10A NCAC 13P .0905 is proposed for readoption with substantive changes 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 .9901, .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 relates to the 19 Trauma Center's level of designation, shall be met for renewal designation-20 (4) $A \underline{a}$ 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 hospital and the OEMS. 22 (5) The the composition of a Level I or II site survey team shall be the same as that specified in Rule 23 .0904(k) of this Section. 24 (6) The the composition of a Level III site survey team shall be the same as that specified in Rule 25 .0904(1) of this Section. 26 (7) On on the day of the site visit the hospital shall make available all requested patient medical 27 charts. 28 (8) The the primary reviewer of the site review team shall give a verbal post-conference report 29 representing a consensus of the site review team at the summary conference. A written consensus 30 report shall be completed, to include a peer review report, by the primary reviewer and submitted 31 to OEMS within 30 days of the site visit. team. The primary reviewer shall complete and submit 32 to the OEMS a written consensus report that includes a peer review report within 30 days of the 33 site visit. 34 (9) The the report of the site survey team and a staff recommendation shall be reviewed by the State 35 Emergency Medical Services Advisory Council at its next regularly scheduled meeting which is 36 more than 30 days following the site visit. Based upon the site visit report and the staff 37 recommendation, the State Emergency Medical Services Advisory Council shall recommend to

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- the OEMS that the request for Trauma Center renewal be approved; approved with a contingency(ies) due to a deficiency(ies) requiring a focused review; approved with a contingency(ies) not due to a deficiency(ies) requiring a consultative visit; or denied.
- Hospitals hospitals with a deficiency(ies) have up to 10 working business days prior to the State EMS Advisory Council meeting to provide documentation to demonstrate compliance. If the hospital has a deficiency that cannot be corrected in this period prior to the State EMS Advisory Council meeting, the hospital, instead of a four-year renewal, shall be given 12 months by the OEMS to demonstrate compliance and undergo a focused review, review that may require an additional site visit. The hospital shall retain its Trauma Center designation during the focused review period. If compliance is demonstrated within the prescribed time period, the hospital shall be granted its designation for the four-year period from the previous designation's expiration date. If compliance is not demonstrated within the time period, as specified by OEMS, the Trauma Center designation shall not be renewed. To become redesignated, the hospital shall submit an updated RFP and follow the initial applicant process outlined in Rule .0904 of this Section.
- (11) The the final decision regarding trauma center renewal shall be rendered by the OEMS.
- (12) The 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.
- (13) hospitals with a deficiency(ies) shall submit an action plan to the OEMS to address the deficiency(ies) within 10 business days following receipt of the written final decision on the trauma recommendations.
- (13) (14) The the four-year renewal date that may be eventually granted shall not be extended due to the focused review period.
- (c) For hospitals choosing Subparagraph (a)(2) of this Rule:

- (1) At at least six months prior to the end of the Trauma Center's designation period, the trauma center must shall notify the OEMS of its intent to undergo an ACS verification visit. It must shall simultaneously define in writing to the OEMS its trauma primary catchment area. Trauma Centers choosing this option must shall then comply with all the ACS' verification procedures, as well as any additional state criteria as outlined in Rule .0901, .0902, or .0903, Rule .0901 of this Section, as apply to their level of designation.
- When when completing the ACS' documentation for verification, the Trauma Center must shall ensure access to the ACS on-line PRQ (pre-review questionnaire) to OEMS. The Trauma Center must shall simultaneously complete any documents supplied by OEMS to verify compliance with additional North Carolina criteria (i.e., criteria that exceed the ACS criteria) and forward these to the OEMS and the ACS.

(3) The the OEMS shall notify the Board of County Commissioners within the trauma center's trauma primary catchment area of the Trauma Center's request for renewal to allow 30 days for comments.

- (4) The the Trauma Center must shall make sure the site visit is scheduled to ensure that the ACS' final written report, accompanying medical record reviews and cover letter are received by OEMS at least 30 days prior to a regularly scheduled State Emergency Medical Services Advisory Council meeting to ensure that the Trauma Center's state designation period does not terminate without consideration by the State Emergency Medical Services Advisory Council.
- (5) The composition of the Level I or Level II site team must be as specified in Rule .0904(k) of this Section, except that both the required trauma surgeons and the emergency physician may be from out of state. Neither North Carolina Committee on Trauma nor North Carolina College of Emergency Physician membership is required of the surgeons or emergency physician, respectively, if from out of state. The date, time, and all proposed site team members of the site visit team must be submitted to the OEMS for review at least 45 days prior to the site visit. The OEMS shall approve the site visit schedule if the schedule does not conflict with the ability of attendance by required OEMS staff. The OEMS shall approve the proposed site team members if the OEMS determines there is no conflict of interest, such as previous employment, by any site team member associated with the site visit. any in-state review for a hospital choosing Subparagraph (a)(2) of this Rule, except for the OEMS staff, shall be from outside the local or adjacent RAC in which the hospital is located.
- (6) The composition of the Level III site team must be as specified in Rule .0904(I) of this Section, except that the trauma surgeon, emergency physician, and trauma nurse coordinator/program manager may be from out of state. Neither North Carolina Committee on Trauma nor North Carolina College of Emergency Physician membership is required of the surgeon or emergency physician, respectively, if from out of state. The date, time, and all proposed site team members of the site visit team must be submitted to the OEMS for review at least 45 days prior to the site visit. The OEMS shall approve the site visit schedule if the schedule does not conflict with the ability of attendance by required OEMS staff. The OEMS shall approve the proposed site team members if the OEMS determines there is no conflict of interest, such as previous employment, by any site team member associated with the site visit. the composition of a Level I, II, or III site survey team for hospitals choosing Subparagraph (a)(2) of this Rule shall be as follows:
 - (A) one out-of-state trauma surgeon who is a Fellow of the ACS, experienced as a site surveyor, who shall be the primary reviewer;
 - (B) one out-of-state emergency physician who works in a designated trauma center, is a member of the American College of Emergency Physicians or the American Academy of Emergency Medicine, and is boarded in emergency medicine by the American Board of Emergency Physicians or the American Osteopathic Board of Emergency Medicine;

| 1 | | (C) one out-of-state trauma program manager with an equivalent license from another state; |
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| 2 | | <u>and</u> |
| 3 | | (D) OEMS staff. |
| 4 | <u>(7)</u> | the date, time, and all proposed site team members of the site visit team shall be submitted to the |
| 5 | | OEMS for review at least 45 days prior to the site visit. The OEMS shall approve the site visit |
| 6 | | schedule if the schedule does not conflict with the ability of attendance by required OEMS staff. |
| 7 | | The OEMS shall approve the proposed site team members if the OEMS determines there is no |
| 8 | | conflict of interest, such as previous employment, by any site team member associated with the |
| 9 | | site visit. |
| 10 | (7) <u>(8)</u> | All all state Trauma Center criteria must shall be met as defined in Rules .0901, .0902, and .0903 |
| 11 | | Rule .0901 of this Section, for renewal of state designation. An ACS' verification is not required |
| 12 | | for state designation. An ACS' verification does not ensure a state designation. |
| 13 | (8) <u>(9)</u> | ACS reviewers shall complete the state designation preliminary reporting form immediately prior |
| 14 | | to the post conference meeting. This document and the ACS final written report and supporting |
| 15 | | documentation described in Subparagraph (c)(4) of this Rule shall be used to generate a staff |
| 16 | | summary of findings report following the post conference meeting for presentation to the NC |
| 17 | | EMS Advisory Council for redesignation. |
| 18 | (9) <u>(10)</u> | The the final written report issued by the ACS' verification review committee, the accompanying |
| 19 | | medical record reviews (from from which all identifiers may be removed), removed and cover |
| 20 | | letter must shall be forwarded to OEMS within 10 working business days of its receipt by the |
| 21 | | Trauma Center seeking renewal. |
| 22 | (10) <u>(11</u> |) The the OEMS shall present its summary of findings report to the State Emergency Medical |
| 23 | | Services Advisory Council at its next regularly scheduled meeting. The State EMS Advisory |
| 24 | | Council shall recommend to the Chief of the OEMS that the request for Trauma Center renewal be |
| 25 | | approved; approved with a contingency(ies) due to a deficiency(ies) requiring a focused review; |
| 26 | | approved with a contingency(ies) not due to a deficiency(ies); or denied. |
| 27 | (11) <u>(12</u> | 2) The the OEMS shall notify the hospital in writing of the State Emergency Medical Services |
| 28 | | Advisory Council's and OEMS' final recommendation within 30 days of the Advisory Council |
| 29 | | meeting. |
| 30 | (13) | the final decision regarding trauma center designation shall be rendered by the OEMS. |
| 31 | (12) <u>(14</u> |) Hospitals hospitals with contingencies, as the result of a deficiency(ies), as determined by OEMS, |
| 32 | | have up to 10 working business days prior to the State EMS Advisory Council meeting to provide |
| 33 | | documentation to demonstrate compliance. If the hospital has a deficiency that cannot be |
| 34 | | corrected in this time period prior to the State EMS Advisory Council meeting, the hospital, |
| 35 | | instead of a four year three-year renewal, may undergo a focused review (to to be conducted by |
| 36 | | the OEMS OEMS whereby the Trauma Center is given 12 months by the OEMS to demonstrate |
| 37 | | compliance. Satisfaction of contingency(ies) may require an additional site visit. The hospital |

| 1 | | shall retain its Trauma Center designation during the focused review period. If compliance is |
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| 2 | | demonstrated within the prescribed time period, the hospital shall be granted its designation for the |
| 3 | | four year three-year period from the previous designation's expiration date. If compliance is not |
| 4 | | demonstrated within the time period, as specified by OEMS, the Trauma Center designation shall |
| 5 | | not be renewed. To become redesignated, the hospital shall submit a new RFP and follow the |
| 6 | | initial applicant process outlined in Rule .0904 of this Section. |
| 7 | (15) | hospitals with a deficiency(ies) shall submit an action plan to the OEMS to address the |
| 8 | | deficiency(ies) within 10 business days following receipt of the written final decision on the |
| 9 | | trauma recommendations. |
| 10 | (16) | the three-year renewal date that may be eventually granted shall not be extended due to the |
| 11 | | focused review period. |
| 12 | (d) If a Traum | a Center currently using the ACS' verification process chooses not to renew using this process, it |
| 13 | must notify the | OEMS at least six months prior to the end of its state trauma center designation period of its |
| 14 | intention to exe | rcise the option in Subparagraph (a)(1) of this Rule. Upon notification, the OEMS shall extend the |
| 15 | designation for | one additional year to ensure consistency with hospitals using Subparagraph (a)(1) of this Rule. |
| 16 | (e) Renewal sha | all be for a period not to exceed four years. If the hospital chooses the option in Subparagraph (a)(2) |
| 17 | of this Rule, the | renewal shall coincide with the three-year designation period of the ACS verification. |
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| 19 | History Note: | Authority G.S. 131E-162; <u>143-508;</u> 143-509(3); |
| 20 | | Temporary Adoption Eff. January 1, 2002; |
| 21 | | Eff. April 1, 2003; |
| 22 | | Amended Eff. April 1, 2009; January 1, 2009; January 1, 2004. <u>2004</u> ; |
| 23 | | Readoption Eff. January 1, 2017. |