#### State of Board of Health Agenda March 19, 2015 – 9:00 a.m. Perimeter Center – Boardroom 2

Call to Order and Welcome Bruce Edwards, Chair

Pledge of Allegiance Dr. Steven Escobar

Introductions Mr. Edwards

Review of Agenda Joseph Hilbert

Director of Governmental and Regulatory Affairs

Approval of December 4, 2014 Minutes Mr. Edwards

Commissioner's Report Marissa Levine, MD, MPH, FAAFP

State Health Commissioner

Budget Update Michael McMahon

Administration Operations Director

Legislative Update Mr. Hilbert

Break

Abortion Facility Licensure Status Report Erik Bodin, Director

Office of Licensure and Certification

Regulatory Action Update Mr. Hilbert

**Public Comment Period** 

**Regulatory Action Items** 

Regulations for the Immunization of School Children Laurie Forlano, DO, Director 12VAC5-110 Office of Epidemiology

(Fast track amendments)

Working Lunch

Lunch Speaker - Robin D. Pearce, MSN, RN-BC, Trauma/Critical Care Coordinator

Office of Emergency Medical Services Overview of Virginia's Trauma System

2015 Virginia Trauma Center Designation Manual Gary Brown, Director

Office of Emergency Medical Services

Appointment of Nominating Committee Mr. Edwards

Member Reports

Other Business

Adjourn



MARISSA J. LEVINE, MD, MPH INTERIM STATE HEALTH COMMISSIONER PO BOX 2448 RICHMOND, VA 23218

TTY 7-1-1 OR 1-800-828-1120

#### **MEMORANDUM**

DATE: February 12, 2015

TO: Virginia State Board of Health

FROM: Laurie Forlano, DO, MPH

Director, Office of Epidemiology

SUBJECT: Fast Track Amendments – Regulations for the Immunization of School Children

The agency is proposing to update existing Regulations for the Immunization of School Children (12VAC5-110) in response to comments received during the most recent periodic review. The proposed regulatory action also clarifies regulatory sections that have been found to be confusing to the public.

The proposed amendments update references to forms and immunization schedules and address the increasing use of electronic medical records. Requirements for the four vaccines required after the fourth birthday will be made uniform. The agency proposes to clarify that pneumococcal conjugate vaccine is not required for children enrolling in kindergarten and to add mumps to the list of diseases for which demonstration of immunity is acceptable. These and the other proposed technical amendments are not anticipated to result in significant changes to current practice.

The Board of Health is asked to approve this fast track action at its March 2015 meeting. Following approval, the proposed amendment would be submitted to the Virginia Regulatory Town Hall to initiate Executive Branch review.



Form: TH-04



townhall.virginia.gov

# Fast-Track Regulation Agency Background Document

Agency name	Department of Health, Office of Epidemiology	
Virginia Administrative Code (VAC) citation(s)		
Regulation title(s)	e(s) Immunization of School Children	
Action title	Amend Regulations for the Immunization of School Children following periodic review	
Date this document prepared	January 21, 2015	

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.* 

#### **Brief summary**

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Existing regulations will be updated in response to comments received as a result of periodic review. In addition, issues identified since the Regulations were last amended will be addressed. For example, pneumococcal conjugate vaccine should not be required for children entering kindergarten and demonstration of immunity to mumps through laboratory testing should be acceptable. Increasing use of electronic records requires modification to accommodate these technological changes.

# **Acronyms and Definitions**

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

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ACIP means the Advisory Committee on Immunization Practices, a group of medical and public health experts that develop recommendations on how to use vaccines to control diseases in the United States.

AAP means the American Academy of Pediatrics.

HPV means human papillomavirus.

# Statement of final agency action

Please provide a statement of the final action taken by the agency including:1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

The State Board of Health approved this regulatory action on March 19, 2915.

# Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Statutory authority to promulgate these regulations is granted to the State Board of Health by sections 22.1-271.2 and 32.1-46 of the *Code of Virginia*.

## **Purpose**

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

Regulations are necessary to ensure children are protected to the extent possible from vaccine-preventable diseases and to protect indirectly the health of all Virginians. Recent periodic review of existing regulations identified sections that are unclear or should be modified to address technological changes since the last regulatory action.

# Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

Some suggested changes are the result of comments received during the periodic review process. Additional changes are suggested to clarify issues that have been identified by others since the most recent amendments were enacted. None of the suggested changes will change any currently required immunizations or result in significant changes to current practice.

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#### **Substance**

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

Amendments to the current regulations will:

- Update and clarify definitions;
- Remove references to outdated versions of forms and ACIP schedules:
- Clarify that a printout of an electronic record can be accepted without the signature of a nurse or physician;
- Clarify that pneumococcal conjugate vaccine is not required for children enrolling in kindergarten;
- Clarify how long after the fourth birthday is allowable for those vaccines that are required to be administered on or after the fourth birthday;
- Add mumps to the list of diseases for which demonstration of immunity is acceptable;
- Clarify that the certificate of religious exemption must be notarized; and,
- Update responsibilities of admitting officials.

#### Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

The primary advantages to the agency and the public are that current regulations ensure that children are appropriately protected to the extent possible from vaccine preventable diseases. This also indirectly protects the health of all citizens of Virginia. Proposed changes should help clarify and simplify processes for providing and documenting immunizations required for school attendance. No disadvantages to the public or the Commonwealth are anticipated.

# Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements. The proposed regulations are written in response to the *Code of Virginia* §32.1-46 that requires children to be immunized and also requires an annual review of the section.

## Localities particularly affected

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Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

All localities in Virginia would be affected by the proposed regulation.

# Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The agency believes that the proposed amendment to the regulations is the least burdensome option to meet the requirements of the Code and comply with current immunization practices as recommended by the Advisory Committee for Immunization Practices, the American Academy of Pediatrics and the American Academy of Family Physicians.

# **Economic impact**

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: a) fund source / fund detail; and b) a delineation of one-time versus on-going expenditures	There will be very little, if any, fiscal impact as a result of the proposed changes.
Projected cost of the new regulations or	There will be very little, if any, fiscal impact as a
changes to existing regulations on localities.	result of the proposed changes.
Description of the individuals, businesses, or	Health care providers may be affected by the
other entities likely to be affected by the new	changes but the impact is expected to be minimal.
regulations or changes to existing regulations.	Several changes are the result of provider
	suggestions.
Agency's best estimate of the number of such	All providers who immunize school-age children will
entities that will be affected. Please include an	be affected by these regulations. At most it is
estimate of the number of small businesses	estimated that this would affect about 4200 private

<b></b>	'
<b>affected.</b> Small business means a business entity,	providers and 135 public health clinics.
including its affiliates, that:	
a) is independently owned and operated and;	
b) employs fewer than 500 full-time employees or	
has gross annual sales of less than \$6 million.	
All projected costs of the new regulations or	The Department of Health projects no additional
changes to existing regulations for affected	costs as a result of these amendments.
individuals, businesses, or other entities.	
Please be specific and include all costs	Changes will not place any additional reporting or
including:	recordkeeping requirements upon providers or
a) the projected reporting, recordkeeping, and	schools beyond what is already required and may
other administrative costs required for	reduce the amount of time needed to comply with
compliance by small businesses; and	current requirements.
b) specify any costs related to the development	
of real estate for commercial or residential	
purposes that are a consequence of the	
proposed regulatory changes or new	
regulations.	
Beneficial impact the regulation is designed	Proposed changes are expected to clarify existing
to produce.	areas of confusion and may reduce the amount of
	time needed to comply with school immunization
	requirements.
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Form: TH-04

#### **Alternatives**

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

The regulations are mandated by the *Code of Virginia*. The Agency believes the regulations provide the best solution in response to the law.

# **Public participation notice**

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

# Periodic review and small business impact review report of findings

If this fast-track is the result of a periodic review/small business impact review, use this form to report the agency's findings. Please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review and (2) indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health,

safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

Form: TH-04

Commenter	Comment	Agency response
Craig Gill, Pfizer Inc.	Modify the Regulations to incorporate a requirement for all meningococcal vaccinations in accordance with ACIP recommendations.	The Agency agrees that this is good public health practice; however, an amendment to the <i>Code of Virginia</i> would be necessary in order to implement this requirement.
William C. Rees, MD President, VA Chapter, AAP	Require HPV vaccine for both males and females.	The Agency agrees that this is good public health practice; however, an amendment to the Code of Virginia would be necessary.
William C. Rees, MD	Begin routine meningococcal vaccine at age 11 or 12 with a booster at age 16.	The Agency agrees that this is good public health practice; however, an amendment to the <i>Code of Virginia</i> would be necessary.
Sandra Zieve, MD, Patient First	A printout of an electronic record should serve as proof of adequate immunization without the signature of a nurse or physician.	The Agency agrees that electronic records should be addressed as part of the proposed changes.
Sandra Zieve, MD	There is no provision that states how the school documents that the parent/guardian has reviewed materials about the HPV vaccine.	Requiring that a form be signed will require an amendment to the Code of Virginia.
Tia Campbell, MSN, Dept. of Education	The school form reference should be updated to the current version.	The Agency agrees and has incorporated this change in the proposed changes.
Douglas Mitchell, MD, Professor of Pediatrics	The section that refers to HPV vaccine in females should be changed to not be gender specific.	This change to the HPV section will require an amendment to the Code of Virginia.
Douglas Mitchell, MD	The current document refers to the 2010 version of the ACIP recommendations.	The Agency agrees that the current version of the ACIP schedule should be incorporated.

The regulation is required by the *Code of Virginia*; there is no conflict or overlap with federal law or regulations as there are none related to immunizations required for school attendance. The regulation was most recently amended in 2010 with the required periodic review initiated in 2014. Complaints received from the public were not about the complexity of the regulation but rather references to outdated forms (Campbell, Mitchell). Comments (Gill, Rees, Zieve) included requests for expansion of requirements or additional documentation rather than any reduction in the number of vaccines or documentation required for school attendance. Technology has expanded the use of electronic medical records that clearly identify the provider without the need for a signature. The Agency recognizes the need to modify the regulation in view of this; a comment was also received (Zieve) about this issue.

# Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

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Parents are required by the *Code of Virginia* to have their children immunized. The regulations allow exemptions for medical reasons or if immunizations conflict with religious beliefs. All required vaccines are provided at no cost to parents at local health departments.

## **Detail of changes**

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an <u>emergency regulation</u>, please list separately: (1) all differences between the **pre**-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.

For changes to existing regulation(s), use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5- 110-10		Refers to an outdated version of the school form – MCH 213F	Changes the reference to state "the most current version of Form MCH 213"
12VAC5- 110-10		Requires a provider to sign or stamp a copy of the immunization record.	Adds that a signature is not required for the immunization record if the record is an electronic printout of a record from the provider's electronic health system.
12VAC5- 110-10		Defines "immunization schedule"	Changed to "immunization schedules" to clarify that all ACIP recommended schedules, including the catch-up information can be used to assess compliance.
12VAC5- 110-70		Diphtheria, Tetanus, and Pertussis refer to a dose required after the fourth birthday	Language is added to clarify that the dose must be administered after the fourth birthday and prior to entering kindergarten to eliminate confusion about how long after the fourth birthday is acceptable to obtain this dose. This change is consistent with that already in place for the varicella and measles vaccines.
12VAC5- 110-70		Acellular pertussis vaccine is currently required.	"Acellular" will be removed from the description so that children who received the whole cell version of the vaccine will

		not be required to receive additional unnecessary doses in order to be in compliance.
12VAC5- 110-70	Pneumococcal conjugate vaccine is required for children up to the age of 60 months.	Clarifies that this vaccine is not required for enrollment in any grade level, kindergarten through grade 12 but only for children in day care or preschool.
12VAC5- 110-80	States that no certificate of immunization is required if a Certificate of Religious Exemption is submitted to the admitting official	Clarifies that the affidavit must be appropriately completed and notarized to be acceptable.
12VAC5- 110-80	Allows exemption to immunization requirement if student demonstrates antibodies against rubeola, rubella, or varicella in sufficient quantity to ensure protection.	Adds mumps to this list in order to be consistent with current ACIP recommendations.
12VAC5- 110-90	Requires admitting officials to transfer records to the school to which a student is transferring within 30 days of transfer.	Reduces the time permitted to 10 days to better facilitate transfers and limit the time students may be unable to attend school
12VAC5- 110-90	Requires admitting officials to submit a report summarizing the immunization status of students in his school.	Clarifies that the report should report student status as of the first day of school and changes the version of the form to state "most current".
12VAC5- 110-90	Removes the reporting requirement specific to sixth grade.	Allows modifications to the reporting form to maintain consistency with any future requirements that may be implemented.

Form: TH-04

If a new regulation is being promulgated, use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements

#### Project 4210 - none

#### **DEPARTMENT OF HEALTH**

#### Amend immunization regs following periodic review

#### Part I

#### **Definitions**

#### 12VAC5-110-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Adequate immunization" means the immunization requirements prescribed under 12VAC5-110-70.

"Admit" or "admission" means the official enrollment or reenrollment for attendance at any grade level, whether full-time or part-time, of any student by any school.

"Admitting official" means the school principal or his designated representative if a public school; if a nonpublic school or child care center, the principal, headmaster or director of the school or center.

"Board" means the State Board of Health.

"Commissioner" means the State Health Commissioner.

"Compliance" means the completion of the immunization requirements prescribed under 12VAC5-110-70.

"Conditional enrollment" means the enrollment of a student for a period of 90 days contingent upon the student having received at least one dose of each of the required vaccines and the student possessing a plan, from a physician or local health department, for completing

his immunization requirements within the ensuing 90 calendar days. If the student requires more than two doses of hepatitis B vaccine, the conditional enrollment period, for hepatitis B vaccine only, shall be 180 calendar days.

"Documentary proof" means an appropriately completed copy of the most current version of Form MCH 213F 213 signed by a physician or his designee, registered nurse, or an official of a local health department. A copy of the immunization record signed or stamped by a physician or his designee, registered nurse, or an official of a local health department indicating the dates of administration including month, day, and year of the required vaccines, shall be acceptable in lieu of recording these dates on Form MCH 213F213, as long as the record is attached to Form MCH 213F 213 and the remainder of Form MCH 213F213 has been appropriately completed. A printout of an immunization record from the provider's electronic health record can be accepted without a signature or stamp. For a new student transferring from an out-of-state school, any immunization record, which contains the exact date (month/day/year) of administration of each of the required doses of vaccines, is signed by a physician or his designee or registered nurse, and complies fully with the requirements prescribed under 12VAC5-110-70 shall be acceptable.

"Immunization" means the administration of a product licensed by the FDA to confer protection against one or more specific pathogens.

"Immunization schedules" means mean the recommended schedules for persons aged 0 through 18 years developed and published by the Centers for Disease Control and Prevention (CDC), the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP).

"Physician" means any person licensed to practice medicine in any of the 50 states or the District of Columbia.

"School" means:

- 1. Any public school from kindergarten through grade 12 operated under the authority of any locality within this Commonwealth;
- 2. Any private or religious school that offers instruction at any level or grade from kindergarten through grade 12;
- 3. Any private or religious nursery school or preschool, or any private or religious child care center required to be licensed by this Commonwealth;
- 4. Any preschool classes or Head Start classes operated by the school divisions within this Commonwealth; and
- 5. Any family day home or developmental center.

"Student" means any person who seeks admission to a school, or for whom admission to a school is sought by a parent or guardian, and who will not have attained the age of 20 years by the start of the school term for which admission is sought.

"Twelve months of age" means the 365th day following the date of birth. For the purpose of evaluating records, vaccines administered up to four days prior to the first birthday (361 days following the date of birth) will be considered valid.

#### Part III

#### Immunization Requirements

#### 12VAC5-110-70. Immunization requirements.

Every student enrolling in a school shall provide documentary proof of adequate immunization with the prescribed number of doses of each of the vaccines and toxoids listed in the following subdivisions, as appropriate for his age according to the immunization schedules. Spacing, minimum ages, and minimum intervals shall be in accordance with the immunization schedules. A copy of every student's immunization record shall be on file in his school record.

- 1. Diphtheria Toxoid. A minimum of four properly spaced doses of diphtheria toxoid. One dose shall be administered on or after the fourth birthday and prior to entering kindergarten.
- 2. Tetanus Toxoid. A minimum of four properly spaced doses of tetanus toxoid. One dose shall be administered on or after the fourth birthday and prior to entering kindergarten.
- 3. Acellular Pertussis Vaccine. A minimum of four properly spaced doses of acellular pertussis vaccine. One dose shall be administered on or after the fourth birthday. A booster dose shall be administered prior to entering the sixth grade.
- 4. Poliomyelitis Vaccine. A minimum of four doses of poliomyelitis vaccine with one dose administered on or after the fourth birthday and prior to entering kindergarten.
- 5. Measles (Rubeola) Vaccine. One dose of live measles vaccine administered at age 12 months or older, and a second dose administered prior to entering kindergarten.
- Rubella Vaccine. A minimum of one dose of rubella virus vaccine administered at age
   months or older.
- 7. Mumps Vaccine. One dose of mumps virus vaccine administered at age 12 months or older and a second dose administered prior to entering kindergarten.
- 8. Haemophilus Influenzae Type b (Hib) Vaccine. A complete series of Hib vaccine (i.e., up to a maximum of four doses of vaccine as appropriate for the age of the child and the age at which the immunization series was initiated). The number of doses administered shall be in accordance with current immunization schedule recommendations. Attestation by the physician or his designee, registered nurse, or an official of a local health department on that portion of Form MCH 213G pertaining to Hib vaccine shall mean that the child has satisfied the requirements of this section. This section shall not

apply to children older than 60 months of age or for admission to any grade level, kindergarten through grade 12.

- 9. Hepatitis B Vaccine. A minimum of three doses of hepatitis B vaccine for all children. The FDA has approved a two-dose schedule only for adolescents 11 through 15 years of age and only when the Merck brand (RECOMBIVAX HB) Adult Formulation Hepatitis B vaccine is used. The two RECOMBIVAX HB adult doses must be separated by a minimum of four months. The two dose schedule using the adult formulation must be clearly documented in the Hepatitis B section on Form MCH 213G.
- 10. Varicella (Chickenpox) Vaccine. All children born on and after January 1, 1997, shall be required to have one dose of chickenpox vaccine on or after 12 months of age and a second dose administered prior to entering kindergarten.
- 11. Pneumococcal Conjugate Vaccine (PCV). A complete series of PCV (i.e., up to a maximum of four doses of vaccine as appropriate for the age of the child and the age at which the immunization series was initiated). The number of doses administered shall be in accordance with current immunization schedule recommendations. Attestation by the physician or his designee, registered nurse, or an official of a local health department on that portion of Form MCH 213G pertaining to PCV vaccine shall mean that the child has satisfied the requirements of this section. This section shall not apply to children older than 60 months of age or for admission to any grade level, kindergarten through grade 12.
- 12. Human Papillomavirus (HPV) Vaccine. Three doses of properly spaced HPV vaccine for females, effective October 1, 2008. The first dose shall be administered before the child enters the sixth grade.

#### 12VAC5-110-80. Exemptions from immunization requirements.

A. Religious and medical exemptions. No certificate of immunization shall be required of any student for admission to school if:

- 1. The student or his parent or guardian submits a <u>notarized Certificate</u> of Religious Exemption (Form CRE 1), to the admitting official of the school to which the student is seeking admission. Form CRE 1 is an affidavit stating that the administration of immunizing agents conflicts with the student's religious tenets or practices. The form is available on the Division of Immunization website at http://www.vdh.virginia.gov//Epidemiology/Immunization/requirements.htm; or
- 2. The school has written certification on either of the documents specified under "documentary proof" in 12VAC5-110-10 from a physician, registered nurse, or a local health department that one or more of the required immunizations may be detrimental to the student's health. Such certification of medical exemption shall specify the nature and probable duration of the medical condition or circumstance that contraindicates immunization.
- 3. Upon the identification of an outbreak, potential epidemic, or epidemic of a vaccinepreventable disease in a public or private school, the commissioner has the authority to require the exclusion from such school of all children who are not immunized against that disease.
- B. Demonstration of existing immunity. The demonstration in a student of antibodies against mumps, rubeola, rubella, or varicella in sufficient quantity to ensure protection of that student against that disease, shall render that student exempt from the immunization requirements contained in 12VAC5-110-70 for the disease in question. Such protection should be demonstrated by means of a serological testing method appropriate for measuring protective

antibodies against <u>mumps</u>, rubeola, rubella, or varicella respectively. Reliable history of chickenpox disease diagnosed or verified by a health care provider shall render students exempt from varicella requirements.

C. HPV vaccine. Because the human papillomavirus is not communicable in a school setting, a parent or guardian, at the parent's or guardian's sole discretion, may elect for the parent's or guardian's child not to receive the HPV vaccine, after having reviewed materials describing the link between the human papillomavirus and cervical cancer approved for such use by the board.

#### Part IV

#### Procedures and Responsibilities

#### 12VAC5-110-90. Responsibilities of admitting officials.

A. Procedures for determining the immunization status of students. Each admitting official or his designee shall review, before the first day of each school year, the school medical record of every new student seeking admission to his school, and that of every student enrolling in grade six for compliance with the requirements prescribed in 12VAC5-110-70. Such review shall determine into which one of the following categories each student falls:

- 1. Students whose immunizations are adequately documented and complete in conformance with 12VAC5-110-70. Students with documentation of existing immunity to measles, rubella, or varicella as defined in 12VAC5-110-80 B shall be considered to be adequately immunized for such disease.
- 2. Students who are exempt from the immunization requirements of 12VAC5-110-70 because of medical contraindications or religious beliefs provided for by 12VAC5-110-80.

- 3. Students whose immunizations are inadequate according to the requirements of 12VAC5-110-70.
- 4. Students without any documentation of having been adequately immunized.
- B. Notification of deficiencies. Upon identification of the students described in subdivisions A 3 and 4 of this section, the admitting official shall notify the parent or guardian of the student:
  - 1. That there is no, or insufficient, documentary proof of adequate immunization in the student's school records.
  - 2. That the student cannot be admitted to school unless he has documentary proof that he is exempted from immunization requirements pursuant to 12VAC5-110-70.
  - 3. That the student may be immunized and receive certification by a licensed physician, registered nurse, or an official of a local health department.
  - 4. How to contact the local health department to receive the necessary immunizations.
- C. Conditional enrollment. Any student whose immunizations are incomplete may be admitted conditionally if that student provides documentary proof at the time of enrollment of having received at least one dose of the required immunizations accompanied by a schedule for completion of the required doses within 90 calendar days, during which time that student shall complete the immunizations required under 12VAC5-110-70. If the student requires more than two doses of hepatitis B vaccine, the conditional enrollment period, for hepatitis B vaccine only, shall be 180 calendar days. If a student is a homeless child or youth and does not have documentary proof of necessary immunizations or has incomplete immunizations and is not exempted from immunization as described in 12VAC5-110-80, the school administrator shall immediately admit such student and shall immediately refer the student to the local school division liaison, who shall assist in obtaining the documentary proof of, or completing, immunizations. The admitting official should examine the records of any conditionally enrolled

student at regular intervals to ensure that such a student remains on schedule with his plan of completion.

D. Exclusion. The admitting official shall, at the end of the conditional enrollment period, exclude any student who is not in compliance with the immunization requirements under 12VAC5-110-70 and who has not been granted an exemption under 12VAC5-110-80 until that student provides documentary proof that his immunization schedule has been completed, unless documentary proof that a medical contraindication developed during the conditional enrollment period is submitted.

E. Transfer of records. The admitting official of every school shall be responsible for sending a student's immunization records or a copy thereof, along with his permanent academic or scholastic records, to the admitting official of the school to which a student is transferring within 30 10 days of his transfer to the new school.

F. Report of student immunization status. Each admitting official shall, within 30 days of the beginning of each school year or entrance of a student, or by October 15 of each school year, file with the State Health Department through the health department for his locality, a report summarizing the immunization status of the students in his school as of the first day of school. This report shall be filed using the web-enabled reporting system or on the most current version of Form SIS 4, the Student Immunization Status Report, and shall contain the number of students admitted to that school with documentary proof of immunization, the number of students who have been admitted with a medical or religious exemption and the number of students who have been conditionally admitted. The report for students entering the sixth grade shall include the number with a booster dose of tetanus, diphtheria, or pertussis containing vaccine within the last five years.

G. Each admitting official shall ensure that the parent or guardian of a female to be enrolled in the sixth grade receives educational materials describing the link between the human

papillomavirus and cervical cancer. Materials shall be approved by the board and provided to the parent or guardian prior to the child's enrollment in the sixth grade.

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-110)

2010 Recommended Immunization Schedule for Persons Aged 0 through 6 Years, U.S. Department of Health and Human Services.

2010 Recommended Immunization Schedule for Persons Aged 7 through 18 Years, U.S. Department of Health and Human Services.

2015 Recommended Immunization Schedules for Persons Aged 0 Through 18 Years, U.S. Department of Health and Human Services.

#### March 19, 2015

#### **MEMORANDUM**

TO: Virginia State Board of Health

FROM: Gary R. Brown

Director, Office of Emergency Medical Services

SUBJECT: Statewide Trauma Center Designation Manual Revision

Section 32.1-111.3 of the Code of Virginia requires the Board of Health to develop and maintain a comprehensive, coordinated, emergency medical care system in the Commonwealth and prepare a Statewide Emergency Medical Services Plan. The objectives of such plan and the system include, but are not limited to, "establishing and maintaining a process for designation of appropriate hospitals as trauma centers and specialty care centers based on an applicable national evaluation system."

As part of this statutory requirement, the Virginia Department of Health's Office of Emergency Medical Services is concluding a two and one half year project to revise the <u>Virginia Trauma Center Designation Manual</u>. The revised document underwent a full review utilizing the American College of Surgeons, Committee on Trauma's <u>Resources for the Optimal Care of the Injured Patient 2006</u> as the national standard to base Virginia's trauma standard against. The final draft of the American College of Surgeons, Committee on Trauma's <u>Resources for the Optimal Care of the Injured Patient 2014</u> was also utilized to ensure no significant changes in the newer national standard would affect Virginia's document.

The proposed <u>Virginia Trauma Center Designation Manual</u> was developed in collaboration with the Trauma System Oversight and Management Committee (TSO&MC) and other stakeholders. Five workgroups were established including an administrative workgroup, education/credentialing workgroup, operational workgroup, performance improvement workgroup, and special needs workgroup. Eight quarterly meetings, thirteen workgroup sessions, and many hours of research were dedicated to this project. Daylong meetings were utilized to perform line-by-line reviews of the draft.

Trauma Center Designation Manual Page Two

Additional pediatric stakeholders requested to participate in the process and four additional meetings were held focusing on the pediatric criteria. Two of these meetings were daylong meetings that included a review of each pediatric criterion against its most current national standard. The Emergency Medical Services for Children (EMSC) committee was also requested to review the proposed document and it also held a special called meeting to examine and provide input on the pediatric specific criteria. The opinions of the EMSC committee were adopted by the TSO&MC.

Despite the extraordinary effort put forth by trauma stakeholders to create this document and make every effort to accommodate new stakeholders from the pediatric community, an issue remains unresolved. Children's Hospital of the King's Daughters (CHKD), which has never been designated as a trauma center, has requested that the State Health Commissioner allow CHKD to become "co-designated" with Sentara Norfolk General Hospital. Unfortunately, no national standard exist for allowing two individual hospitals to "co-designate."

The Code of Virginia requires that Virginia trauma center criteria be based on an applicable national standard. CHKD is requesting relief from core trauma designation criteria including surgeon response, performance improvement, and trauma education. CHKD has been encouraged to approach the TSO&MC and request the committee evaluate the possibility of developing a process of "co-designating". To date, CHKD has twice by-passed the TSO&MC: first approaching the State Health Commissioner and secondly approaching the Chair of the Emergency Medical Services Advisory Board.

The proposed Virginia Trauma Center Designation Manual was approved by the TSO&MC of the State Emergency Medical Services Advisory Board on September 4, 2014 and by the full the Emergency Medical Services Advisory Board on November 5, 2014.

At the March 19, 2015 meeting of the State Board of Health, the Virginia Department of Health's Office of Emergency Medical Services will present the 2015 Virginia Trauma Center Designation Manual. This will provide an opportunity for Board members to ask questions and provide input, and also provide interested parties the opportunity to provide public comment during the meeting. We plan to present the 2015 Virginia Trauma Center Designation Manual, revised as appropriate, to the Board for its consideration and approval, as the Commonwealth's standard for designating hospitals as trauma centers, at the June 2015 Board meeting.

# 2015

Virginia Department of Health's Office of Emergency Medical Services

Robin D. Pearce, Trauma/Critical Care Coordinator

# [VIRGINIA TRAUMA CENTER DESIGNATION MANUAL]

The purpose of the Virginia Trauma Designation Manual is to provide information and specific criteria on how trauma center designation is acquired and maintained.

# **Manual Version History Log**

Version Number	Release Date	Page(s) Affected	Description
V2015.1	2/16/2014	All	First release pre 3/5/2014 TSO&MC
V2015.1	9/4/2014		Approved by TSO&MC
V2015.1	11/5/2014		Approved EMS Advisory Board with
			amendments.
V2015.2	11/5/2014	22	Language clarified to describe how
			pediatric hospitals should manage the
			non–routine patient that are 15 years
			of age or older.
V2015.2	11/5/2014	30 (criterion 5.4)	Interpretive guidance updated to
			clarify that the trauma surgeon for
			level I, IB, and peds shall be in-house.
			This requirement already existed in
			criterion 6.8.

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#### **Preface**

The purpose of the Virginia Trauma Center Designation Manual (Manual) is to provide information to hospitals, physicians, nurses, and administrators about trauma designation and verification in the Commonwealth of Virginia. This Manual contains the criteria and standards effective January 1, 2015, for the five designation levels of trauma designation recognized within the Commonwealth of Virginia.

Virginia trauma center standards are based upon national standards put forth by the American College of Surgeons (ACS) (ACS/COT, Resources for the Optimal Care of the Injured Patient, 2006), the Resources for the Optimal Care of the Injured Patient (2014), and the American College of Emergency Physicians (ACEP). Burn center criteria are based upon the American Burn Association's (ABA) standards (ACS/COT, Resources for Optimal Care of the Injured Patient 2006, Chapter 14, 2006). Neither set of standards is wholly adopted. Instead, stakeholder group input is utilized to adapt the standards to best fit the Virginia Trauma System. The State Board of Health (BOH) is the final approving body for these standards.

Development of the Manual begins with Virginia's statewide trauma committee, the Trauma System Oversight and Management Committee (TSO&MC). Once approved by the TSO&MC the Manual is presented to the Emergency Medical Services Advisory Board (EMS Advisory Board) for its approval. The EMS Advisory Board and the TSO&MC are advisory to the State Board of Health (BOH) and the Office of Emergency Medical Services (OEMS). Authority to approve the Manual rests solely with the BOH.

The purpose of the trauma designation process is to ensure a consistent minimum level performance of trauma centers in Virginia and to promote continued improvement and development of experienced centers thereby reducing morbidity and mortality of the traumatically and thermally injured patients of all ages.

Please direct questions or requests for further information or resources to the Virginia Department of Health's (VDH), Office of Emergency Medical Services (OEMS) Trauma/Critical Care Coordinator, 1041 Technology Park Drive, Glen Allen, Virginia 23059 or (804) 888–9100.

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#### **Definitions**

**Adult Trauma Patient** – A trauma patient 15 years of age or older.

**Burn Center** – A hospital that has been designated by the State Health Commissioner as a trauma/burn center after meeting the Level I trauma center and Level I burn center criteria contained within this document.

**Burn Patient** – A patient requiring treatment of burn–related injuries who should be referred to a designated trauma/burn center in the Commonwealth of Virginia for assessment and care. See the Burn Patient Criteria section on page 68 for details on the severity of burn injury that should be managed by trauma or burn designated hospital.

**Burn Service** – An organized approach (within the designated trauma center) to the care of burn patients with a focus on performance improvement, education, and outreach. Burn Service administrative leadership addresses burn center standards under the direction of the Burn Medical Director.

**Burn Unit** – The designated geographic area within a hospital that the majority of acute burn patients receive care.

**Critical Deficiency** – When a trauma center demonstrates an absence or inadequate mechanism to address a specific critical criterion or criteria. Critical deficiencies shall be corrected as directed in this document to receive an unconditional designation.

**Designated Trauma Center** – The process by which the Virginia Department of Health (VDH) identifies hospitals that are prepared to consistently provide care to the traumatized patient.

Emergency Medical Services for Children (EMSC) – A state program supported by the Health Resources and Services Administration focused on supporting the emergency medical needs of the pediatric population.

**Experienced/Mature Trauma Center** – A designated trauma center that has completed at least one successful three–year verification cycle.

**Immediately Available** – For the purpose of this document immediately is defined by the physical presence of the health professional in a stated location able to provide care to the trauma patient within 15 minutes.

**Level I** – Level I trauma centers have an organized trauma response and are required to provide definitive trauma care for every aspect of injury from prevention through rehabilitation. These facilities must have adequate depth of resources and personnel with the capability of providing leadership, education, research, and system planning.

**Level IB** – Meet all the requirements for Level I trauma center designation and the additional criteria specific to being designated as a trauma/burn center (denoted as Level IB trauma center). Designated trauma/burn centers must provide burn care across the age spectrum.

**Pediatric Designation** – Trauma centers designated as a pediatric trauma center will meet all the requirements of Level I trauma center designation, unless specified in the document, and additional pediatric criteria not required of other levels of designation. Hospitals that only manage pediatric patients will be required to meet Level I criteria for patients less than 15 years of age.

**Level II** – Level II trauma centers have an organized trauma response and are also expected to provide initial definitive care, regardless of the severity of injury. Level II trauma centers must provide definitive trauma care for patients 15 years and older and provide immediate assessment, resuscitation, stabilization, emergency surgery, and arrange for the transfer of trauma patients under 15 years old as needed. The specialty requirements may be fulfilled by on call staff members, which are immediately available to the patient. Due to some limited resources, Level II centers may have to transfer more complex injuries to a Level I center. Level II centers should also take on responsibility for education and system leadership within their region.

**Level III** – Level III centers, through an organized trauma response, can provide prompt assessment, resuscitation, stabilization, and emergency surgery for patients across the age spectrum. Level III centers may arrange for the transfer of trauma patients to a hospital that can provide definitive trauma care that cannot be managed by the resources dedicated to Level III designation. Level III centers should also take on responsibility for education and system leadership within their region.

**Non–Critical Deficiency** – The trauma or trauma/burn center demonstrates an absence or inadequate mechanism to address a specific non–critical criterion or criteria. While there is not an immediate negative impact on patient care, continuation of the present status will result in erosion of the program and development of a critical deficiency. Non–critical deficiencies seen during two consecutive site reviews shall be elevated to a critical deficiency.

**Pediatric Trauma Patient** – A trauma patient that is less than 15 years of age.

**Promptly available** – For the purpose of this document promptly is defined by the physical presence of the health professional in a stated location able to provide care to the trauma patient within 30 minutes

**Tracer Methodology** – The process involves interviewing the caregivers to evaluate the quality and safety of the patient care process. The process also includes reviewing the care of patients actively being managed at the time of a trauma center designation site review. By evaluating the actual delivery of care services, less time is devoted to examining written policies and procedures.

**Trauma Center** – A hospital that has been designated by the State Health Commissioner as a trauma center after demonstrating it meets the criteria throughout this document.

**Team Leader** – A surgeon that serves as the head of a trauma center site review team. This is typically a surgeon involved in an active trauma service.

**Trauma Patient** – The identification of patients that should be referred to a designated trauma center in the Commonwealth of Virginia for assessment and care. The Statewide Trauma Triage Plan (VDH/OEMS, 2011) sets the minimum standard for defining a trauma patient.

**Trauma Registrar** – The individual(s), responsible for entering, analyzing, and evaluating the data maintained in each trauma center's trauma registry.

**Trauma Service** — The medical and surgical services that direct and coordinate the care of acutely injured patients.

**Trauma Team** – A multidisciplinary healthcare team that is predetermined to provide an organized approach to providing trauma care.

**TSO&MC** – Trauma System Oversight and Management Committee is a subcommittee of the EMS Advisory Board and advises the OEMS and/or BOH. This is the Commonwealth's trauma stakeholder committee that works to develop, maintain, and improve Virginia's trauma system under the auspices of the BOH.

**Virginia Statewide Trauma Registry (VSTR)** – In Virginia, all hospitals that provide emergency services are required by the *Code of Virginia* §32.1–116.1 to report to the VSTR. The VSTR is used by Virginia's trauma system for performance improvement, research, injury prevention, resource utilization, and the creation of state standards and benchmarks.

#### **Abbreviations**

- **ABLS** Advanced Burn Life Support sponsored by the American Trauma Society.
- ACLS Advanced Cardiac Life Support sponsored by the American Heart Association (AHA).
- **ACS** American College of Surgeons.
- ACS/COT American College of Surgeons Committee on Trauma.
- ATCN Advanced Trauma Care for Nurses sponsored by the Society for Trauma Nurses.
- **ATLS** Advanced Trauma Life Support course sponsored by the ACS.
- **BOH** State Board of Health.
- C Critical criterion.
- **CEN** Certified Emergency Nurse.
- **CRNA** Certified Registered Nurse Anesthesiologist.
- **CEO** Chief Executive Officer.
- **CATN** Course in Advanced Trauma Nursing sponsored by the Emergency Nursing
- Association.
- **COT** Committee on Trauma.
- **CT** Computed Tomography Scanning.
- CEU Continuing Education Unit.
- **CME** Continuing Medical Education.
- **DOA** Dead on arrival.
- ECG Electrocardiogram.
- **ED** Emergency Department.
- **EMS** Emergency Medical Services.
- EMSC Emergency Medical Service for Children.
- **ENA** Emergency Nurses Association.
- **ENPC** Emergency Nurses Pediatric Course sponsored by the ENA.
- **ENT** Ear, Nose, and Throat surgery service.
- **ETT** Endotracheal tube.
- **ISS** Injury severity score.
- **ICU** Intensive Care Unit.
- **ICD9** Ninth edition of International Classification of Disease.
- **ICD10** Tenth edition of International Classification of Disease.
- **ICP** Intracranial pressure.
- IV Intravenous.
- **LPN/LVN** Licensed professional nurse/licensed vocational nurse.
- **MRI** Magnetic resonance imaging.
- **MD** Medical doctor.
- NC Non–critical Criterion.
- **OEMS** The Virginia Office of Emergency Medical Services.

**OR** – Operating room.

**PALS** – Pediatric Advanced Life Support sponsored by the American Heart Association.

**PI** – Performance improvement; used to describe quality assurance efforts (QA/QI/CQI).

PACU – Post Anesthesia Care Unit.

**PGY4/PGY5** – postgraduate year; classification system for residents in postgraduate training. The number after PGY indicates the year of residency the physician is in since graduating from medical school.

**PHTLS** – Prehospital Trauma Life Support sponsored by the ACS/COT.

**RN** – Registered Nurse.

**RTTDC** – Rural Trauma Team Development Course sponsored by the ACS.

STN – Society of Trauma Nurses.

**TEH** – Trauma education hour(s) is the equivalent of 60 minutes of trauma education.

TMD - Trauma Medical Director.

TNCC – Trauma Nurse Core Curriculum course sponsored by the ENA.

**TPM** – Trauma Program Manager; traditionally called the trauma nurse coordinator (TNC); this position varies by center and is more frequently a trauma director or trauma program manager. This position will be referred to as the TPM throughout this document for reasons of editing only.

**TSO&MC** – The Trauma System Oversight and Management Committee; this is the Commonwealth's statewide trauma advisory committee.

**VDH** – Virginia Department of Health.

**VDH/OEMS** – Virginia Department of Health's Office of Emergency Medical Services.

**VSTR** – Virginia Statewide Trauma Registry.

# **Trauma Center Designation**

This resource document, The Virginia Trauma Center Designation Manual, and other materials are available at <a href="www.vdh.virgina.gov/oems">www.vdh.virgina.gov/oems</a>. Virginia trauma center criteria are based on the *Resources for Optimal Care of the Injured Patient: 2006* (ACS/COT, Resources for the Optimal Care of the Injured Patient, 2006) and the Resources for the Optimal Care of the Injured Patient (2014).

The Trauma System Oversight and Management committee (TSO&MC), a subcommittee of the EMS Advisory Board (Advisory Board), is tasked with advising the State Board of Health (BOH) and the Office of Emergency Medical Services in matters related to the Virginia's trauma system, trauma center designation, and the Virginia Statewide Trauma Registry (VSTR).

Each subcommittee of the EMS Advisory Board maintains a vision, mission statement, and core objectives that are accepted by the full EMS Advisory Board. The TSO&MC's are as follows:

**Vision** – The TSO&MC will collaborate to support a statewide inclusive trauma system through evaluation, planning, and performance improvement.

**Mission** – To advise the BOH and the OEMS with maintaining an inclusive system that ensures when the severity and incidence of trauma cannot be prevented, that all injured persons within the Commonwealth have rapid access to optimal, equitable, and efficient specialized trauma care to prevent further disability or death utilizing a public health approach.

**Core Objectives** – Advise the OEMS on matters relating to:

- ➤ Maintaining a process for designating hospitals as trauma centers (§ 32.1–111.3:A.10).
- ➤ Maintaining a statewide pre—hospital and inter—hospital trauma triage plan (§ 32.1–111.3:19.B).
- ➤ Maintaining a performance improvement process that supports the trauma center designation process, trauma triage plan, and improves trauma care throughout Virginia (§ 32.1–111.3:B.3).

(The vision, mission statement, and core objectives were created during the process to revise the August 13, 2010 EMS Advisory Board Bylaws)

The process of designation is voluntary on the part of the hospitals in the Commonwealth. It is meant to identify those hospitals that will make a commitment to provide a given level of care

for the seriously injured and/or burned patient and who welcome public acknowledgment of that capability. System knowledge of trauma and burn care capabilities, with improved prehospital categorization of trauma patients will help all those involved in the trauma and burn care delivery system make decisions that are in the best interest of the patient.

### The designation process is as follows:

- Any hospital that desires consideration for designation will make a request to the Virginia Department of Health's (VDH) OEMS Trauma/Critical Care Coordinator. The request, with statement of community need or justification, and its impact on the regional trauma system will be included with the hospital's application for designation. The application can be obtained on—line at <a href="http://www.vdh.virginia.gov/OEMS/Trauma/TraumaSystem.htm">http://www.vdh.virginia.gov/OEMS/Trauma/TraumaSystem.htm</a> or from the VDH/OEMS Trauma/Critical Care Coordinator.
- ➤ Items that comprise a complete trauma center designation application can be found in the application document titled <a href="http://www.vdh.virginia.gov/OEMS/Trauma/LinksDocuments.htm">http://www.vdh.virginia.gov/OEMS/Trauma/LinksDocuments.htm</a>.
- ➤ The application for designation should include the hospital name, parent company, chairperson of its board of directors, chief executive officer (CEO), nurse executive, administrator in charge of the trauma service, trauma medical director, trauma program manager, and the emergency department medical director.
- ➤ The Trauma/Critical Care Coordinator will review the application for the appearance of compliance with the required standards stated in this Manual. Additional clarifying documents or information may be required.
- ➤ A trauma center designation site review (site review) will only be scheduled after a hospital can demonstrate the appearance that it meets trauma center criteria, compliance with the VSTR data submission requirements (see criterion 10.2), and compliance with the Commonwealth's prehospital and interhospital trauma triage plan (VDH/OEMS, 2011).
- A site review will be scheduled within six months of receiving a completed application. The hospital will receive an agenda, list of documents required to be available, and personnel needed to be available at the time of the site review 30 days prior to the confirmed site review date.

- An initial site review will be scheduled for the purpose of awarding provisional status as a trauma center. Upon completion of one year as a provisional trauma center, the hospital will be required to submit an interim report describing any changes since designation as a provisional center and undergo a modified site review.
- The modified site review will be conducted by a site review team consisting of a surgeon team leader, a trauma/critical care RN, and the OEMS Trauma/Critical Care Coordinator. If there are no critical deficiencies identified during the modified site review, the site review team will recommend that the hospital be unconditionally designated as a trauma center by the State Health Commissioner (Commissioner).
- > Site review teams will be composed of the following roles:
  - o For Level I and Level IB trauma center designation:
    - An out-of-state trauma surgeon (upon request of the applying hospital and /or review team).
    - An in–state trauma surgeon/team leader.
    - A trauma/critical care nurse.
    - An ED physician.
    - A hospital administrator.
    - OEMS Trauma/Critical Care Coordinator.
  - For Level II and Level III trauma center designations
    - An in—state trauma surgeon/team leader.
    - An ED physician.
    - A trauma/critical care nurse.
    - A hospital administrator.
    - OEMS Trauma/Critical Care Coordinator.
  - o For pediatric trauma center designations
    - A pediatric trauma surgeon will be added to the above team.
    - A pediatric critical care RN will be added to the above team.
- ➤ At the conclusion of each site review, the site review team members will submit a summary of their findings and recommendations through a written team report to the Commissioner.
- This report may be developed on—site by the site review team or through individual reports submitted by the team members to the team leader, who in turns develops a summary report. If the team report is not completed on—site, team members will have their summary to the team leader within 14 days. The team leader will have their report

and team members' reports to the OEMS Trauma/Critical Care Coordinator within 30 days of the site review date.

- ➤ The site review team may share the draft copy of the summary report to the candidate hospital at the conclusion of the review.
- ➤ OEMS staff may edit the draft team report for grammatical errors, spelling errors, and meet regulatory language without changing the intent of the site review team, prior to submission to the Commissioner.
- A trauma center designation verification site review will be required triennially. The triennial site review is based upon the date of full site review dates and not modified site review dates. Site review teams may recommend the verification cycle be of a lesser time period as deemed necessary.
- The finalized report will be submitted to the Commissioner for consideration to designate the hospital as a provisional trauma center for a one—year period or a designated trauma center for two—year period from the date of notification. Provisional trauma center designation is granted after an initial site review and full designation after the modified site review noted supra.
- ➤ Designation is at the discretion of the Commissioner and variations of designation cycles may be utilized, as well as special conditions.
- > The hospital will receive a copy of the final version of the site review team's final report along with the Commissioner's determination to grant or deny trauma center designation.
- In the event that the hospital disagrees with the report, the hospital may choose to initiate an appeals process as outlined on page 56 within the Administrative Guidelines section of this document.

#### **Trauma Center Verification**

Trauma center verification is the process used to confirm that existing designated trauma centers are maintaining the resources and ability to meet trauma center designation criteria. The process of trauma center verification is similar to initial trauma center designation as outlined in the previous section and is as follows:

- A written renewal notice will be sent by the OEMS Trauma/Critical Care Coordinator to the hospital's Chief Executive Officer (CEO) with a courtesy copy to the trauma medical director and trauma program manager approximately six months prior to the expiration of the current designation.
- ➤ The hospital applying for trauma center verification shall submit proposed site review dates as prescribed by the OEMS within 30 days of receiving the renewal notice.
- ➤ The hospital will receive a confirmation date from OEMS within 30 days of the submitted proposed site review dates.
- ➤ The hospital shall submit a complete designation application no later than 60 days prior to the confirmed site review date. The completed application will include the following items:
  - Acknowledgement that the OEMS trauma center file has been reviewed.
  - Submissions to the VSTR are up to date per the established submission schedule.
    - January 1<sup>st</sup> thru March 31st due on May 31<sup>st</sup>
    - April 1<sup>st</sup> thru June 30<sup>th</sup> due on August 31<sup>st</sup>
    - July 1<sup>st</sup> thru September 30<sup>th</sup> due on November 30<sup>th</sup>
    - October 1<sup>st</sup> thru December 31<sup>st</sup> due on February 28<sup>th</sup>/29<sup>th</sup>
  - A signed Trauma Center Code of Conduct (electronic form provided).
  - A completed Trauma Center Capabilities form (electronic form provided).
  - A current Organizational Chart describing the relationship of the trauma service within the hospital organizational structure.
  - An impact statement as stated later in the criteria.
  - Completion of the Trauma Center Criteria Checklist applicable to the Level of designation being applied for (electronic form provided).
  - Submission of a completed Trauma Center Questionnaire (electronic form provided).
  - A list of all emergency physicians employed in the ED during the verification cycle (includes locum tenens).

- A list of all surgeons performing trauma call during the verification cycle (includes locum tenens).
- A copy of the trauma call schedule for the most recent three consecutive months.
- A copy of the trauma team activation/alert criteria for your hospital.
- A copy of your hospital's trauma team roles & responsibilities policy/procedure.
- A copy of all trauma activation/alert policies.
- An official copy of the Trauma Medical Director's (TMD) job description.
- Evidence of the TMD's board certification(s).
- Evidence of the TMD's current ATLS certification.
- Evidence of the TMD's compliance with continuing medical education (CME) requirements.
- Evidence of the TMD's attendance at a national conference (if applicable).
- Evidence of the Burn Medical Director's board certification (if applicable).
- Evidence of the Burn Medical Director's compliance with CME requirements (if applicable).
- A copy of the Trauma Program Manager's (TPM) job description (include Organizational Chart).
- Evidence of the TPM's compliance with trauma educational hour (TEH) requirements.
- Evidence of the TPM's attendance at a national conference (if applicable).
- A copy of the Burn Manager's job description (if applicable).
- Evidence of the Burn Manager's compliance with burn specific educational hour requirements (if applicable).
- A copy of each trauma registrars' (registrar) job description.
- Evidence of each registrar's compliance with continuing educational requirements.
- Provide a complete list of current nursing staffs that serve as the trauma team primary nurse in the trauma resuscitation room. Include whether the trauma team nurses possess active TNCC, ATCN, or CATN certifications.
- Evidence of the Emergency Medical Director's board certification.
- Evidence of the Emergency Medical Director's CME.
- Evidence of the Emergency Medical Director's current ATLS or the identified designee's current ATLS.
- Performance improvement (PI) process flow diagram.
- PI worksheet/tracking Sheet.
- PI plan/policy.
- Any other documents as requested.
- The site review team will be composed of a trauma surgeon/team leader, an emergency medicine representative, a trauma/critical care nurse, hospital administration

representative, and the OEMS Trauma/Critical Care Coordinator. The OEMS Trauma/Critical Care Coordinator can cover any vacant position except for the surgeon/team leader role if needed.

- > The site review day will occur as follows:
  - There will be an opening conference with the key hospital staffs that routinely provide direct and ancillary services to trauma patients and the site review team. The key individuals include, but are not limited to: the TMD, TPM, Burn Medical Director, Emergency Medicine Medical Director, the hospital administrator that is the immediate supervisor for the trauma service, the liaisons from orthopedic surgery, anesthesiology, radiology, and neurosurgery and pediatric surgery if applicable, trauma nurse clinicians, nurse managers from the ED, operating room (OR), intensive care units (ICU), pediatric and trauma nursing floors, trauma registrar, PI coordinator, rehabilitation medicine, lab/blood blank representatives, local EMS Chiefs, and OMDs.
  - After the opening conference Trauma Service staffs will provide a presentation demonstrating their performance improvement process to the site review team.
     The presentation should include PI cases that have resulted in operational and clinical policy/protocol changes.
  - The site review team will tour the hospital with the hospital staff person that is in an equivalent role to the team member. Appointments for individual meetings between the site review administrative team member and the hospital's CEO, Chief Nursing Officer (CNO), and the administrator that is the immediate supervisor of the trauma service shall be arranged.
  - The site review team shall be provided with a work area to privately review
    hospital medical records. The team may also use a tracer methodology and
    review charts of active patients. Medical records are chosen in advance by the
    VDH/OEMS using the VSTR, EMS registry, other validated sources, and from
    any public concerns submitted to the OEMS. Additional medical records may be
    requested during the review.
  - There shall be a review of PI documentation.
  - There will be an exit conference with the TMD, TPM, and the hospital administrator with direct responsibility for the trauma service, and the CEO and CNO if desired.

- At the conclusion of each site review, the site review team will document their findings in the form of team report that includes the strengths, opportunities for improvement, noncritical deficiencies, and critical deficiencies observed during the site review.
- > The site review team members will include in the team report a recommendation to the Commissioner of whether the hospital should be verified as a designated trauma center.
- > The team report may be developed on—site by the site review team or through individual reports submitted by the team members to the team leader, who in turns develops a summary report. If the team report is not completed on-site team members will have their summary to the team leader within 14 days. The team leader will have their report and team members' reports to the OEMS Trauma/Critical Care Coordinator within 30 days of the site review date.
- The site review team may share the draft copy of the summary report with the trauma center at the conclusion of the site review.
- > OEMS staff may edit the draft team report for grammatical errors, spelling errors, and meet regulatory language without changing the intent of the site review team, prior to submission to the Commissioner.
- The finalized team report will be submitted to the Commissioner for consideration to verify the hospital as a designated trauma center.
- Acting upon the recommendation of the site review team, the Commissioner may verify the designation of the trauma center for a three-year period from the date of the full site review.
- > Designation is at the discretion of the Commissioner and variations of designation cycles may be utilized, as well as special conditions.
- A trauma center designation verification site review will be required triennially. The triennial site review is based upon the date of the initial full site review and not modified site review date(s). Site review teams may recommend the verification cycle be of a lesser time period as deemed necessary.
- > If a trauma or trauma/burn center fails to meet critical criteria/receives a critical deficiency during a site review or by other evidence, the hospital will receive written notification by the OEMS Trauma/Critical Care Coordinator.

- The trauma center will submit a written plan of correction for each critical deficiency within 30 days after formal written notification. The trauma center will have six months, from the date of notification to correct all deficiencies and undergo a modified site review performed by the team leader, OEMS staff, and other team members as needed from the initial review. The team leader may be replaced for extenuating circumstances. The team leader may also deem a repeat review unnecessary with the submission of appropriate documentation that demonstrates the deficiency has been corrected.
- ➤ If the deficiencies are not corrected within the six—month period, trauma center designation will be withdrawn by the Commissioner. If the hospital desires designation as a trauma center, it must wait a minimum of six months and reapply.

# **Burn Center Designation**

The purpose of the burn center designation process is to ensure consistent performance of trauma/burn centers in Virginia and to promote continued improvement and development of experienced burn centers and thereby reducing morbidity and mortality of the thermally injured patient.

The intent of this document is to outline the criteria for the designation and verification of trauma/burn centers in Virginia. This document defines the essential components of burn centers in Virginia and outlines administrative guidelines describing the procedures and steps required for the process and interpretive guidelines describing how burn center criteria should be evaluated during a site review.

The objective is to provide a consistent, objective, and meaningful approach to the designation and verification process. Hospitals seeking burn center designation must be physically co-located with a Level I trauma center.

### **Pediatric Trauma Center Designation**

All designated trauma centers are required to provide emergent stabilization and life or limb saving emergency surgery for trauma patients of all ages. All trauma centers are required to provide definitive trauma care for trauma patients 15 years of age and older based on their level of designation.

As of this version of the Commonwealth's Trauma Center Designation Manual, any hospital that solely treats a pediatric population (for the purposes of the Virginia Trauma System, pediatric is defined as less than 15 years of age) may be granted trauma center designation.

If a "pediatric hospital" wishes to seek and maintain trauma center designation, it shall meet all criteria for Level I trauma center designation adjusted as age appropriate for trauma patients less than 15 years of age. The pediatric hospital that is designated as a trauma center shall not routinely treat trauma patients 15 years of age or older. The pediatric hospital should have a policy in place that addresses the management of patients 15 years of age and older. The pediatric hospital's trauma performance program should have audit filters in place to monitor for these patients and assure they receive the same level of care and response as other patients.

In such a case that a pediatric hospital exists as a trauma center, the State or regional trauma triage plan for its catchment area will clearly define the appropriate point-of-entry plan for utilization of this resource for patients under 15 years of age.

## Trauma Center Criteria

The criteria are listed below as either "C," which are critical criteria or "NC" which are noncritical criteria. Failure to meet any single critical criterion constitutes a failure to pass designation or verification. Receiving the same non-critical criteria during two consecutive designation or verification site reviews constitutes a failure to pass designation or verification.

Level:	I	IB	Peds	II	III
1. Organization Requirements					
1.1. The Trauma Service shall be a recognizable service line within the hospital.	С	С	С	С	С
1.2. There shall be evidence of the hospital's Board of Directors supporting the Trauma Service's care for all levels of designation sought.	С	С	С	I	_
1.3. There shall be evidence of the hospital's Board of Directors support for the Trauma Service.	_	_	С	С	С
Measure: current resolution that is reaffirmed triennially from the lequivalent body.	Board	of Di	irectors	or	
1.4. Support of the hospital's Board of Directors. (The Board of Directors shall be notified of applications for all levels of trauma designation, verification, and approval by the State Health Commissioner after a site review).	С	С	С	С	С
1.5. The hospital shall provide sufficient infrastructure and support to the trauma service to ensure the adequate provision of trauma care.	С	С	С	С	С
1.6. There shall be evidence of support for trauma center designation by the hospital's medical staff executive committee.	С	С	С	С	С
Measure: current resolution that is reaffirmed triennially from the committee or equivalent body.	nedic	al sta	ff execu	ative	
1.7. Hospital administration shall be supportive of the trauma service.	С	С	С	C	С
1.8. Upper level administrative personnel shall demonstrate knowledge, familiarity, and commitment to maintaining trauma center at all levels of designation.	С	С	С	С	С
1.9. Upper level administration participation shall be available to support the trauma service as needed for issues that require a higher level of authority to accomplish resolution of issues.	С	С	С	С	С
1.10. There shall be evidence of an annual trauma service specific budget that includes utilization of funding received from the Trauma Center Fund.	С	С	С	С	С

Level:	I	IB	Peds	II	III
1.11. The hospital shall provide adequate human and physical resources to provide acute trauma care consistent with its level of trauma center designation.	NC	NC	NC	NC	NC

Interpretive Guidance: Institutions should have an allocated budget for the trauma or burn program(s); however the institution can demonstrate compliance with the criteria by documenting that the expenses and revenues associated with the program are routinely evaluated. Development and maintenance of any level of trauma center requires non–clinical time, space, equipment and supplies. Allowances for these should be included in the budget. As the number of patients admitted to the service increases, it is reasonable to expect increasing demands in terms of non–clinical time and support. For example, according to ACS recommendations, a full time registrar is expected to manage information entry and retrieval on 750 patients or less. The site review team should identify sufficient resources to support non–clinical activities. They will be aware of the fact that multiple management responsibilities may prevent functioning at full time status.

There should also be demonstrated effort to identify costs related to the trauma service. It is important for the hospital leadership to be aware of costs in order to avoid sudden discoveries of expenses and equally sudden withdrawals. Additionally, it is difficult to determine if resources are adequate if program expenses are unknown. In recent years, trauma centers have also been asked to provide information on the cost of trauma care in order to assess the overall fiscal impact on Virginia healthcare; in this setting provision of general information on expenses and reimbursement is a means of participation in the trauma system. There is currently no standard reporting format for expenses, reimbursement, and budgetary allocations. Financial information on the trauma or burn program should be collected and reported to the administration, TMD, and TPM in a manner which is meaningful and useful for planning.

2.	Trau	ma Service Infrastructure					
	2.1.	The Trauma Service shall be an identifiable service within the hospital.	С	С	C	С	С
	2.2.	The Trauma Service shall have a surgeon as its director/physician—in—charge (referred to throughout this Manual as the TMD.)	С	C	C	С	С

The institution may choose to add an emergency physician co-director to the program. The presence of a co-director does not change requirements for experience, education, and participation of the surgeon in the program. Advantages of a co-director include assistance in performing administration, coordination, education, and evaluation of care normally assigned to the surgeon director. Additionally, the emergency physician will provide a different emphasis on the management of trauma with a greater focus on acute resuscitation. No requirements are provided for the position of trauma co-director. However; if the institution chooses to include this position, it must provide a job description and qualifications.

2.3.	The Trauma Service shall have a trauma director/trauma program manager/trauma nurse coordinator (referred to throughout this document as the TPM.)	C	С	С	С	С
2.4.	The Trauma Service shall have a trauma registrar(s).	С	С	С	С	С

	Level:	I	IB	Peds	II	III
2.5.	There shall be a trauma service manual that reflects the actual procedures and protocols being practiced on the service.	С	С	С	С	С
2.6.	There shall be an identifiable trauma response for the resuscitation of seriously or potentially seriously injured patients.	С	С	С	С	С
2.7.	There shall be a consistent implementation of the trauma response as described in the trauma service manual.	С	С	С	С	С
2.8.	The Trauma Service shall have a written mission statement describing the provision of comprehensive trauma care within a trauma system.	С	С	С	С	С
2.9.	The Trauma Service shall have an impact statement describing the role of the trauma center in the regional trauma system.	NC	NC	NC	NC	NC
2.10.	The Trauma Service shall develop and maintain a long—term strategic plan.	NC	NC	NC	NC	NC

Interpretive Guidance: This version of the designation criteria continues to emphasize continuous development and improvement. Presence of a planning process for the program(s) (which may include a business or strategic plan) allows for anticipated response to changes in the trauma care environment as well as possible improvements in delivery of care. Programs are expected to show progress and capacity for change in response to environmental stresses. During the site review opening conference, the director will be asked to list strengths and weaknesses of the program.

Weakiiess	ses of the program.					
2.11.	The TMD shall participate in trauma call.	C	C	C	C	C
2.12.	The TMD shall be active in delivering clinical care to trauma patients.	С	С	С	С	С
2.13.	The TMD shall have the responsibility and authority to determine each general surgeon's ability to perform trauma call.	NC	NC	NC	NC	NC
2.14.	The TMD shall oversee all aspects of multidisciplinary trauma care from the time of injury to discharge.	С	С	NC	С	С
2.15.	The TMD shall have the responsibility and authority to ensure compliance with trauma center designation and verification criteria.	NC	NC	NC	NC	NC
2.16.	The TMD shall be involved in the development of the hospital's bypass/diversion protocol development.	NC	NC	NC	NC	NC
2.17.	The TMD shall be involved in the decisions regarding bypass.	NC	NC	NC	NC	NC
2.18.	The TMD shall participate in regional and national trauma organizations.	NC	NC	NC	NC	NC

Level:	I	IB	Peds	II	III				
Interpretive Guidance: It is essential that the TMD remain active in development and management of the trauma system on the state and regional level. This will be demonstrated by evidence of attendance and participation in regional, state, or national level trauma system and trauma performance groups.									
2.19. The TMD shall be actively involved in prehospital personnel training, the performance improvement/patient safety program process, and development of trauma components of EMS.	NC	NC	NC	NC	NC				
2.20. The TMD shall be involved in trauma research which includes the need to create a publication of results and presentations.	С	С	_	1	ı				
2.21. The Trauma Service shall have a dedicated full time equivalent (FTE) for a TPM.	С	С	С	C	C				
Interpretive Guidance: The TPM is essential to the integration and smooth functioning of the trauma service. This individual acts as the liaison between the trauma service and the hospital services necessary to provide care for the multiply injured patient. The TPM also is the primary contact and resource for the nursing services required for trauma care from the time of admission to rehabilitation and follow up care. On most services the TPM also provides the logistical support for implementing the performance improvement program.									
2.22. The TPM shall have overall management responsibilities for the trauma service.	С	С	С	С	С				
2.23. There shall be a defined job description delineating the TPM role and responsibilities.	С	С	С	С	С				
Interpretive Guidance: While specific job descriptions vary based organization and support, it is essential that a job description be prewhat is expected. An organizational tree should indicate reporting documents should outline sufficient levels of authority for the TPM nursing and ancillary services and to perform any other tasks outline.	esent a relation I to pe	and ac onship erform	curatel s. The PI, int	se two	o with				
2.24. The TPM shall be reflected in the hospital's organizational chart.	С	С	С	С	С				
2.25. The Trauma Service shall have an additional FTE dedicated to the Trauma Service. This additional FTE may be utilized for outreach, PI, education, or other essential trauma related needs that best supports the growth and sustainment of the individual trauma service as determined by the TPM.	С	С	С	С	NC				
Interpretive Guidance: Some programs include more than one nurs these positions may vary for example: trauma case manager, trauma program where there is a Trauma Program Manager) etc. The requ the individual identified as being primarily responsible for the trauma nursing or other position is assigned to the trauma service, there mu	a nurs ireme na ser	e coon nts ab vice.	rdinato ove ap Howe	r (in a ply on ver, if	aly to				

position, inclusion in the program organizational chart and plan for education commensurate

with the position described.

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	Level:	I	IB	Peds	II	Ш			
2.26. The Trauma Registrar shall be a minir FTE dedicated to the trauma registry.	num of one full	C	С	С	С				
2.27. The Trauma Registrar shall be a minir FTE dedicated to the trauma registry.	num of one-half	_	_	_	_	С			
Interpretive Guidance: The trauma registrar is responsible for extracting information from charts, maintaining the trauma registry and developing and delivering reports from the registry. This role is vital in the maintenance of a robust PI program and in delivery of required trauma registry data to the state. The minimum requirement for Level I and II centers is a full time registrar; however, with larger services more registrars or assistants are necessary.									
In order to extract information from patient char trauma service works, as well as, terminology, c used to describe the severity of trauma. The educonsists of 24 hours in three—years on trauma, crans hours is optimal for a part time registrar, there may proportional to the portion of time spent in that proportional to the portion of time spent in that proportional to the portion of time spent in that proportional to the portion of time spent in that proportional to the portion of time spent in that proportional to the portion of time spent in that proportional to the portion of time spent in that proportional to the portion of time spent in that proportional to the portion of time spent in that proportional to the portion of time spent in that proportional to the portion of time spent in that proportional to the portion of time spent in that proportional to the portion of time spent in that proportion of time spent in that proportional to the portion of time spent in that proportional to the portion of time spent in that proportional to the portion of time spent in that proportion of time spent in the proportion of time spent in that proportion of time spent in the proportion of time spe	oding and the use of acational program for itical care, registry, must be an education	of vari or a fi , or da	ous so all timata co	coring s ne traur llection	systen na reg 1. Wh	ns istrar			
2.28. The maximum number of patients/reco any single trauma registrar shall not ex FTE based upon the most current Nati Bank (ACS/COT, National Trauma De recommendation for patient inclusion trauma registry. FTE requirements sh based on this number.	sceed 750 per onal Trauma Data ataset, 2014) into a hospital	С	С	С	С	С			
2.29. The Trauma Registrar(s) shall have ad allotted for the level of tasks expected		NC	NC	NC	NC	NC			
2.30. There shall be a defined job description Trauma Registrar's roles and responsi		C	С	C	С	C			
Interpretive Guidance: The job description for t need to access patient records and to extract data extraction from charts, registry maintenance, and	a. Key elements of			-					
2.31. The Trauma Registrar shall be identifi hospital's organizational chart.	ed on the	С	С	С	С	С			
3. Burn Service Infrastructure									
3.1. The Burn Service shall be integrated in Service at a state designated/verified I center.		_	С	_	_	_			
3.2. The Burn Service shall formally estab an organized Burn Service that is resp coordinating the care of burn patients.	onsible for	_	С	_	_	_			
3.3. The Burn Service shall have demonstr administrative commitment to the care burns. This is demonstrated by admin leadership and financial support for pe	able medical and e of patients with istrative	-	С	_	_	_			

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	Level:	I	IB	Peds	II	III
	maintain the elements as outlined throughout this					
2.4	Manual.					
3.4.	The Burn Service shall maintain an organizational chart that identifies key Burn Service staffs within the Burn	_	С	_	_	_
	Service and hospital.					
3.5.	<ul> <li>The Burn Service shall maintain a policy and procedural manual that is reviewed annually by the Burn Medical Director and Burn Program Manager. Policies and procedures shall include the following components: <ul> <li>The administration of the Burn Service.</li> <li>Staffing on the burn unit.</li> <li>Criteria for admission to the burn unit by the Burn Service.</li> <li>Use of burn unit beds by other medical and surgical services.</li> <li>Use of "tanking" and dressing facilities by non-burn program physicians.</li> <li>Pediatric and adult procedural sedation available for procedures.</li> <li>Criteria for admission, discharge, and follow-up care.</li> <li>The availability of beds and transfer of burn patients to other medical surgical units within the hospital.</li> <li>How burn care will be managed in areas of the hospital other than the burn unit.</li> </ul> </li> </ul>	-	С		_	
3.6.	The Burn Service shall have hospital policies and procedures for the use of allograft tissues and they shall be in compliance with all federal, state, and Joint Commission requirements and when feasible and appropriate, with standards of the <u>American Association of Tissue Banks</u> (AATB, 2012).	ı	С	_	-	-
3.7.	The Burn Service shall admit an average of 50 or more burn patients annually with acute burn injuries averaged over three–years.	ĺ	С	_	_	_
3.8.	There shall be at least one FTE attending burn surgeon staff involved in the management of burn patients for each 200 acute inpatients admitted annually.	_	С	_	_	_
3.9.	The Burn Medical Director shall be granted the necessary authority to direct and coordinate all care for patients admitted to the Burn Service.	_	С	_	_	_
3.10.	The Burn Medical Director may appoint a qualified attending burn surgeon to participate in the care of the	_	C	_	_	_

		Level:	I	IB	Peds	II	III
		patients on the Burn Service.					
	3.11.	The Burn Medical Director shall be the physician of record or overseeing the outcomes of all surgeons within the program for 50 or more burn patients annually or one third of the burn patients admitted annually, averaged over a three–year period.	ı	С	_	ı	ı
	3.12.	The Burn Service shall maintain an on–call schedule for residents and attending staff burn surgeons available to the Burn Service. Residents and staff surgeons shall be primarily available on a 24–hour per day basis.	-	С	_	1	1
	3.13.	If residents rotate on the Burn Service, the Burn Medical Director, or his or her designee, shall be responsible for an orientation program for new residents.	ı	С			
	3.14.	Each burn unit shall have a method to determine acuity levels of the patients in determining staffing needs. The system shall be used to determine daily staffing needs.	ı	C			
	3.15.	The Burn Service shall have an educational program for medical staff members, including emergency medicine attending physicians and residents.	-	С	_		
4.	Pedia	atric Trauma Service Infrastructure					
	4.1.	Hospitals that pursue designation as pediatric trauma centers shall meet the Level I requirements in this document except adult only criteria.	-	_	С	1	-
	4.2.	Annually admits 200 or more injured children younger than 15 years of age.		-	С	1	-
	4.3.	An organized pediatric trauma service led by a pediatric trauma medical director must be present.	_	_	С		_
	4.4.	The Pediatric Trauma Service shall have a Pediatric Trauma Program Manager.	_	-	С	_	_
	4.5.	The Pediatric Trauma Program Manager shall be a 1.0 FTE.	_	-	NC	_	_
	4.6.	Pediatric trauma centers shall have a pediatric trauma registrar.	_	-	С	_	_
5.	Trau	ma Team Response					
	5.1.	There shall be a clearly delineated trauma team response to the arrival of the patient with suspected or known major trauma in the ED 24 hours per day.	С	С	С	С	С

Interpretive Guidance: The hallmark of a trauma service is the trauma team response. This must be described in the trauma service manual and demonstrated on chart review for any site review type other than provisional. The goal of the trauma team response is to expedite the diagnosis

	Level:	I	IB	Peds	II	III
and man	agement of injuries for the trauma patient.					
5.2.	A minimum of two attending level physicians shall respond to all highest tiered responses, each of whom is either an anesthesiologist, ED physician, or general surgeon. A qualified general surgeon is expected to participate in major therapeutic decisions and be present in the ED for major resuscitations and at operative procedures on all seriously injured patients.	С	С	С	С	С
5.3.	All physicians on the pediatric trauma team shall have pediatric board certification in their respective specialties. When the numbers of pediatric surgeons on staff are too few to sustain the pediatric trauma call, general surgeons who are board certified or board eligible by the American Board of Surgery, according to current requirements, may perform pediatric trauma call. In this circumstance, they shall be credentialed by the hospital to provide pediatric trauma care, be members of the adult trauma call schedule, and be approved by the Pediatric Trauma Director.	-	_	С	-	_
5.4.	The hospital shall establish a policy detailing the expected time for the trauma surgeon to arrive at the bedside in the ED for patients meeting the highest level of alert. The goal shall be to have the trauma surgeon meet the patient in the ED upon the patient's arrival and that policy shall state that the trauma surgeon's response does not exceed 15 minutes from the arrival of the patient in the ED. A PGY4 or PGY5 general surgery resident capable of assessing emergent situations, providing control, and leadership of the care of the trauma patient may meet this requirement. In the event that this requirement is provided by a resident, the trauma surgeon shall be immediately available.	С	С	С	С	-

Interpretive Guidance: As stated in criterion 6.8, there shall be in-house trauma surgery coverage for levels I, IB, and Peds. If general surgeons perform the initial trauma response for pediatric or burn patients, they must be credentialed by the hospital to manage these specialties and meet other related criterion in this manual.

Every center must have a procedure for a full team response. This means that all team members (including the surgeon) are included and every effort is made to assure that the team is available *at the bedside* at the time of patient arrival. In addition, an operating suite must be immediately and arrangements include the rapid access to red blood cells for transfusion. The assumption is that the critically injured patient may require very rapid intervention for stabilization and surgical intervention for definitive care of injuries.

	Level:	I	IB	Peds	II	III
5.5.	The hospital shall establish a policy detailing the expected amount of time for the trauma surgeon to arrive at the bedside in the ED for patients meeting the highest level of alert. The goal shall be to have the trauma surgeon meet the patient in the ED upon the patient's arrival and that policy shall state that the trauma surgeon's response does not exceed 30 minutes from arrival of the patient in the ED. A PGY4 or PGY5 general surgery resident capable of assessing emergent situations, providing control, and leadership of the care of the trauma patient may meet this requirement. In the event that this requirement is provided by a resident, the attending trauma surgeon shall be promptly available.	-	_	_	1	С
5.6.	Trauma/general surgeons participating in the Trauma Service and taking active call shall be dedicated to the hospital while on trauma call.	C	C	С	C	C
5.7.	The emergency physician shall be a designated member of the trauma team and may direct resuscitation and care of the patient until the arrival of the trauma team leader. A PGY3 level emergency medicine resident may fulfill this function provided there is an attending emergency medicine physician present in the ED.  When a pediatric ED is required by criterion 13.22 or 13.24 a Pediatric Emergency Medicine (PEM) fellow may fulfill this function within the pediatric ED only	С	С	С	С	С
	provided there is an attending emergency medicine physician present in the ED.					
5.8.	There shall be RN's, PA's, NP's, LPN/LVN's and nursing assistants / technicians in adequate numbers in the initial resuscitation area based on acuity and trauma team composition as outlined in the Trauma Service's Trauma Service Manual, policies, or processes.	С	С	С	С	С
5.9.	There shall be a written protocol for the expectations and responsibilities of the trauma nurse and other team members during trauma resuscitations.	C	С	С	C	C

Interpretive Guidance: The site review team will review the trauma service manual, patient records, and the quality improvement program to determine the following:

- Alerts occur as described in the trauma service manual.
- Criteria are appropriate.
- Criteria address the needs of severely injured patients.
- That the full team response is timely.
- Tiered response is used as indicated in the trauma service manual.

	Level:	I	IB	Peds	II	III				
5.10.	Nursing documentation for trauma activation patients shall be on a trauma flow sheet or electronic medical record equivalent.	С	С	С	С	С				
Interpretive Guidance: Electronic medical records vary from hospital to hospital. Ideally there should be staff available for assistance to navigate the record to adequately review for arrival times, timely documentation, vital signs, and to assist the site review team in reviewing documentation.										
6. Medi	ical/Surgical Services Availability									
6.1.	The trauma center shall be capable of performing emergent trauma care to patients of all ages.	С	С	С	С	С				
6.2.	The trauma center shall be capable of providing all the services prescribed by the criteria in this manual for trauma patients 15 years of age or older.	С	С	_	С	С				
6.3.	Designated trauma centers cannot exceed a maximum diversion time of five percent.	NC	NC	NC	NC	NC				
6.4.	The trauma center shall avoid diverting burn patients except for rare instances such as loss of power, etc. This includes patients arriving by EMS and from referral hospitals within the region.	_	С	_	_	-				
6.5.	The decision to transfer an injured patient during the acute care phase is based solely on the needs of the patient.	NC	NC	NC	NC	NC				
6.6.	There shall be a mechanism in place to allow for direct physician—to—physician contact for arranging patient transfers.	NC	NC	NC	NC	_				
6.7.	Definitive surgical care shall be instituted by the trauma surgeon in a timely fashion.	_	_		С	C				
6.8.	There shall be in—house 24 hours per day capabilities in general surgery with two separate posted call schedules (one for trauma and one for general surgery). In those instances where a physician may simultaneously be listed on both schedules, there shall be a defined back—up surgeon listed on the schedule to allow the trauma surgeon to provide care for the trauma patient. A PGY4 or PGY5 capable of assessing emergent situations in their respective specialties may fulfill this requirement. The PGY4 or PGY5 shall be capable of providing surgical treatment immediately and provide control and leadership for the care of the trauma patient.	С	С	С	_					

Interpretive Guidance: There must be a mechanism in place for acquiring additional surgeons if the first call surgeon is in the operating room with a patient or there are multiple simultaneous trauma patients requiring major resuscitation and / or surgery.

Level:	I	IB	Peds	II	III
The hospital shall have clinical capabilities in general surgery available 24 hours per day with two separate posted call schedules (one for trauma and one for general surgery). In those instances where a physician may simultaneously be listed on both schedules, there shall be a defined back—up surgeon listed on the schedule to allow the trauma surgeon to provide care for the trauma patient. A PGY4/PGY5 capable of assessing emergent situations in their respective specialties may fulfill this requirement. The PGY4 or PGY5 shall be capable of providing surgical treatment immediately and provide control and leadership for the care of the trauma patient.	_	_	_	С	С
6.9. Any adult trauma center that annually admits 100 or more injured children younger than 15 years of age shall have its entire trauma/general surgeon staff which performs trauma call, credentialed for pediatric trauma care by the hospital's credentialing body.	NC	NC	_	NC	NC
6.10. Pediatric trauma centers shall have at least two surgeons, board—certified or eligible for certification by the American Board of Surgery according to current requirements in pediatric surgery.	_	_	NC	1	-
6.11. The trauma surgeon shall remain active in the clinical management of the trauma patient during the acute phase of care. The trauma surgeon may collaborate with other specialties to enhance the quality of care rendered in the ICU or PICU as applicable.	С	С	С	С	С
6.12. The trauma service shall work collaboratively with the pediatric critical care providers and the service shall be aware of all significant clinical changes.	NC	NC	NC	ı	_
6.13. There shall be a mechanism for documenting the trauma surgeon's presence for all trauma operative procedures.	NC	NC	NC	NC	NC
6.14. The ED shall have a designated medical director.	С	С	С	С	С
6.15. The ED has an appropriate number of physicians to ensure immediate care for injured patients.	С	С	С	С	С
6.16. There shall be at least two ED physicians who are board–certified or board eligible in pediatric emergency medicine.	_	_	С	_	_
6.17. There shall be 24 hour per day staffing by physicians physically present in the ED. This shall include an attending emergency physician.	С	С	С	С	С
6.18. The pediatric section of the ED shall be staffed by individuals credentialed by the hospital to provide pediatric trauma care in the respective areas.	_	_	С	ı	_

	Level:	I	IB	Peds	II	III			
Interpretive Guidance: The intent of this criterion is to assure that there is always qualified									
medical staff to care for pediatric trauma patients.									
	Orthopedic surgery service shall be on–call and promptly available.	С	С	C	C	C			
Measure:	Call schedules shall be available to site review teams.								
6.20.	Orthopedic team members shall have a dedicated trauma call schedule with a second backup available.	NC	NC	NC	NC	NC			
6.21.	On staff, there shall be at least one board–certified surgeon or one surgeon eligible for certification by an appropriate board according to the current requirements of that board that also has had pediatric fellowship training.	_	_	С	_				
6.22.	There shall be at least one additional board—certified orthopedic or surgeon eligible for certification by an appropriate board according to the requirements of that board, who is identified with demonstrated skills and interest in pediatric trauma care.	ı	_	NC	ı	ı			
6.23.	There shall be an orthopedic liaison designated to the trauma service.	NC	NC	NC	NC	NC			
6.24.	There shall be an anesthesiologist in–hospital 24 hours a day immediately available to respond to assist with managing difficult airways.	С	С	С	_	_			
6.25.	There shall be an anesthesiologist on call and promptly available to assist with managing difficult airways 24 hours per day.	_	_	_	С	С			
6.26.	An anesthesiologist shall be present for all emergent operative procedures on major trauma patients.	С	С	С	С	С			
	There shall be an anesthesiologist in–house 24 hours a day. (Requirements may be met by anesthesia residents; CRNAs capable of assessing emergent situations in trauma patients and providing any indicated treatment. Anesthesia personnel shall be capable of providing anesthesia service for surgical trauma cases including major vascular, neurosurgical, pediatric, orthopedic, thoracic, ENT, and other required surgical cases. If residents or CRNAs are used, a staff anesthesiologist shall be present in the OR suite during surgery. Training and experience in both invasive and non–invasive monitoring is essential.)	С	С	С	-	_			
6.28.	There shall be an anesthesiologist available 24 hours a day. Anesthesia personnel shall be capable of providing anesthesia service for surgical trauma cases including	_	_	_	С	_			

	Level:	I	IB	Peds	II	Ш
	major vascular, neurosurgical, pediatric, orthopedic, thoracic, ear, nose and throat (ENT), and other required surgical sub–specialties involved in trauma cases. If residents or CRNAs are used, a staff anesthesiologist shall be present in the OR suite during surgery. Training and experience in both invasive and non–invasive monitoring are essential.					
	Anesthesiologist shall be on–call and promptly available for trauma patients. Requirements shall be filled by anesthesia personnel capable of assessing emergent situations in trauma patients and providing any indicated treatment. Anesthesia personnel shall be capable of providing anesthesia service for surgical trauma cases including: major vascular, neurosurgical, pediatric, orthopedic, thoracic, ENT, and other required surgical sub–specialties involved in trauma cases. If residents or CRNAs are used, a staff anesthesiologist shall be present in the OR suite during surgery. Training and experience in both invasive and non–invasive monitoring is essential.	-	_	_		С
	Response times shall not exceed 30 minutes.		I			
6.30.	There shall be an anesthesiology liaison designated to the trauma service.	NC	NC	NC	NC	NC
6.31.	An attending neurosurgeon shall be promptly available. The in–house requirement may be fulfilled by an in–house neurosurgery resident, surgeon, nurse practitioner, or physician assistant designee who has special competence, as judged by the Chief of Neurosurgery, in the care of patients with neural trauma and who is capable of initiating diagnostic procedures.	С	С	С	Ι	-
	An attending neurosurgeon shall be promptly available. This requirement may be fulfilled by a resident, surgeon, nurse practitioner, or physician assistant designee who has special competence, as judged by the Chief of Neurosurgery, in the care of patients with neural trauma and who is capable of initiating diagnostic procedures. This may be on–call from outside of the hospital.	_	_	_	С	_
6.33.	If a neurosurgeon is responsible for more than one hospital at the same time, there shall be a second backup schedule.	С	С	С		_

Level:	I	IB	Peds	II	III
6.34. If an attending neurosurgeon is not dedicated to the Level II trauma center, the center shall have a backup call list OR the center shall demonstrate no more than 24 emergency neurosurgical procedures per year AND the center shall provide a neuro–trauma diversion plan.	_	_	_	С	_
6.35. There shall be at least one surgeon board certified or board eligible for certification by the American Board of Neurological Surgery according to the current requirements of that board who also has had pediatric fellowship training.	_	_	С	-	_
6.36. There shall be at least one additional board–certified neurosurgeon or surgeon eligible for certification by the American Board of Neurological Surgery according to the requirements of that board, who is identified with demonstrated skills and interest in pediatric trauma care.	_	_	NC	_	_
6.37. There shall be a neurosurgical liaison designated to the trauma service.	NC	NC	NC	NC	-
6.38. There shall be the following age appropriate surgical sub–specialty services physically present within 30 minutes of request for a threat to life or limb and the need to go to the OR and promptly available as otherwise needed.					
6.38.1. Thoracic surgery	С	С	С	С	_
6.38.2. Maxillofacial, E.N.T., and plastic surgery	С	С	С	С	_
6.38.3. Gynecological surgery/obstetrical surgery	С	С	С	С	_
6.38.4. Urological surgery	С	С	С	С	_
6.38.5. Ophthalmic surgery	С	С	С	NC	_
6.38.6. Cardiac surgery	С	С	С	_	_
6.38.7. Pediatric surgery	С	С	С	_	_
6.38.8. Hand surgery.	С	С	С	_	_
6.38.9. Microvascular/replant surgery	С	С	С	_	_
6.38.10. Oral surgery (may be part of <u>6.38.2</u> )	С	С	С	_	_
6.39. There shall be the following age appropriate non–surgical sub–specialties and shall be promptly available as needed.					
6.39.1. Internal medicine	С	С	_	С	С
6.39.2. Pathology	С	С	С	С	С
6.39.3. Radiology	С	С	С	С	С
6.39.4. Cardiology	С	С	С	С	_

Level:	I	IB	Peds	II	III
6.39.5. Interventional radiology	С	С	С	C	_
6.39.6. Neurology	С	С	С	C	_
6.39.7. Pulmonology	С	С	С	_	_
6.39.8. Gastroenterology	С	С	С	_	_
6.39.9. Hematology	С	С	С		_
6.39.10. Infectious disease	С	С	С	_	_
6.39.11. Nephrology	С	С	С	_	_
6.39.12. Pediatrics	С	С	С	_	_
6.39.13. Psychiatry	С	С	С	_	_

Interpretive Guidance: The purpose of the sections on clinical capabilities is to ensure that the trauma center is capable of providing the services required for its level of designation, as denoted by being marked as essential and being able to manage corresponding injury types on a full time basis.

The hospital must offer each of the relevant services, although dedicated call to the trauma center is not necessary and the specialist need not be immediately available. A 24–hour call schedule for the program is NOT necessary. The hospital has the flexibility of organizing a plan to manage corresponding injuries on site in a manner best suited to staff and resources. For example, in the absence of a 24-hour call schedule for ENT, the center may have a plan for immediate coverage of maxillofacial trauma patients with a rotating call schedule. PI processes should be in place to oversee the plan and to identify any potential problems. The plan may NOT involve transfer of patients with the injury type of concern.

	1 3 3 3 1					
6.40.	There shall be a designated surgical director or codirector for the ICU.	С	С	C	С	-
6.41.	There shall be at least two physicians who are board-certified or eligible for certification by the American Board of Pediatrics according to current requirements in pediatric critical care medicine or in pediatric surgery and surgical critical care by the American Board of Surgery.	_	_	С	_	_
6.42.	There shall be in–house physician coverage immediately available for the ICU 24 hours per day. This physician cannot be the sole physician for the ED.	C	C	C	C	-
6.43.	There shall be pediatric critical care physician coverage immediately available in the PICU 24 hours per day.	_	С	С	_	_
6.44.	The PICU shall be staffed by individuals credentialed by the hospital to provide pediatric trauma care in their respective areas.	_	_	С	_	_
6.45.	The surgical director of the PICU shall actively participate in the administration of the PICU, as	_		С	_	_

	Level:	I	IB	Peds	II	III
	evidenced by the development of pathways and protocols for care pediatric surgical patients in the PICU and in unit—based performance improvement.					
6.46	Pediatric surgeons or trauma surgeons with pediatric privileges shall be included in all aspects of care of injured children admitted to an ICU.	ı	_	NC	_	_
6.47	. There shall be an OR(s) promptly available 24 hours per day.	С	С	C	C	C
6.48	For burn cases there shall be an OR(s) available 24 hours per day with the Burn Service having timely access for urgent/emergent cases. This is defined as "within six hours of posting".	١	С	ı	1	-
6.49	There shall be OR personnel in–house and immediately available 24 hours per day.	С	С	С	С	_
6.50	The OR staffs shall be fully dedicated to the duties in the OR and not have functions requiring their presence outside of the OR.	C	С	С	С	C
6.51	. There shall be OR personnel promptly available 24 hours per day. This requirement may be fulfilled using in–house or on–call staff.	ı	_		I	C
6.52	There shall be a second OR team on—call and promptly available when the in—house team is participating in an operative case.	С	С	С	С	_
6.53	There shall be PACU nursing staff promptly available 24 hours per day. This requirement may be fulfilled using in–house or on–call staff.	С	С	С	С	C
7. Tra	uma Nursing					
7.1.	The TPM shall be a RN.	С	С	С	С	С
7.2.	The TPM shall possess experience in emergency/critical care nursing.	С	С	С	С	_
7.3.	The TPM shall obtain 30 TEH per three—year verification cycle of which 50 percent shall be via an extramural source. This may be prorated by the OEMS Trauma/Critical Care Coordinator for new hires or shorter periods of time due to extenuating circumstances.	С	С	С	С	С
7.4.	The TPM shall attend one national or international meeting within the three—year verification or designation period.	С	С	С	С	С
7.5.	The Burn Program Manager shall be a RN with a baccalaureate or higher degree that has two more years of experience in acute burn care and serves the function	ı	C	_	ı	_

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	Level:	I	IB	Peds	II	III
	of the Burn Program Manager. This manager shall work closely with the Burn Medical Director to develop policies and procedures and the burn PI program. The Burn Program Manager may have other administrative duties within the medical center, but shall commit at least 25 percent of their FTE for every 150–inpatient admissions to the Burn Service.					
7.6.	The Burn Program Manager shall participate in eight or more hours of burn related education annually or 24 hours averaged over a three–year period.	_	С	_	1	
7.7.	The trauma registrar(s) shall obtain 24 TEH per three- year verification cycle of which 50 percent shall be from an extramural source.	NC	NC	NC	NC	NC
7.8.	If assistants are used to supplement the registrar position sufficient training shall be provided.	NC	NC	NC	NC	NC
7.9.	All nursing staff members participating in the trauma team response shall have documented trauma specific orientation.	С	С	С	С	С
7.10.	All nursing staff members who participate in the acute care of trauma patients, including those working on nursing units that regularly provide care to trauma patients such as general surgery, orthopedics, neuroscience, progressive care, ICU, PICU, post–anesthesia care unit (PACU), OR, ED, and pediatrics shall have a minimum of four hours of trauma specific education hours (TEH) annually.	С	С	С	С	С
7.11.	More than 50% of all nursing staff members who directly participate as a member in the trauma team must have a current TNCC, ATCN course, or CATN certification.	С	С	С	С	С

Interpretive Guidance: Nursing TEH may encompass care of the trauma patient in any aspect of the continuum; from point of injury, to rehabilitation, and injury prevention. Acceptable means of education may include but are not limited to use of equipment, processes, and protocols, PI, conferences, workshops, symposiums, scientific assemblies, in services, refresher courses, participation in a simulation lab, online education, classes, skills labs, case studies, journal article reviews, and providing course instruction and lectures.

- Course instruction hours will be awarded only for the trauma specific content presented and may be used toward credit only once in a 12 month period.
- Registrars in addition to the education options listed above, approved areas include: developing spreadsheets and other custom reports, injury identification, scoring and any database functions primarily associated with trauma; statistics and data analysis.

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**External Source** – national and international conferences, online or self–study courses or professional journal articles with appropriate documentation, seminars and webinars, mission, goodwill or training activities/events/excursions with appropriate documentation.

The appropriateness of course content must be approved by the TPM. This does not apply to fully recognized national certification courses. Documentation of content such as a course outline, bibliography, competency validation checklist, or manual may be considered in evaluating a trauma specific focus.

Recognized national certification courses include:

- ENPC Emergency Nurses Pediatric Course
- TNCC Trauma Nurse Core Curriculum (ENA)
- ATCN Advanced Trauma Care for Nurses (STN)
- PHTLS Prehospital Trauma Life Support
- RTTDC Rural Trauma Team Development Course
- ABLS Advanced Burn Life Support
- National Disaster Management Courses
- CATN Course in Advanced Trauma Nursing (ENA)

#### Excluded national certification courses:

- ACLS Advanced Cardiac Life Support
- PALS Pediatric Advanced Life Support
- NALS Neonatal Advanced Life Support
- Or any education or training with a non–trauma specific content.

7.12.	There shall be a Burn Service orientation program that documents nursing competencies specific to the care and treatment burn patients including critical care, wound care, and rehabilitation that is age appropriate.	_	С	_	_	_	
7.13.	Burn center nursing staff members who participate in the resuscitation of the burn patient shall be provided with a minimum of an additional two burn specific nursing education hours. These hours may be either intramural or extramural.	_	С	I		_	
7.14.	There shall be documentation of trauma and burn specific orientation and continuing education for pediatric and burn care if these patients are regularly admitted to the trauma center.	С	С	С	ı	_	
7.15.	For trauma centers with a pediatric ICU (PICU) there shall be a nursing staff that specializes in pediatric critical care.	С	I	С	ı	_	
7.16.	ICU nursing staff members shall be educated in trauma care.	С	С	С	С	С	
7.17.	The patient to nurse ratio shall not exceed 2:1 for	C	C	C	C	$\overline{\mathbf{C}}$	

		Level:	I	IB	Peds	II	Ш
		critically ill patients in the ICU.					
	7.18.	acquisition of additional staffing on a 24 per hour basis to support all patient care areas units with increased patient acuity and/or volume, multiple emergency procedures, and admissions shall exist.	С	С	С	С	С
	7.19.	Each nursing unit shall have a copy of their staffing plan available for review during the site review.	С	С	С	C	С
8.	Ancil	llary Services					
	8.1.	Radiological Services shall be available 24 hours per day.	С	С	С	C	С
	8.2.	Radiological procedures for pediatric patients shall follow <u>ALARA</u> (as low as reasonable necessary) standards (NRC, 2013).	С	С	С	С	С
	8.3.	Radiological interpretations by a radiologist shall be available.	С	С	C	C	C
	8.4.	Critical radiological information shall be verbally communicated to the trauma team in a prompt manner and final reports accurately reflect communications, including changes between preliminary and final interpretations.	NC	NC	NC	NC	NC
	8.5.	Computed Tomography (CT) Scanning shall be available.	С	С	С	С	С
	8.6.	Angiography/interventional radiology shall be available.	С	С	С	C	-
	8.7.	Magnetic Resonance Imaging (MRI) shall be available.	С	С	С	C	_
	8.8.	Sonography shall be available.	С	С	С	C	_
	8.9.	There shall be a radiology technician in–house.	С	С	С	С	С
	8.10.	There shall be a CT technologist in-house.	С	С	С	С	С
	8.11.	There shall be cardiac emergency carts with standard resuscitative equipment, medications, airway management, and IV therapy available in radiology suites used for trauma patients.	С	С	С	С	С
	8.12.	There shall be at least one radiologist appointed as liaison to the Trauma Services.	NC	NC	NC	NC	NC
	8.13.	Clinical Laboratory Services shall be available 24 hours per day.	С	С	С	C	С
	8.14.	Standard analysis of blood, urine, other body fluids, and a comprehensive blood bank shall be available.	С	С	С	С	С
1	8.15.	Blood typing and cross matching shall be available.	С	С	C	C	С

	Level:	I	IB	Peds	II	III
8.16.	The blood bank shall have an adequate supply of red blood cells, fresh frozen plasma, platelets, cryoprecipitate, and appropriate coagulation factors to meet the needs of injured patients.	С	С	С	С	_
8.17.	The blood bank shall have an adequate supply of red blood cells, fresh frozen plasma, and appropriate coagulation factors to meet the needs of injured patients.	_	_	_	-	С
8.18.	There shall be a massive transfusion protocol in place.	С	С	C	С	_
8.19.	A respiratory therapist shall be available to care for trauma patients 24 hours per day.	С	С	С	С	С
8.20.	There shall be renal dialysis services available 24 hours per day or a transfer agreement in place.	С	С	С	NC	_
8.21.	There shall be physical therapists available.	C	С	C	C	C
8.22.	There shall be occupational therapists available.	NC	NC	C	NC	_
8.23.	Rehabilitative services, physical and occupational therapy specialists shall be available during the acute phase of trauma care.	NC	NC	NC	NC	-
8.24.	There shall be access to rehabilitation services capable of managing burn patients.	_	С	_	1	_
8.25.	Rehabilitative services shall be available within its physical facilities or to a freestanding rehabilitation hospital.	NC	NC	NC	NC	_
8.26.	The hospital shall provide speech therapy services.	NC	NC	NC	NC	_
8.27.	A social services consultation/case management shall be available to the injured patient.	NC	NC	NC	NC	_
Trauma c	ve Guidance: Early discharge planning is essential for patienters may avail themselves of a variety of consulting serve plans such as social workers, case managers, patient representations.	vices	to faci	ilitate a	pprop	riate
8.28.	There shall be pediatric social services available.	_	_	С	_	_
8.29.	Pediatric trauma patients with prolonged hospitalizations shall have their academic needs assessed and met as clinically indicated.		NC	NC	_	_
8.30.	There shall be child life and support programs available.		NC	NC	_	_
8.31.	The trauma center shall have an established relationship with a recognized organ procurement agency.	С	С	С	С	С

		Level:	I	IB	Peds	II	III
	8.32.	There shall be a recognizable mandated reporter process and appropriate resources in place to identify when to initiate and engage Child Protective Services (CPS) and/or Adult Protective Services (APS).	С	С	С	С	С
	8.33.	Pediatric trauma centers must have a mechanism in place to assess children for maltreatment.	_	_	С	_	_
		There shall be a written policy for triggering notification of the organ procurement agency.	C	С	С	C	С
	8.35.	There shall be written protocols for the declaration of brain death.	C	С	С	C	С
9.	Medi	ical Staff Education and Credentials					
	9.1.	Supporting documentation shall be available for medical staff education and credentials for designation/verification site reviews. Attestations and tracking sheets are not acceptable as evidence for education.	С	С	С	С	С
	9.2.	The TMD shall be a board certified/eligible general surgeon.	C	С	_	C	C
	9.3.	The TMD shall have a minimum of three years experience with a trauma service or be trauma fellowship trained.	С	С	С	1	_
	9.4.	The TMD shall have 30 hours of Category I trauma/ critical care CME every three—years and attend one national meeting whose focus is trauma or critical care.	С	С	С	С	С
	9.5.	The TMD shall maintain current ATLS provider or instructor certification.	C	С	С	С	С
	9.6.	All general/trauma surgeons shall be board certified / eligible in general surgery.	С	С	С	С	С
	9.7.	Pediatric general/trauma surgeons shall be board certified/eligible in pediatric surgery.	С	С	С		_
	9.8.	Each surgeon, emergency physician, nurse practitioner, or physician's assistant participating/taking call in the program or could possibly be caring for trauma alert patients in the ED shall complete 30 Category I CME in trauma/critical care across the three—year verification period. Updating ATLS may be included in these CME.	С	С	С	С	С
	9.9.	In pediatric trauma centers 12 hours of the 30 hours CME in <u>criterion 9.8</u> shall be pediatric trauma specific.	_	_	С	_	_
	9.10.	In pediatric trauma centers, other specialists (in anesthesiology, neurosurgery, orthopedic surgery, emergency medicine, radiology, and rehabilitation)	_	_	С	_	_

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providing care to injured children who are not pediatric—trained providers should also have sufficient training and experience in pediatric trauma care and be knowledgeable about current management of pediatric trauma in their specialty. The service must make specialty—pediatric education available for these specialists.					
9.11. All general/trauma/pediatric surgeons shall have successfully completed an ATLS course at least once.	С	С	C	C	C
9.12. The Burn Medical Director shall be a licensed physician with board certification(s) by the American Board of Surgery or the American Board of Plastic Surgery.	_	С	_	1	_
9.13. The Burn Medical Director shall have completed a one—year fellowship in burn treatment or shall have experience in the care of patients with acute burn injuries for two or more years during the previous five years at a VDH or ACS verified/designated Level I trauma center.	_	С	_	ı	_
9.14. The Burn Medical Director shall participate in CME on burn related education at a minimum of 30 hours averaged over a three–year period and attend one national/regional meeting.	_	С	_	1	-
9.15. Privileges for physicians participating in the Burn Service shall be determined by the medical staff credentialing process and approved by the Burn Medical Director.	_	С		1	-
9.16. The Burn Medical Director shall be the physician of record or overseeing the outcomes of all surgeons within the program for 50 or more burn patients annually or one third of the burn patients admitted annually, averaged over a three–year period.	_	С	_	I	_
9.17. Attending staff burn surgeons shall be board certified or eligible in general or plastic surgery.	_	С	_	-	-
9.18. Attending staff burn surgeons shall have completed a one—year fellowship in burn treatment or shall have experience in the care patients with acute burn injuries for two or more years during a previous five years at a designated Level I trauma center.	_	С	_	-	_
9.19. Attending staff burn surgeons shall participate in CME of burn related education at a minimum of 30 hours or more averaged over a three–year period.	_	С	_	_	_

	Level:	I	IB	Peds	II	Ш
9.20.	The Pediatric Trauma Medical Director must be certified or eligible for certification by the American Board of Surgery according to the requirements for pediatric surgery or alternatively, a pediatric surgeon who is a fellow of the American College of Surgeons with a special interest in pediatric trauma care, and must participate in trauma call.	_	_	С	_	_
9.21.	The Pediatric Trauma Medical Director shall have 30 hours of category I trauma/critical care CME every three years. Of these hours 12 shall be clinical pediatric trauma related.	-	_	С	_	_
9.22.	The Emergency Medicine Medical Director shall have 30 hours of Category I CME every three years and attend one national meeting with some content in trauma or critical care.	С	С	С	С	С
9.23.	The Emergency Medicine Medical Director or designee shall maintain a current ATLS instructor or participant certification.	С	С	С	С	С
9.24.	ED physicians shall be board certified /eligible in emergency medicine or pediatric emergency medicine by the American Board of Medical Specialties, the Bureau of Osteopathic Specialist or the Royal College of Physicians and Surgeons of Canada. Emergency department physicians not board as noted above shall hold another board certification and the meet in 9.8 and 9.27.	С	С	С	С	С
9.25.	ED physicians shall meet the CME requirements in criterion 9.8.	С	С	С	С	С
9.26.	All emergency medicine boarded ED physicians shall possess a current ATLS or have successfully completed the ATLS course at least once.	С	С	С	С	С
9.27.	ED physicians that are not board certified in emergency medicine shall maintain current ATLS instructor or provider certification.	C	С	С	С	С
9.28.	There shall be documentation available for ATLS and continuing education as outlined throughout this document. Attestations and tracking sheets are not acceptable as evidence for education.	С	С	С	С	С
9.29.	Orthopedic surgeons performing trauma call shall be board certified within five years of successfully completing residency.	С	С	С	С	С
9.30.	Neurosurgeons performing trauma call shall be board certified within five years of successfully completing	С	С	С	С	_

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residency.					
9.31. The surgical director of the ICU shall have added certification in surgical critical care from the American Board of Surgery.	С	С	_	С	_
9.32. The primary burn therapist (PT/OT) shall have eight hours of burn related education annually, or 24 hours averaged over a three—year period.	_	С	_	I	_
10. Performance Improvement					
10.1. The Trauma Service shall have an organized PI program to examine the care of the injured patient within the hospital that looks towards improving outcomes by decreasing complications and improving.	С	С	С	С	С
Interpretive Guidance: The presence of a PI program is critical to t center. While every hospital participates in PI, not every PI program trauma or burn program. Site review teams will be looking for a present to trauma and burn patients; one that covers multidisciplinary issue trauma and burn care from pre—hospital care to rehabilitation. The Director, TPM, and/or Burn Manager shall have oversight for the program 10.2. Participation in the VSTR as mandated by the <u>Code of</u>	m add ogran s as w TMD	lresse n spec vell as ), Burn	s the ne cifically all pha	eds of orients	f a ited
<ul> <li>Virginia § 32.1–116.1. Data shall be submitted on the schedule noted in (10.3) below and include all patients:</li> <li>With an ICD10–CM code(s) of S00–S99, T07, T14, T20–T28 with 7<sup>th</sup> digit character modifier of A, B, or C. (D through S are excluded), and</li> <li>Were admitted to the hospital, or</li> <li>Were admitted for observation (not ED observation unless held in the ED due to no inpatient bed availability), or</li> <li>Were transferred from one hospital to another for treatment of acute trauma, or</li> <li>The patient dies within the hospital due to injury (includes, the ED and DOA's).</li> <li>Note: VSTR requirements relate to all patients meeting these criteria hospital–wide and shall not be interpreted as limited to Trauma Service patients or limited to patients within the trauma center's in–house trauma registry.</li> </ul>	С	С	С	С	C
10.3. Compliance with criterion 10.2 above shall per the schedule published by the VDH/OEMS. The current schedule is on a quarterly basis at a minimum. The submission schedule is based on the patient's discharge date from the hospital and shall be the following	С	С	С	С	С

registry and State's trauma registry.	Leve	l: I	IB	Peds	II	III
holiday, the due date shall be the next regular state business day.  10.4. There shall be a procedure in place to monitor the validity of data being entered into the hospital's trauma registry and State's trauma registry.  NC N	<ul> <li>January 1<sup>st</sup> thru March 31<sup>st</sup> – due on May 31<sup>st</sup></li> <li>April 1<sup>st</sup> thru June 30<sup>th</sup> – due on August 31<sup>st</sup></li> <li>July 1<sup>st</sup>. thru September 30<sup>th</sup> – due on November 30<sup>th</sup></li> <li>October 1<sup>st</sup> thru December 31<sup>st</sup> – due on February</li> </ul>					
validity of data being entered into the hospital's trauma NC NC NC NC registry and State's trauma registry.	holiday, the due date shall be the next regular state business					
10.5 The trauma center shall be able to identify the trauma	validity of data being entered into the hospital's trauma	NC	NC	NC	NC	NC
population within their hospital.    NC   NC   NC   NC   NC   NC   NC   N	10.5. The trauma center shall be able to identify the trauma population within their hospital.	NC	NC	NC	NC	NC

Measure: The center shall have a means of identifying injured patients within its facility such as a standard query/report that can be pulled from the hospital's admission records and not solely depend upon Trauma Service tracking methods.

Interpretive Guidance: Need to identifying patients that did not receive a trauma team response but met criteria or may have benefitted from trauma consultation.

10.6. Mature trauma centers' PI programs shall utilize VSTR or the Nation Trauma Data Bank (NTDB) data for institutional, regional, or state research or for benchmarking for PI or injury prevention programs.	NC	NC	NC	NC	NC
10.7. Pediatric trauma centers shall submit data to the NTDB.	_	_	NC		1
10.8. The Trauma Service shall have the authority to address PI issues that involve multiple disciplines.	NC	NC	NC	NC	NC
10.9. The Trauma Service shall have adequate support from administration and defined lines of authority to ensure comprehensive evaluation of all aspects of trauma care.	С	С	С	С	С
10.10. There shall be a written trauma specific PI plan (including burn as applicable).	С	С	С	С	С
10.11. There shall be a written pediatric trauma specific PI plan.	_		С	-	İ
10.12. Any adult trauma center that annually admits 100 or more injured children younger than 15 years of age shall have a pediatric–specific trauma performance improvement/patient safety program.	NC	NC	_	NC	NC

Interpretive Guidance: Written PI plan(s) should be provided and should describe the following:

- Selection of audit filters
- Management of unique events or reports

Level:	I	IB	Peds	II	III
<ul> <li>Review of information and reports received</li> <li>Routing of pre-hospital care, nursing, and medical s</li> <li>Means of implementing change</li> <li>Documentation with regard to implementing change</li> <li>Maintenance and review of PI plan</li> <li>Describe who has the authority and responsibility to</li> </ul>			the nla	ın	
10.13.Each trauma center shall maintain a document that reflects the functional process for providing case specific complimentary and/or constructive feedback to the top three referring/receiving facilities for extraordinary situations.	С	С	С	C	С
10.14. Each trauma center shall have in place a method for showing their involvement with the EMS agencies and/ or personnel within its region. The trauma center shall be involved in EMS education, PI and a method of providing complimentary and/or constructive feedback in general or case specific as needed.	С	С	С	С	С
10.15. The Burn Service shall offer education on current burn concepts of emergency and inpatient care treatment to pre–hospital and hospital care providers within its service area.	_	С	_	_	_
10.16. There shall be a multi–disciplinary forum that includes the TMD, ED Director, TPM, liaisons from orthopedic surgery, anesthesiology, neurosurgery, and radiology as specific issues present for multidisciplinary review of care of the injured patient including policies, procedures, system issues, and outcomes. The forum may include pre–hospital, nursing, ancillary personnel, a hospital administrator, and other physicians involved in trauma care. (The peer review committee meeting in (10.17), below, may be combined with this meeting.)	С	С	С	С	С
10.17. The hospital shall have a structured trauma peer review committee which shall have a method of evaluating trauma care. This committee shall meet at least quarterly and include physicians representing pertinent specialties that includes at a minimum, trauma surgery, pediatric surgery (if applicable), emergency medicine, orthopedics, anesthesiology, neurosurgery, and may include hospital management and other subspecialties as required. The TPM or their designee(s) may be a member. Outcomes of peer review shall be incorporated into the educational and policy program of the Trauma Service. (The forum in (10.16) may be	С	С		С	С

Level:	I	IB	Peds	II	III
combined with this meeting.)					
10.18. The burn PI program multidisciplinary committee, which oversees the PI program, shall meet at least quarterly. Sufficient documentation shall be maintained to verify problems, identify opportunities for improvement, document corrective actions, and note resolved issues.	_	С	_	_	_
10.19. Burn morbidity and mortality conferences shall be held every other month and include physicians other than the immediate burn care team to ensure objective review of the presentations. Attendees at this conference shall include specialists and other committee members that do not practice in the trauma center.	1	С	_		-
10.20. There shall be a burn patient care conference held at least weekly to review and evaluate the status of each burn patient admitted to the burn unit. The conference shall include, but not be limited to, a burn physician, critical care intensivist, burn nurse, respiratory therapist, social work, burn occupational therapy or physical therapy, dietitian, and clinical psychologist.	1	С	_	_	-
by the Pediatric Medical Director with participation from the core pediatric/general surgeons and liaisons from pediatric/general surgery, orthopedic surgery, neurosurgery, emergency medicine, pediatric critical care medicine, radiology, and anesthesiology to improve trauma care be reviewing selected deaths, complications, and sentinel events with the objectives of identification of issues and appropriate responses.	-	_	С		_
10.22. All pediatric and general surgeons performing trauma call shall attend at least 50 percent of the pediatric trauma peer review meetings and their attendance must be documented.	-	_	NC	_	_
10.23. There shall be 50 percent attendance by committee members (or designee) at multi–disciplinary and peer review meetings.	C	С	C	C	С
10.24. The TMD shall ensure that the information and findings of peer review are documented and disseminated to non–core surgeons performing trauma call.	C	С	С	С	С
10.25. Burn patient care conferences shall be documented in the progress notes of each patient and in the minutes of the patient care conference kept separately.	_	С	_	_	_
10.26. The PI program shall follow these state audit filters at a	C	C	C	С	C

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Level:	I	IB	Peds	II	III
minimum.					
<ul> <li>Morbidity, mortality, and complication reviews</li> </ul>					
classified as anticipated, or not anticipated with					
or without opportunity for improvement.					
<ul> <li>Appropriateness of trauma alert activations.</li> </ul>					
<ul> <li>Surgeon response time to highest tier activations.</li> </ul>					
<ul> <li>Anesthesia response time.</li> </ul>					
• OR team response.					
<ul> <li>Surgeon arrival in OR time.</li> </ul>					
<ul> <li>Changes in radiology results between initial</li> </ul>					
reading and final report.					
Organ donation rate.					
Transfers.					
10.27. The PI program shall follow these additional state audit					
filters:					
<ul> <li>Missed intubations,</li> </ul>					
<ul> <li>Unplanned extubations,</li> </ul>					
<ul> <li>Extubation within 24 hours of rapid sequence</li> </ul>					
intubation (excluding operative procedures),					
<ul> <li>Hypocapnia or Hypocapnia,</li> </ul>					
<ul> <li>Resuscitation volumes,</li> </ul>	C	С	C	_	_
<ul> <li>Vascular access problems,</li> </ul>					
<ul> <li>Unplanned operation following non–operative</li> </ul>					
management,					
<ul> <li>Unplanned hypothermia,</li> </ul>					
<ul> <li>Nosocomial pneumonia,</li> </ul>					
<ul> <li>Missed injury, and</li> </ul>					
Transfers.					
10.28. The PI program shall participate in the creation of					
institutional and regional based audit filters as identified	NC	NC	NC	NC	_
by the institution or regional PI committees.					
	1	L	l	L	

Interpretive Guidance: Every center must audit its trauma (including burn) deaths. In addition, the center should include audit filters based on its previous experience, those filters recommended by the State and filters designed to identify potential problems. Because each center is different, a list of audit filters will not only include the State audit filters, but institutionally needed filter.

Process filters which evaluate whether or not a process is observed are valuable when developing a new trauma service or setting up a procedure for a currently existing program.

Outcome filters describe the results of trauma and burn care. While death is certainly the ultimate outcome filter, a PI plan should address other outcomes such as disability at discharge or time to definitive procedures. Experienced trauma and trauma centers are expected to place

Level: I IB Peds II III

increasing emphasis on outcome oriented audit filters; their PI plan and program and are judged accordingly.

While deviation from the description of the alert system in the trauma service manual may occur from time to time, the site team will be evaluating the program for patterns of deviation especially in instances where the pattern is not identified by the institution's PI plan and addressed through the plan. Examples of such patterns include, but are not restricted to:

- Delay in calling a full team response until after the patient is evaluated.
- Severely injured patients or patients requiring emergent surgery not receiving full team response.
- Frequent need for upgrades in tiered response.
- Delay in arrival of team members for full team response.
- Mortality or morbidity attributable to delays in team arrival.
- The PI plan does not identify and address issues in team response.

The figure de de fiel fuelling wild water des field in team fee	P •	•			
10.29.If greater than 10 percent of injured patients are admitted to non–surgical services, there shall be a PI process to demonstrate the appropriateness of this practice.	NC	NC	NC	NC	NC
10.30. The PI program shall define when the attending surgeon's immediate hospital presence is required.	С	С	С	С	С
10.31. The Burn Service shall provide ongoing review and analysis of nosocomial infection data and risk factors that relate to infection prevention and control for burn patients. These data shall be available to the burn team to assess infection risk factors that relate to infection prevention and control for burn patients.	_	С	_	_	_
10.32.Each trauma center shall annually collaborate with the top three referring / receiving facilities to assess, plan, implement, and evaluate the physician and nursing trauma educational needs of those facilities transferring severely injured patients.	С	С	С	С	С
10.33. Each trauma center shall collaborate with the top three regional transferring / receiving facilities to design and provide an annual hospital specific registry report by using the hospitals PI infrastructure for transmission.	С	С	С	С	С
10.34. The PI program shall demonstrate the application of outcome and benchmarking based activity.	NC	NC	NC	NC	NC
10.35. There shall be a demonstrable relationship between PI outcomes and new or revised clinical protocols.	С	С	С	С	_
10.36. The Burn Service shall conduct audits released annually that include, but are not limited to, the severity of burn mortality, incidence of complications and length of	_	С	_	_	_

Level:	I	IB	Peds	II	III
hospitalization.					
10.37. The PI program shall include regional trauma systems.	NC	NC	NC	NC	NC
10.38. There shall be a trauma research program designed to produce new knowledge applicable to the care of injured patients to include an identifiable institutional review board process.	С	С	_	_	_
10.39. The trauma research program shall be designed to produce new knowledge applicable to the care of injured patients to include; three adult peer reviewed publications and one pediatric peer reviewed publication over a three—year period that could originate in any aspect of the trauma service.	С	С	_	1	-
10.40. There shall be nursing specific trauma research program designed to produce new knowledge applicable to the care of the injured patients. There shall be a minimum of one publication per three—year verification cycle.	NC	NC		-	-
11. Disaster Planning and Management					
<ul> <li>11.1. There shall be demonstration that the trauma center participates in disaster preparation and management.</li> <li>Shall meet the disaster—related requirements for the Joint Commission for Accreditation of Healthcare Organizations or other CMS approved accreditation organization.</li> <li>A surgeon from the trauma panel shall participate on the hospital's disaster committee.</li> <li>Hospital drills that test the individual hospital's disaster plan shall be conducted every six months.</li> <li>Trauma Centers shall have a hospital disaster plan described in the hospital's policy and procedure manual or equivalent.</li> </ul>	С	С	С	С	С
12. Community Outreach / Injury Prevention					
12.1. Each trauma center shall have in place a method for showing their involvement with the community in their region. The trauma center shall be involved in community awareness of trauma and the trauma system.	С	С	С	С	С
12.2. The Burn Service shall document burn specific participation in public awareness programs.	-	С	_	_	_
12.3. There shall be documentation that injury prevention activities are based upon regional needs.	С	С	С	C	С
13. Facilities and Equipment					
The ED:					

Level:	I	IB	Peds	II	Ш
13.1. There shall be resource information on pediatric medication dosing and equipment sizes i.e. a Broselow Tape.	С	С	С	С	С
13.2. There shall be airway control and ventilation equipment (laryngoscopes with a variety of straight and curves blades, endotracheal tubes (ETT) of all sizes, bag valve mask, and methods to continually provide supplemental oxygen.)	С	С	С	С	С
13.3. There shall be equipment to manage a difficult airway.	С	С	C	С	С
13.4. There shall be suction devices in adequate numbers to be able to care for the multi system trauma patient.	С	С	С	С	С
13.5. There shall be CO <sub>2</sub> detection device(s) to confirm placement of ETT	С	С	С	C	С
13.6. There shall be a cardiac monitor immediately available with capabilities to include ECG, pacing, and external and internal defibrillation	С	С	С	C	С
13.7. There shall be large caliber venous access and intraosseous devices available.	С	С	С	C	C
13.8. There shall be thermal control equipment for blood and IV fluids.	С	С	С	C	С
13.9. There shall be an IV fluid and blood rapid infuser for administration and warming of IV fluid and blood products located in the ED.	С	С	С	C	С
13.10. There shall be sterile surgical sets / trays to include airway control, cricothyrotomy, thoracotomy, vascular access, chest tube insertion, peritoneal lavage, and central line access.	С	С	С	С	С
13.11. There shall be thermal control equipment for cooling and warming patients.	С	С	С	С	С
13.12. There shall be availability of sonography to perform FAST (focused assessment with sonography for trauma) exams.	С	С	С	C	С
13.13. There shall be pediatric equipment available that meets the most current recommended list by the American College of Pediatrics "Guidelines for Care of Children in the Emergency Department" (AAP/ACEP, 2009)	С	С	С	C	С
The Burn Unit:					
13.14. The Burn Unit shall maintain an identified nursing unit where staffs specialize in burn care.	_	С	_	_	_
13.15. There shall be an identified Burn Unit that is a fixed physical and geographic location within the hospital for the treatment and coordination of burn care.	_	С	_	_	_

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Level:	I	IB	Peds	II	Ш
13.16. The burn unit shall have effective means of isolation that is consistent with the principles of universal precautions and barrier technique to decrease the risk of cross infection and cross–contamination.	_	С	_	-	_
13.17. There shall be a specific area as designated by the Burn Medical Director for wound care assessment and treatment which would include the capability for minor wound debridement, escharotomy, wound cleansing, procedural techniques such as line placement, and overall assessment.	_	С	_	ī	-
The Burn Unit shall have the following equipment for burn patients of all ages:					
13.18. There shall be weight–measuring devices.	_	С	_	_	_
13.19. There shall be thermal control equipment for cooling and warming patients.	_	С	_	1	_
13.20. There shall be bedside and central ECG, pulse oximetry, and pressure monitoring devices.	_	С	_	1	_
13.21. There shall be electrocautery available in the Burn Unit.	-	С	_	-	_
13.22. Any adult trauma center that annually admits 100 or more injured children younger than 15 years of age shall have a pediatric emergency department.	NC	NC	_	NC	NC
13.23. Any adult trauma center that annually admits 100 or more injured children younger than 15 years of age shall have a PICU.	NC	NC	_	NC	NC
13.24. There shall be a pediatric ED area.	_	_	С	_	_
13.25. There shall be a pediatric ICU.	_	_	С	_	_
The OR:					
13.26. There shall be the capability for resuscitation, stabilization, continuous monitoring of temperature, hemodynamics, and gas exchange.	С	С	С	С	С
13.27. There shall be a rapid infuser for the administration and warming of IV fluids and blood products in the OR.	С	С	С	С	C
13.28. There shall be thermal control equipment for cooling and warming patients in the OR.	С	С	С	С	С
13.29. There shall be 24 hour per day x-ray capability, including C-Arm image intensifier.	С	С	С	С	С
13.30. There shall be endoscopes and bronchoscopes in the OR.	С	С	C	C	С
13.31. There shall be adequate equipment available in the OR to perform craniotomies.	С	С	С	С	С

Level:	I	IB	Peds	II	III
13.32. There shall be the capability of fixation of long bones.	С	С	С	С	С
13.33. There shall be adequate equipment to assure the capability of surgical treatment of pelvic fractures including, but not limited to, open pelvic fractures and acetabular fractures requiring complex surgical interventions.	С	С	С	Ι	_
13.34.In the event that patients are boarded in the PACU as ICU overflow patients, then the equipment listed for the ICU.	С	С	С	С	С
The ICU(s):					
13.35. There shall be a fixed physical and geographic location within the hospital identified as the pediatric intensive care unit (PICU).	_	С	С	ı	_
13.36. There shall be a fixed physical and geographic location within the hospital identified as the ICU.	С	С	С	C	C
There shall be the following equipment appropriate for the age of patients managed in the ICU:					
13.37. There shall be a fixed physical and geographic location within the hospital identified as the intensive care unit (ICU).	С	C	С	C	С
13.38. There shall be resource information on pediatric medication dosing and equipment i.e. a Broselow Tape.	С	С	C	C	C
13.39. There shall be adequate airway control and ventilation equipment (laryngoscopes with a variety of straight and curved blades, ETT of all sizes, bag valve masks, suction devices in adequate numbers, and methods to continually provide supplemental oxygen.)	С	С	С	С	С
13.40. There shall be equipment to manage a difficult airway.	С	С	С	С	С
13.41. There shall be a temporary transvenous pacer.	С	С	C	C	С
13.42. There shall be the availability of portable cardiac monitor immediately available with capabilities to include ECG, pacing, and external and internal defibrillation.	С	С	С	С	С
13.43. There shall be mechanical ventilators available in the ICU.	С	С	С	C	C
13.44. There shall be patient weighing devices in the ICU	С	С	C	C	C
13.45. There shall be temperature control devices for patients.	С	С	C	С	C
13.46. There shall be thermal control equipment for blood and IV fluids.	С	С	С	С	С
13.47. There shall be a rapid infuser device for the	C	C	С	С	C

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Level:	I	IB	Peds	II	III
administration and warming of IV fluids and blood products.					
13.48. There shall be an intracranial pressure—monitoring device.	C	C	C	С	C

# **Administrative Guidelines**

## **Purpose:**

The purpose of the administrative and interpretive guidelines is to provide information pertaining to the process of designation and verification of trauma and trauma/burn centers in Virginia. It is divided into two sections: 1) administrative guidelines describing the procedures and steps required for the process, and 2) interpretive guidelines describing how trauma and burn center criteria should be evaluated during a site review. The document is designed to be used with Virginia trauma center Criteria.

The objective is to provide a consistent, objective, and meaningful approach to the designation process.

# **Background:**

In Virginia, the lead EMS agency is the VDH/OEMS. The VDH/OEMS coordinates the development and administration of trauma center designation throughout the state. The earliest Level I trauma centers were designated in 1983 and 1984. Burn specific designation was introduced to the designation manual in 2012. Pediatric trauma designation was added in 2015.

The trauma system in Virginia is inclusive. All hospitals with 24-hour emergency departments provide some degree of trauma and burn care. The decision to become a designated trauma center is voluntary. Designation carries a cost related to the fact that the trauma programs shall be continuously available for patients who may or may not require their services. Triage guidelines act to direct severely injured patients to the nearest appropriate trauma center.

Designation occurs at five levels, Level I, IB, IP, II, and III. Level I, IB, IP, and II trauma centers should be capable of managing severely injured patients. Level I, IB, and IP centers shall demonstrate a higher level of commitment to research, prevention, and education. Level III centers demonstrate an increased commitment to trauma care, managing moderately injured patients and rapidly resuscitating and transferring more severely injured patients. Undesignated hospitals must recognize, resuscitate, and transfer most trauma patients.

All hospitals whether designated or not should make every effort possible to participate in and to improve the trauma system. Due to the unexpected nature of injury, trauma patients and their families cannot choose their location of care. It is incumbent upon the healthcare system to provide these patients with the most optimal care possible regardless of location and circumstances. The purpose of the designation process is to assure consistent performance of

entry-level trauma centers and to promote continued improvement and development of experienced centers.

#### I. **Record Keeping**

Overview: The trauma system in Virginia is dynamic. Centers change in response to pressure of the healthcare environment and criteria and processes for evaluation change as trauma and burn care evolves. Maintaining records consistently over a period of time achieves several purposes. It provides a series of system snapshots over time. It allows centers and VDH/OEMS to refer back to actions taken in the past. Finally, it allows a summation of trauma and trauma/burn center performance rather than a series of unrelated and disjointed episodic views. In order to accomplish these goals, the records must be identifiable, consistent, accessible, and maintained in a predictable fashion.

- a. Documents and revisions of documents will be numbered and maintained by the VDH/OEMS. This process is put into place to avoid confusion with regard to which version of a document is in use during the site review. When a trauma or trauma/burn center is scheduled for a review, the Trauma/Critical Care Coordinator will provide the title and effective date of the documents to be used during the review. These will include the trauma and trauma/burn center criteria and the administrative and interpretive guidelines, as well as any other documents considered to be pertinent.
- b. Each trauma center will have a file maintained for a period of not less than ten years after the most recent trauma review. The file will include:
  - i. Records of each site review to the institution with the following information:

### 1. Designation Items:

- a. Written preliminary report and suggested remediation by site review team,
- b. Written documentation of remediation,
- c. Closure of remediation,
- d. The final report of the site review team, including specific findings and remediation, and
- e. Copy of written action by the Commissioner (designation).

### 2. Site Review Documents:

- a. Site Review Agenda,
- b. Site Review Team Roster, and
- c. Version of (by revision date) trauma center criteria used for site review.

# 3. Written Application Including:

- a. Acknowledgement that the VDH/OEMS trauma designation file has been reviewed (signed),
- b. Trauma Center Code of Conduct,
- c. Trauma Center Capabilities,
- d. Current Organizational Chart,
- e. Impact Statement,
- f. Checklist,
- g. Questionnaire,
- h. List of physicians,
- i. Trauma team alert criteria (roles, responsibility, and policies),
- j. TMD job description,
- k. Trauma Nurse Coordinator job description (include an Organizational Chart),
- 1. Trauma Registrar job description and evidence of CME requirements (as applicable),
- m. Performance improvement plan,
- n. Performance improvement process flow diagram,
- o. Verification renewal letter, and
- p. VSTR audit.
- ii. Any records pertaining to any voluntary or involuntary withdrawal of designation.
- iii. Any additional communication pertaining to designation status between the center and the VDH/OEMS or the Commissioner.
- iv. A summary of activity related to the center (a list of dates, nature of actions and resulting status of center.)
- c. A copy of the current trauma center file will be sent to the TPM and to the TMD at the time of request for verification or designation. These individuals will review the information contained for accuracy and provide written confirmation to VDH/OEMS.
- d. Management of records during review:
  - i. Each member of the site review team will receive a copy of the trauma center file in its entirety at least two weeks prior to the review, and
  - ii. Team members will receive electronic or written application material at least two weeks prior to the review.
- e. Preliminary report of findings may be made available to the center prior to the time of departure of the site review team:

- i. The center may receive a written copy of preliminary report listing issues of concern, strengths and areas for improvement; and
- ii. The team may also provide specific preliminary suggestions for remediation in writing at time of departure.
- f. The team leader will provide written confirmation of preliminary findings and remediation or amended findings and remediation within one week of finishing the site review.
- g. After any conditions of remediation have been satisfied, the site review team leader will provide the VDH/OEMS with written notice of closure of remediation.

# II. Application for Review

- a. Six months prior to the date a center is due for site review, the Trauma/Critical Care Coordinator for the VDH/OEMS will notify the TPM and provide the following:
  - i. Application to be completed,
  - ii. Copy of trauma center file on CDROM, and
  - iii. Copy and version number of criteria, administrative and interpretive guidelines AIG to be used during review.

# b. Application will include:

- i. Signed Trauma Center Code of Conduct,
- ii. Completed Trauma Center Capabilities Form,
- iii. Current Organizational Chart describing the relationship of the trauma service within the hospital organizational structure,
- iv. Impact Statement: the impact statement describes the role of the trauma center or proposed center in the system it serves. The statement acts as an argument for the existence the center and its essential contributions to the community,
- v. Level I, IB, IP, II or III Checklist for appropriate level requested (electronic form provided),
- vi. Completed Trauma Center Questionnaire,
- vii. Current complete list of emergency physicians and mid-level providers,
- viii. Current complete list of trauma surgeon's performing trauma call,
- ix. Current complete list of nursing staff members that serve as the primary trauma team nurse in the trauma bay/room. The list of trauma team nurses should include whether the nurse possesses active TNCC, ATCN, or CATN,

- x. Copies of current TNCC, ATCN, and CATN should be made available to the site review team,
- xi. Trauma team activation/alert criteria for your hospital,
- xii. Trauma team roles and responsibilities policy,
- xiii. Trauma alert policies,
- xiv. TMD job description,
- xv. Burn Medical Director job description (as applicable),
- xvi. Evidence of TMD's board certification(s), current ATLS, CME, and national conference attendance (as applicable),
- xvii. TPM job description (include an organizational chart),
- xviii. Burn manager/coordinator job description (as applicable),
- xix. Evidence of TPM's TEH and national conference attendance (as applicable),
- xx. Evidence of the Burn Manager/Coordinator's burn education hours (if applicable),
- xxi. Trauma registrar job description and evidence of TEH requirements (as applicable),
- xxii. Emergency Medical Director's board certification(s), CME and current ATLS or the identified designee's current ATLS,
- xxiii. Copy of the program's PI plan,
- xxiv. PI process flow diagram includes how issues get reported to its highest level,
- xxv. PI tracking sheets, and
- xxvi. Other documents as requested.

### **III.** Prior to Review

- a. Prior to review, the site review team shall have:
  - i. Complete copy of trauma center file,
  - ii. Full copy of pre-review application,
  - iii. Current status of center with regard to VSTR provided by VDH/OEMS, and
  - iv. List of any trauma related issues requiring investigation by VDH since last review, along with resolution.

### **IV.** Site Review

Overview: Without trauma and burn patients, a trauma center cannot demonstrate the consistency and effectiveness of procedures and protocols put into place at the time of its inception. In a well-developed system with a strong trauma triage element, severely injured or burned patients will be directed toward existing designated trauma centers. This creates a paradoxical situation; the center should not be designated until it demonstrates

effectiveness, yet cannot demonstrate effectiveness until receiving patients as a trauma center. To remedy this situation, first time institutional reviews will be to survey for a provisional status.

Although it is important for a center to demonstrate its level of performance, the public must not be put at risk for suboptimal care. Therefore, after a center has a provisional status a second review will be held to assess for full designation. The interval will allow the center to put its documented plan for trauma care into action. In addition, the institution will have an opportunity to correct any deficiencies identified by the original site review team. At the time of the second site review (the first designation review) the center will either pass or not pass. Any identified critical deficiencies will result in a mandatory period during which the institution will re evaluate the trauma service prior to beginning the designation process over again.

- a. Provisional center one year period
  - i. At the provisional review, the center must demonstrate that all required mechanisms to meet criteria are in place. The team will confirm that there is a resource, policy, or procedure that addresses the criteria and that it represents a practical and effective approach.
  - ii. The team will identify the following:
    - 1. Critical deficiencies
    - 2. Non-critical deficiencies
    - 3. Potential areas for improvement
  - iii. The presence of critical deficiencies will be cause to withhold provisional designation. The center must re–evaluate its program and if desired, begin the application process again after a period of not less than one year.
  - iv. When non-critical deficiencies exist or in the absence of deficiencies, the program will receive provisional status for a period of one year. During this time, it will function at the identified level and remedy any non-critical deficiencies identified at the first site review.
  - b. Designation: A second site review will occur at the end of the hospital's one year provisional status. The hospital does not have to submit a full application, but should submit an interim report describing any changes since designation as a provisional center, status of non-critical deficiencies noted during the first site review, as well as a trauma service summary from its trauma registry.

The modified site review team will consist of a surgeon team leader, a trauma/critical care nurse reviewer, and the VDH/OEMS Trauma/Critical Care Coordinator. The surgeon team leader or OEMS may add additional members to this team as deemed necessary.

Any critical deficiencies identified at this time will result in the center not receiving designation as a trauma center. The hospital will not function as a trauma center if this occurs and will re–evaluate and revise its current program for at least two years prior to beginning the application process again.

- c. Verification: Following designation, a center will undergo a verification review every three—years having become designated; an institution must continue its developmental process. A progressively sophisticated approach is expected of more experienced centers and is reflected in a number of the criteria. This is particularly apparent in the area of quality assurance. Continuous improvement means continuous change. An experienced program is expected to demonstrate ongoing evaluation of the trauma care system, presenting enhanced approaches to existing problems, or efforts at solving newly identified problems. For this reason, it is unlikely that an experienced program will be successful if unable to present progress and changes over three verification cycles. Verification reviews follow a successful designation review and should document ongoing development of the center and responsiveness to trauma system issues.
  - i. A full application will be submitted for each verification review.
  - ii. In the absence of critical deficiencies or persistent non–critical deficiencies the center will be confirmed at its current level of function.
  - iii. If a non-critical deficiency has been identified for the first time it will be noted in the team leaders' summary. However, if a non-critical deficiency is identified in two out of three sequential reviews, the center will be asked to submit a plan of correction to VDH/OEMS within three months. At the next site review, the center will provide evidence of having implemented the plan and improvement in the area of deficiency identified.

#### V. Withdrawal

Overview: As an advocate for quality trauma and burn care, a trauma center should be able to identify situations in which it no longer meets criteria required for its current level of designation. If this occurs, the center should notify the VDH/OEMS requesting a temporary withdrawal, permanent withdrawal, or request for re–designation (either upgrade or downgrade).

Identification and self–reporting of the problem is more advantageous than waiting for an adverse result of a verification review or complaint resulting in involuntary withdrawal.

a. Temporary: A hospital may request a temporary withdrawal from the system if unforeseen and uncontrollable circumstances prevent the center from functioning at its designated level and if the period of time is expected to be longer than one day and less than three months. Requests for temporary withdrawal greater than three months will require a site review.

Examples include death, disability, resignation, retirement, etc. of key individuals on the trauma service, or an internal disaster such as a fire or flood. A representative from the hospital will notify the VDH/OEMS regarding the request for temporary withdrawal by phone or e-mail as early as possible. Initial notification shall be followed by a written report outlining the circumstances, the plan to correct the circumstances, the anticipated length of temporary withdrawal, and any arrangements to maintain trauma care within the system (e.g. memorandum of understandings with other hospitals, notification of VDH/OEMS) within 14 days. Once the problem has been corrected the trauma center will notify the VDH/OEMS. A site review is not required for re-instatement. If the center is involved in remediation for critical deficiencies at the time of request for temporary withdrawal, the timeline for remediation is not altered and no extension is applied.

- b. Permanent: If a hospital wishes to discontinue its role as a trauma center it may request a voluntary withdrawal. The institution is not required to provide a reason for this although the VDH/OEMS may request information to facilitate evaluation of the trauma system. The hospital should provide the request for voluntary withdrawal in writing. Included with the request should be a copy of the most recent impact statement and suggestions for changes in the system to allow for accommodation of gaps in trauma coverage. Following voluntary withdrawal, a center may apply for re—designation at any level desired after a period of not less than one year. The center will arrange for notification of the public and EMS agencies regarding the change in status. Only one voluntary withdrawal is permitted within a ten—year period of time.
- c. Re-designation (upgrade): The hospital requesting an upgrade in level of trauma center designation will be required to undergo a full site review at the level of redesignation being requested. The site review must occur prior to functioning at the requested level of re-designation. Since this is a new designation, a provisional status will be granted with a follow-up modified site review one year later.

- d. Re–designation (downgrade): If a hospital requests a downgrade in level of designation, a modified site review will be performed to assure the hospital is functioning at the level of designation being requested.
- e. Involuntary: An involuntary withdrawal occurs when a center fails to remediate critical deficiencies as outlined by the site review team, or if a review by a site review team or VDH/OEMS representative determines that further function as a trauma center would be a risk to patient safety or extremely detrimental to the system. If this occurs, the center has the option of an appeals process outlined below. At the time of an involuntary withdrawal, the VDH/OEMS will provide notification to the public and to EMS providers in the area. Following the first involuntary withdrawal, an institution may request re–designation after a period of not less than three–years. After any subsequent involuntary withdrawals the institution will not be permitted to apply for re–designation sooner than five years.

# VI. Appeal

If a hospital, whether designated or attempting to be designated, has a grievance with findings relating to the enforcement of the Virginia trauma center criteria by the VDH/OEMS, a site review team leader, a site review team member, the TSO&MC, or any subcommittee formed from the TSO&MC, has the right to file an appeal.

The appeals process will follow the Administrative Process Act (APA) of Virginia § 2.2–4000. Notice of intent to appeal should be documented and submitted to VDH/OEMS as stipulated in § 2.2–4000. Failure to follow the APA guidelines can result in the appeal not being heard.

### VII. Variances and Exemptions

Any designated trauma center that wishes to request a variance or exemption from any of the criteria or procedures required by the trauma center designation process shall do so in writing. A variance provides the hospital with temporary relief from a criterion or procedure and an exemption provides permanent relief from a specific criterion. All variances and exemptions become void upon implementation of a revised Trauma and Burn Center Designation Manual.

To submit a request for a variance or exemption the designated trauma center may file a written request for a variance with the VDH/OEMS Trauma/Critical Care Coordinator. The following additional requirements apply:

- 1. The written variance or exemption request shall be submitted by the hospital's administrative leadership.
- 2. The request shall be submitted to the VDH/OEMS Trauma/Critical Care Coordinator.
- 3. The request shall clearly state:
  - a. The criterion that is the focus of the variance/exemption.
  - b. A detailed description of why the request is being made.
  - c. A detailed impact statement describing any alternative action that will occur to mitigate the effects on patient care or operational procedures.
  - d. Describe how the regional trauma system will be informed if applicable.
  - e. Provide any transfer agreements and transfer policies as applicable.
  - f. Provide any supporting facts or data that support granting a variance or exemption.
  - g. Provide letters of support from regional hospitals, EMS agencies, or others as applicable.
- 4. The VDH/OEMS Trauma/Critical Care Coordinator will review the request and make a recommendation to approve or disapprove the request to the State Health Commissioner.
- 5. The VDH/OEMS will provide the State Health Commissioner with any facts such as national standards that relate, either positively or negatively, to the request.
- 6. This process may take 2 8 weeks.

# VIII. Site Review Team Member Roles, Training, and Recruitment

- 1. Site review team member roles (refer also to site review checklist for more details)
  - a. A surgeon team leader officiates over the site review team and provides a written summary and recommendation to the State Health Commissioner. The surgeon team leader will review the surgical capabilities of the hospital and determine if they meet essential criteria for the level of designation/verification being sought.
  - b. An emergency medicine physician will review the ED's response to trauma patients. This would include whether there is an appropriate team response to trauma patients, the care provided during that response and the availability of ancillary services during the initial phase of trauma care.
  - c. The trauma/critical care nurse reviewer will review all phases of nursing care provided by the applying center. This would include assuring there is adequate staffing and equipment available, as well as quality nursing care provided during the trauma team response, within the critical care department and inpatient areas.
  - d. Trauma nurse coordinator's role within the trauma service will also be evaluated by the trauma/critical care nurse reviewer.
  - e. A hospital administrator role will also be utilized to evaluate the overall commitment that the hospitals administration has to the trauma service.

- 2. Training The VDH/OEMS and the TSO&MC may provide a training program, suited for both classroom presentation and self-learning which will assure the site reviewer's knowledge of the current criteria and their role as a site review team member.
- 3. Recruitment –VDH/OEMS and the TSO&MC will assure that there are an adequate numbers of site reviewers. To qualify as a site review team member, the individual will be required to observe a minimum of one site review, receive the site review training, and be approved by vote of the TSO&MC.
- 4. VDH/OEMS will maintain records on individual site reviewer activities including dates, locations, and outcomes of reviews.
- 5. VDH/OEMS will solicit evaluations of site team leader performance.

# **Burn Patient Criteria**

Burn injuries that should be referred to a trauma/burn center for assessment:

The <u>American Burn Association</u> has identified the following injuries that usually require referral to a trauma/burn center.

- ➤ Partial thickness and full thickness burns greater than 10 percent of the total body surface area (BSA).
- > Third degree burns in any age group.
- Full-thickness burns greater than five percent BSA in any age group.
- ➤ Burns that involve the face, hands, feet, genitalia, perineum, or major joints,
- > Electrical burns including lightning injury.
- > Significant chemical burns.
- > Burns with inhalation injury.
- ➤ Burn injury in patients with preexisting medical disorders that could complicate management, prolongs recovery, or affects mortality.
- ➤ Burns and concomitant trauma (such as fractures) when the burn injury poses greater risk of morbidity or mortality. If the trauma poses the greater immediate risk, the patient's condition may be stabilized initially in a trauma center before transfer to a burn center. Physician judgment will be necessary in such situations and should be in concert with the statewide trauma triage plan.
- ➤ Children with burns seen in hospitals without qualified personnel or equipment for their care should be transferred to a burn center with these capabilities.
- ➤ Burn injury in patients who will require special social and emotional or long term rehabilitative support, including cases involving child abuse and neglect.

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