2);*
 28 *Temporary Adoption Eff. January 1, 2002;*
 29 *Eff. April 1, 2003;*
 30 *Amended Eff. January 1, 2009;*
 31 *Readopted Eff. January 1, ~~2017~~ 2017;*
 32 *Amended Eff. July 1, 2018.*