

1 10A NCAC 13P .0904 is readopted with changes as published in 30:24 NCR, pp. 2558-2606, as follows:

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

20 (c) The hospital ~~must~~ shall be ~~actively~~ participating in the ~~state~~ State Trauma Registry as defined in Rule .0102(61)  
21 of this Subchapter, and submit data to the OEMS at least weekly a minimum of 12 months prior to application ~~and~~  
22 ~~include~~ that includes all the Trauma Center's trauma patients as defined in Rule ~~.0102(68)~~ .0102(59) of this  
23 Subchapter who ~~are~~ are:

- 24 (1) ~~either~~ diverted to an affiliated ~~hospital,~~ hospital;
- 25 (2) admitted to the Trauma Center for greater than 24 hours from an ED or ~~hospital,~~ hospital;
- 26 (3) die in the ~~ED,~~ ED;
- 27 (4) are ~~DOA~~ [DOA, DOA] or
- 28 (5) are transferred from the ED to the OR, ICU, or another hospital (including transfer to any  
29 affiliated ~~hospital) a minimum of 12 months prior to application.~~ hospital).

30 (d) OEMS shall review the regional Trauma Registry ~~data,~~ data from both the applicant and the existing trauma  
31 center(s), and ascertain the applicant's ability to satisfy the justification of need information required in  
32 Subparagraphs (b)(1) through (3) of this Rule. ~~Simultaneously,~~ The OEMS shall notify the applicant's primary RAC  
33 ~~shall be notified by the OEMS~~ of the application and ~~be provided~~ provide the regional data submitted by the  
34 applicant as required in Subparagraphs (b)(1) through (3) of this Rule submitted by the applicant for review and  
35 comment. The RAC shall be given ~~a minimum of 30 days to submit any concerns in writing for OEMS'~~  
36 ~~consideration.~~ written comments to the OEMS. ~~If no comments are received, OEMS shall proceed.~~

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

3 ~~(f)~~ (f) OEMS shall notify the hospital in writing of its decision to allow submission of an RFP. ~~The~~ If approved, the  
 4 RAC and Board of County Commissioners in the applicant's primary catchment area shall also be notified by the  
 5 OEMS ~~so that any necessary changes in protocols can be considered.~~ that an RFP will be submitted.

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

8 ~~Hospitals~~ Once the hospital is notified that an RFP will be accepted, the hospital ~~desiring to be considered for~~  
 9 ~~initial trauma center designation~~ shall complete and submit one paper copy with signatures and an electronic copy of  
 10 the ~~completed~~ RFP ~~with signatures~~ to the OEMS at least ~~90~~ 45 days prior to the proposed site visit date.

11 ~~For Level I, II, and III applicants, the~~ The RFP shall demonstrate that the hospital meets the standards for the  
 12 designation level applied for as found in ~~Rules .0901, .0902, or .0903~~ Rule .0901 of this Section.

13 (i) If OEMS does not recommend a site visit based upon failure to comply with ~~Rules .0901, .0902, or .0903~~, Rule  
 14 .0901 of this Section, the OEMS shall send the written reasons ~~shall be forwarded~~ to the hospital in writing within  
 15 30 days of the decision. The hospital may reapply for designation within six months following the submission of an  
 16 updated RFP. If the hospital fails to respond within six months, the hospital shall reapply following the process  
 17 outlined in Paragraphs (a) through (h) of this Rule.

18 (j) If after review of the RFP, the OEMS recommends the hospital for a site visit, the OEMS shall notify the  
 19 hospital within 30 days and the site visit shall be conducted within six months of the recommendation. The site visit  
 20 date shall be mutually agreeable to the The hospital and the ~~OEMS~~. OEMS shall agree on the date of the site visit.

21 ~~Any~~ Except for OEMS representatives, any in-state reviewer for a Level I or II visit ~~(except the OEMS~~  
 22 ~~representatives)~~ shall be from outside the ~~planning region~~ local or adjacent RAC, unless mutually agreed upon by  
 23 the OEMS and the trauma center seeking ~~designation,~~ designation ~~in which~~ where the hospital is located. The  
 24 composition of a Level I or II state site survey team shall be as follows:

- 25 (1) ~~One out of state~~ one out-of-state trauma surgeon who is a Fellow of the ACS, experienced as a  
 26 site surveyor, who shall be ~~designated~~ the primary reviewer;
- 27 (2) ~~One~~ one in-state emergency physician who currently works in a designated trauma center, is a  
 28 member of the American College of Emergency ~~Physicians,~~ Physicians or American Academy of  
 29 Emergency Medicine, and is boarded in emergency medicine ~~(by by the American Board of~~  
 30 ~~Emergency Medicine or the American Osteopathic Board of Emergency Medicine);~~ Medicine;
- 31 (3) ~~One~~ one in-state trauma surgeon who is a member of the North Carolina Committee on Trauma;
- 32 (4) ~~One~~ for Level I designation, one out-of-state trauma ~~nurse coordinator/program manager and one~~  
 33 ~~in-state trauma nurse coordinator/program manager;~~ and program manager with an equivalent  
 34 license from another state;
- 35 (5) for Level II designation, one in-state program manager who is licensed to practice professional  
 36 nursing in North Carolina in accordance with the Nursing Practice Act, Article 9A, Chapter 90 of  
 37 the North Carolina General Statutes; and

1           ~~(5)~~ (6) OEMS Staff.

2 (l) All site team members for a Level III visit shall be from in-state, ~~and all (except for the OEMS representatives)~~  
3 ~~and, except for the OEMS representatives,~~ shall be from outside the ~~planning region~~ local or adjacent RAC ~~in which~~  
4 ~~where~~ the hospital is located. The composition of a Level III state site survey team shall be as follows:

5           (1) ~~One one~~ trauma surgeon who is a Fellow of the ACS, who is a member of the North Carolina  
6 Committee on Trauma and shall be ~~designated~~ the primary reviewer;

7           (2) ~~One one~~ emergency physician who currently works in a designated trauma center, is a member of  
8 the North Carolina College of Emergency ~~Physicians,~~ Physicians or American Academy of  
9 Emergency Medicine, and is boarded in emergency medicine (~~by~~ by the American Board of  
10 Emergency Medicine or the American Osteopathic Board of Emergency ~~Medicine~~); Medicine;

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

14           (4) OEMS Staff.

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

16 (n) The ~~lead researcher~~ primary reviewer of the site review team shall give a verbal post-conference report  
17 representing a consensus of the site review ~~team at the summary conference.~~ team. ~~A written consensus report shall~~  
18 ~~be completed, to include a peer review report, by the primary reviewer and submitted to OEMS within 30 days of~~  
19 ~~the site visit.~~ The primary reviewer shall complete and submit to the OEMS a written consensus report [that  
20 includes a peer review report] within 30 days of the site visit.

21 (o) The report of the site survey team and the staff recommendations shall be reviewed by the State Emergency  
22 Medical Services Advisory Council at its next regularly scheduled meeting ~~which is more than 45 days~~ following  
23 the site visit. Based upon the site visit report and the staff recommendation, the State Emergency Medical Services  
24 Advisory Council shall recommend to the OEMS that the request for Trauma Center designation be approved or  
25 denied.

26 (p) All criteria defined in Rule ~~.0901, .0902, or .0903~~ .0901 of this Section shall be met for initial designation at the  
27 level requested. ~~Initial designation shall not be granted if deficiencies exist.~~

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

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

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

36 (t) If a trauma center changes its trauma program administrative structure (~~such~~ such that the trauma service, trauma  
37 ~~medical director;~~ Medical Director, trauma ~~nurse coordinator/program~~ program ~~manager~~ manager, or trauma

1 registrar are relocated on the hospital's organizational ~~chart~~ chart at any time, it shall notify OEMS of this change in  
2 writing within 30 days of the occurrence.

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

4

5 *History Note: Authority G.S. 131E-162; [~~143-508;~~] 143-508(d)(2); ~~143-509(3);~~*

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

7 *Eff. April 1, 2003;*

8 *Amended Eff. January 1, ~~2009.~~ 2009;*

9 *Readopted Eff. January 1, 2017.*