

1 10A NCAC 13P .0905 is readopted with changes as published in 30:24 NCR, pp. 2558-2606, as follows:

2
3 **10A NCAC 13P .0905 RENEWAL DESIGNATION PROCESS**

4 (a) Hospitals may utilize one of two options to achieve Trauma Center renewal:

- 5 (1) ~~Undergo~~ undergo a site visit conducted by OEMS to obtain a four-year renewal designation; or
6 (2) ~~Undergo~~ undergo a verification visit ~~arranged~~ by the ACS, in conjunction with the OEMS, to
7 obtain a ~~four-year~~ three-year renewal designation.

8 (b) For hospitals choosing Subparagraph (a)(1) of this Rule:

- 9 (1) ~~Prior~~ prior to the end of the designation period, the OEMS shall forward to the hospital an RFP for
10 completion. The hospital shall, within 10 business days of receipt of the RFP, define for OEMS
11 the Trauma Center's trauma primary catchment area. Upon this notification, OEMS shall notify
12 the respective Board of County Commissioners in the applicant's trauma primary catchment area
13 of the request for renewal to allow 30 days for comment.
- 14 (2) ~~Hospitals~~ hospitals shall complete and submit ~~one paper copy and~~ an electronic copy of the RFP to
15 the OEMS and the specified site surveyors at least 30 days prior to the site visit. The RFP shall
16 include information that supports compliance with the criteria contained in Rule ~~.0901, .0902, or~~
17 ~~.0903~~ .0901 of this Section as it relates to the Trauma Center's level of designation.
- 18 (3) ~~All~~ all criteria defined in Rule ~~.0901, .0902, or .0903~~ .0901 of this Section, as it relates to the
19 Trauma Center's level of designation, shall be met for renewal designation.
- 20 (4) ~~A~~ a site visit shall be conducted within 120 days prior to the end of the designation period. ~~The~~
21 ~~site visit shall be scheduled on a date mutually agreeable to the~~ The hospital and the ~~OEMS.~~
22 OEMS shall agree on the date of the site visit.
- 23 (5) ~~The~~ the composition of a Level I or II site survey team shall be the same as that specified in Rule
24 .0904(k) of this Section.
- 25 (6) ~~The~~ the composition of a Level III site survey team shall be the same as that specified in Rule
26 .0904(l) of this Section.
- 27 (7) ~~On~~ on the day of the site ~~visit~~ visit, the hospital shall make available all requested patient medical
28 charts.
- 29 (8) ~~The~~ the primary reviewer of the site review team shall give a verbal post-conference report
30 representing a consensus of the site review ~~team at the summary conference.~~ ~~A written consensus~~
31 ~~report shall be completed, to include a peer review report, by the primary reviewer and submitted~~
32 ~~to OEMS within 30 days of the site visit.~~ team. The primary reviewer shall complete and submit
33 to the OEMS a written consensus report [that includes a peer review report] within 30 days of the
34 site visit.
- 35 (9) ~~The~~ the report of the site survey team and a staff recommendation shall be reviewed by the ~~State~~
36 ~~NC~~ NC Emergency Medical Services Advisory Council at its next regularly scheduled meeting ~~which~~
37 ~~is more than 30 days~~ following the site visit. Based upon the site visit report and the staff

1 recommendation, the ~~State~~ NC Emergency Medical Services Advisory Council shall recommend
 2 to the OEMS that the request for Trauma Center renewal ~~be~~ be:

3 (A) approved;

4 (B) approved with a contingency(ies) due to a deficiency(ies) requiring a focused review;

5 (C) approved with a contingency(ies) not due to a deficiency(ies) requiring a consultative
 6 visit; or

7 (D) denied.

8 (10) ~~Hospitals~~ hospitals with a deficiency(ies) shall have up to 10 ~~working~~ business days prior to the
 9 ~~State EMS~~ NC Emergency Medical Services Advisory Council meeting to provide documentation
 10 to demonstrate compliance. If the hospital has a deficiency that cannot be corrected in this period
 11 prior to the ~~State EMS~~ NC Emergency Medical Services Advisory Council meeting, the hospital,
 12 ~~instead of a four year renewal,~~ shall be given 12 months by the OEMS to demonstrate compliance
 13 and undergo a focused ~~review,~~ review that may require an additional site visit. The need for an
 14 additional site visit is on a case-by-case basis based on the type of deficiency. The hospital shall
 15 retain its Trauma Center designation during the focused review period. If compliance is
 16 demonstrated within the prescribed time period, the hospital shall be granted its designation for the
 17 four-year period from the previous designation's expiration date. If compliance is not
 18 demonstrated within the 12 month time ~~period, as specified~~ period, ~~[set]~~ by OEMS, the Trauma
 19 Center designation shall not be renewed. To become redesignated, the hospital shall submit an
 20 updated RFP and follow the initial applicant process outlined in Rule .0904 of this Section.

21 (11) ~~The~~ the final decision regarding trauma center renewal shall be rendered by the OEMS.

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

25 (13) hospitals with a deficiency(ies) shall submit an action plan to the OEMS to address the
 26 deficiency(ies) within 10 business days following receipt of the written final decision on the
 27 trauma recommendations.

28 (13) ~~[(14)]~~ ~~The~~ ~~[the]~~ four year renewal date that may be eventually granted shall not be extended due to the
 29 focused review period.

30 (c) For hospitals choosing Subparagraph (a)(2) of this Rule:

31 (1) ~~At~~ at least six months prior to the end of the Trauma Center's designation period, the trauma center
 32 ~~must~~ shall notify the OEMS of its intent to undergo an ACS verification visit. It ~~must~~ shall
 33 simultaneously define in writing to the OEMS its trauma primary catchment area. Trauma Centers
 34 choosing this option ~~must~~ shall then comply with all the ACS' verification procedures, as well as
 35 any additional state criteria as ~~outlined~~ defined in ~~Rule .0901, .0902, or .0903,~~ Rule .0901 of this
 36 Section, ~~as~~ that apply to their level of designation.

- 1 (2) ~~When~~ when completing the ACS' documentation for verification, the Trauma Center ~~must~~ shall
2 ensure access to the ACS on-line PRQ (pre-review questionnaire) to OEMS. The Trauma Center
3 ~~must shall~~ simultaneously complete any documents supplied by OEMS ~~to verify compliance with~~
4 ~~additional North Carolina criteria (i.e., criteria that exceed the ACS criteria)~~ and forward these to
5 the ~~OEMS and the ACS.~~ OEMS.
- 6 (3) ~~The~~ the OEMS shall notify the Board of County Commissioners within the trauma center's trauma
7 primary catchment area of the Trauma Center's request for renewal to allow 30 days for
8 comments.
- 9 (4) ~~The~~ the Trauma Center ~~must~~ shall make sure the site visit is scheduled to ensure that the ACS'
10 final written report, accompanying medical record reviews and cover letter are received by OEMS
11 at least 30 days prior to a regularly scheduled ~~State~~ NC Emergency Medical Services Advisory
12 Council meeting to ensure that the Trauma Center's state designation period does not terminate
13 without consideration by the ~~State~~ NC Emergency Medical Services Advisory Council.
- 14 (5) ~~The composition of the Level I or Level II site team must be as specified in Rule .0904(k) of this~~
15 ~~Section, except that both the required trauma surgeons and the emergency physician may be from~~
16 ~~out of state. Neither North Carolina Committee on Trauma nor North Carolina College of~~
17 ~~Emergency Physician membership is required of the surgeons or emergency physician,~~
18 ~~respectively, if from out of state. The date, time, and all proposed site team members of the site~~
19 ~~visit team must be submitted to the OEMS for review at least 45 days prior to the site visit. The~~
20 ~~OEMS shall approve the site visit schedule if the schedule does not conflict with the ability of~~
21 ~~attendance by required OEMS staff. The OEMS shall approve the proposed site team members if~~
22 ~~the OEMS determines there is no conflict of interest, such as previous employment, by any site~~
23 ~~team member associated with the site visit. any in-state review for a hospital choosing~~
24 ~~Subparagraph (a)(2) of this Rule, except for the OEMS staff, shall be from outside the local or~~
25 ~~adjacent RAC in which the hospital is located.~~
- 26 (6) ~~The composition of the Level III site team must be as specified in Rule .0904(l) of this Section,~~
27 ~~except that the trauma surgeon, emergency physician, and trauma nurse coordinator/program~~
28 ~~manager may be from out of state. Neither North Carolina Committee on Trauma nor North~~
29 ~~Carolina College of Emergency Physician membership is required of the surgeon or emergency~~
30 ~~physician, respectively, if from out of state. The date, time, and all proposed site team members~~
31 ~~of the site visit team must be submitted to the OEMS for review at least 45 days prior to the site~~
32 ~~visit. The OEMS shall approve the site visit schedule if the schedule does not conflict with the~~
33 ~~ability of attendance by required OEMS staff. The OEMS shall approve the proposed site team~~
34 ~~members if the OEMS determines there is no conflict of interest, such as previous employment, by~~
35 ~~any site team member associated with the site visit. the composition of a Level I, II, or III site~~
36 ~~survey team for hospitals choosing Subparagraph (a)(2) of this Rule shall be as follows:~~

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

3 (B) one out-of-state emergency physician who works in a designated trauma center, is a
 4 member of the American College of Emergency Physicians or the American Academy of
 5 Emergency Medicine, and is boarded in emergency medicine by the American Board of
 6 Emergency Physicians or the American Osteopathic Board of Emergency Medicine;

7 (C) one out-of-state trauma program manager with an equivalent license from another state;
 8 and

9 (D) OEMS staff.

10 (7) the date, time, and all proposed [site team] members of the site visit team shall be submitted to the
 11 OEMS for review at least 45 days prior to the site visit. The OEMS shall approve the site visit
 12 schedule if the schedule does not conflict with the ability of attendance by required OEMS staff.
 13 The OEMS shall approve the proposed site visit team members if the OEMS determines there is
 14 no conflict of interest, such as previous employment, by any site visit team member associated
 15 with the site visit.

16 (7) (8) ~~All~~ all state Trauma Center criteria ~~must~~ shall be met as defined in ~~Rules .0901, .0902, and .0903~~
 17 Rule .0901 of this ~~Section, Section~~ Section for renewal of state designation. ~~An~~ ACS' verification is not
 18 required for state designation. ~~An~~ ACS' verification does not ensure a state designation.

19 (8) (9) ~~ACS reviewers shall complete the state designation preliminary reporting form immediately prior~~
 20 ~~to the post conference meeting. This document and the~~ The ACS final written report and
 21 supporting documentation described in Subparagraph (c)(4) of this Rule shall be used to generate a
 22 ~~staff summary of findings~~ report following the post conference meeting for presentation to the NC
 23 ~~EMS~~ Emergency Medical Services Advisory Council for ~~redesignation, renewal designation.~~

24 (9) (10) ~~The~~ the final written report issued by the ACS' verification review committee, the accompanying
 25 medical record reviews (~~from from~~ which all identifiers ~~may~~ shall be removed), removed and
 26 cover letter ~~must~~ shall be forwarded to OEMS within 10 ~~working~~ business days of its receipt by
 27 the Trauma Center seeking renewal.

28 (10) (11) ~~The~~ the OEMS shall present its summary of findings report to the ~~State~~ NC Emergency Medical
 29 Services Advisory Council at its next regularly scheduled meeting. The ~~State~~ EMS NC
 30 Emergency Medical Services Advisory Council shall recommend to the Chief of the OEMS that
 31 the request for Trauma Center renewal ~~be~~ be:

32 (A) approved;

33 (B) approved with a contingency(ies) due to a deficiency(ies) requiring a focused review;

34 (C) approved with a contingency(ies) not due to a deficiency(ies); or

35 (D) denied.

1 ~~(11)~~ (12) The the OEMS shall ~~notify~~ send the hospital ~~in writing~~ written notice of the ~~State~~ NC Emergency
 2 Medical Services Advisory Council's and OEMS' final recommendation within 30 days of the NC
 3 Emergency Medical Services Advisory Council meeting.

4 (13) ~~the final decision regarding trauma center designation shall be rendered by the OEMS.~~

5 ~~(12)~~ (14) ~~Hospitals~~ hospitals with ~~contingencies,~~ contingencies as the result of a deficiency(ies), as
 6 determined by OEMS, shall have up to 10 working business days prior to the ~~State EMS NC~~
 7 Emergency Medical Services Advisory Council meeting to provide documentation to demonstrate
 8 compliance. If the hospital has a deficiency that cannot be corrected in this time ~~period~~ period,
 9 ~~prior to the State EMS Advisory Council meeting,~~ the hospital, ~~instead of a four-year~~ [three-year]
 10 renewal, may undergo a focused review ~~(to to~~ be conducted by the ~~OEMS)~~ OEMS whereby the
 11 Trauma Center ~~is~~ shall be given 12 months by the OEMS to demonstrate compliance. Satisfaction
 12 of contingency(ies) may require an additional site visit. The need for an additional site visit is on a
 13 case-by-case basis based on the type of deficiency. The hospital shall retain its Trauma Center
 14 designation during the focused review period. If compliance is demonstrated within the prescribed
 15 time period, the hospital shall be granted its designation for the ~~four-year~~ three-year period from
 16 the previous designation's expiration date. If compliance is not demonstrated within the 12 month
 17 time ~~period, as specified~~ period, ~~[set] by OEMS,~~ the Trauma Center designation shall not be
 18 renewed. To become redesignated, the hospital shall submit a new RFP and follow the initial
 19 applicant process outlined in Rule .0904 of this Section.

20 (15) ~~hospitals with a deficiency(ies) shall submit an action plan to the OEMS to address the~~
 21 ~~deficiency(ies) within 10 business days following receipt of the written final decision on the~~
 22 ~~trauma recommendations.~~

23 ~~[(16) the three year renewal date that may be eventually granted shall not be extended due to the~~
 24 ~~focused review period.]~~

25 (d) If a Trauma Center currently using the ACS' verification process chooses not to renew using this process, it
 26 must notify the OEMS at least six months prior to the end of its state trauma center designation period of its
 27 intention to exercise the option in Subparagraph (a)(1) of this Rule. Upon notification, the OEMS shall extend the
 28 designation for one additional year to ensure consistency with hospitals using Subparagraph (a)(1) of this Rule.

29 ~~[(e) Renewal shall be for a period not to exceed four years. If the hospital chooses the option in Subparagraph~~
 30 ~~(a)(2) of this Rule, the renewal shall coincide with the three year designation period of the ACS verification.]~~

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 32 *History Note:* Authority G.S. 131E-162; ~~[143-508;]~~ 143-508(d)(2); ~~143-509(3);~~
 33 *Temporary Adoption Eff. January 1, 2002;*
 34 *Eff. April 1, 2003;*
 35 *Amended Eff. April 1, 2009; January 1, 2009; January 1, 2004; 2004;*
 36 *Readoption Eff. January 1, 2017.*