

1 10A NCAC 13P .0904 is proposed for readoption with substantive changes 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 have the consult
5 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 Trauma Registry as defined in Rule .0102(61) of
21 this Subchapter, and submit data to the OEMS ~~at least~~ weekly and include all the Trauma Center's trauma patients as
22 defined in Rule ~~.0102(68)~~ .0102(59) of this Subchapter who are either diverted to an affiliated hospital, admitted to
23 the Trauma Center for greater than 24 hours from an ED or hospital, die in the ED, are ~~DOA~~ DOA, or are
24 transferred from the ED to the OR, ICU, or another hospital (including transfer to any affiliated hospital) a minimum
25 of 12 months prior to application.

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

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

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

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

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

8 (i) If OEMS does not recommend a site visit based upon failure to comply with ~~Rules .0901, .0902, or .0903~~, Rule
9 .0901 of this Section, the reasons shall be forwarded to the hospital in writing within 30 days of the decision. The
10 hospital may reapply for designation within six months following the submission of an updated RFP. If the hospital
11 fails to respond within six months, the hospital shall reapply following the process outlined in Paragraphs (a)
12 through (h) of this Rule.

13 (j) If after review of the RFP, the OEMS recommends the hospital for a site visit, the OEMS shall notify the
14 hospital within 30 days and the site visit shall be conducted within six months of the recommendation. The site visit
15 date shall be mutually agreeable to the hospital and the OEMS.

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

20 (1) ~~One out of state~~ one out-of-state trauma surgeon who is a Fellow of the ACS, experienced as a
21 site surveyor, who shall be designated the primary reviewer;

22 (2) ~~One~~ one in-state emergency physician who works in a designated trauma center, is a member of
23 the American College of Emergency Physicians, Physicians or American Academy of Emergency
24 Medicine, and is boarded in emergency medicine (by by the American Board of Emergency
25 Medicine or the American Osteopathic Board of Emergency Medicine); Medicine;

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

27 (4) ~~One~~ for Level I designation, one out-of-state trauma nurse coordinator/program manager and one
28 in state trauma nurse coordinator/program manager; and program manager with an equivalent
29 license from another state;

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

33 ~~(5)~~ (6) OEMS Staff.

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

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

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

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

10 (4) OEMS Staff.

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

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

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

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

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

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

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

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

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

36
37 *History Note: Authority G.S. 131E-162; 143-508; 143-509(3);*

1 *Temporary Adoption Eff. January 1, 2002;*
2 *Eff. April 1, 2003;*
3 *Amended Eff. January 1, ~~2009~~ 2009;*
4 *Readopted Eff. January 1, 2017.*