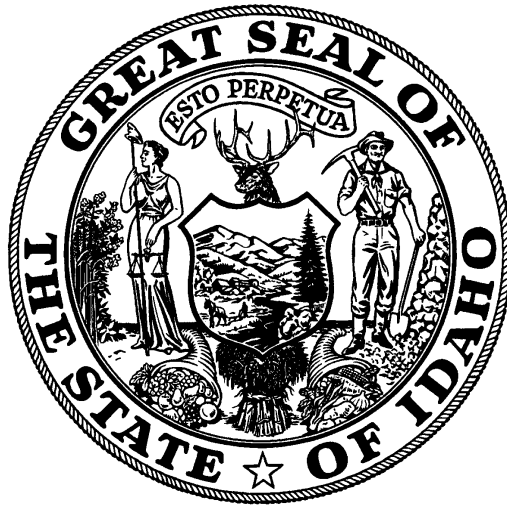


**SUPPLEMENTAL
TEMPORARY RULES
COMMITTEE RULES
REVIEW BOOK**

**Submitted for Review Before
House Health & Welfare Committee
63rd Idaho Legislature
First Regular Session**



Prepared by:

*Office of the Administrative Rules Coordinator
Department of Administration*

January 2015

HOUSE HEALTH & WELFARE COMMITTEE

ADMINISTRATIVE RULES REVIEW

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IDAPA 16 - DEPARTMENT OF HEALTH AND WELFARE

16.02.01 - RULES OF THE IDAHO TIME SENSITIVE EMERGENCY SYSTEM COUNCIL

DOCKET NO. 16-0201-1401 (NEW CHAPTER)

NOTICE OF RULEMAKING - ADOPTION OF TEMPORARY RULE

EFFECTIVE DATE: The effective date of the temporary rule is January 1, 2015.

AUTHORITY: In compliance with Sections 67-5226, Idaho Code, notice is hereby given this agency has adopted a temporary rule. The action is authorized pursuant to Sections 56-1024 through 56-1030, Idaho Code.

DESCRIPTIVE SUMMARY: The following is the required finding and concise statement of its supporting reasons for adopting a temporary rule:

The 2014 Legislature authorized the Idaho Time Sensitive Emergency System of Care, a TSE Council, and Regional TSE Committees. This legislation took effect on July 1, 2014, and requires that rules be adopted to set standards, regions, regional committees, fees, and other requirements for time sensitive emergencies related to trauma, stroke, and heart attacks. This new chapter of rules is currently being published as a temporary rule only. The chapter has been negotiated and based on comments received, the TSE Council has decided to adopt temporary rules for Trauma Center designations, and to continue negotiations on Stroke and Heart Attack designations. Currently, this temporary rule includes:

1. Regions based on community input, the TSE Council, regional TSE committees;
2. Standards and requirements for a statewide emergency systems for trauma, with stroke and heart attack standards being added once those designations criteria have been negotiated based on nationally accepted practices;
3. Criteria of designation levels, fees, application processes, on-site reviews and inspections, waiver policy, enforcement remedies for probation, suspension, revocation, and appeals of Department actions; and
4. Required sections to meet the requirements of the APA and the rules of the Office of the Administrative Rules Coordinator.

TEMPORARY RULE JUSTIFICATION: Pursuant to Sections 67-5226(1), (a), and (b), Idaho Code, the Governor has found that temporary adoption of the rule is appropriate for the following reasons:

This new chapter of rules for the TSE Council is being adopted as a temporary rule to protect the public health, safety, or welfare. Statutes establishing the Idaho Time Sensitive Emergency System were effective on July 1, 2014. The Governor has found that the fees being charged in this rule are necessary to avoid immediate danger and are justified as a temporary rule.

FEE SUMMARY: Pursuant to Section 67-5226(2), the Governor has found that the fee or charge being imposed or increased is justified and necessary to avoid immediate danger and the fee is described herein:

Fees will be charged for hospitals that choose to become TSE designated as a trauma, stroke, or heart attack center. The fees for each designation are payable on an annual or triennial basis. Fees may also be charged for on-site surveys that are required for certain designation levels.

FISCAL IMPACT: The following is a specific description, if applicable, of any fiscal impact on the state general fund greater than ten thousand dollars (\$10,000) during the fiscal year.

The fiscal impact to the state general fund as appropriated by the Legislature for SFY 2015 is \$225,800.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted as provided in the September 3, 2014, Idaho Administrative Bulletin, [Vol. 14-9, page 187](#).

INCORPORATION BY REFERENCE: Pursuant to Section 67-5229(2)(a), Idaho Code, a document is being incorporated by reference into these rules to give it the force and effect of law. The document is not being reprinted in this chapter of rules due to its length, format, and the cost for republication. The document being incorporated by reference is the Time Sensitive Emergency System Standards Manual, Edition 2015-1.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the temporary rule, contact Christian Surjan at (208) 334-6564.

DATED this 30th day of December, 2014.

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FOLLOWING IS THE TEXT OF THE TEMPORARY RULE FOR DOCKET NO. 16-0201-1501

IDAPA 16
TITLE 02
CHAPTER 01

16.02.01 - RULES OF THE IDAHO TIME SENSITIVE EMERGENCY SYSTEM COUNCIL

000. LEGAL AUTHORITY.

The Idaho Time Sensitive Emergency System Council (TSE) is authorized under Section 56-1028, Idaho Code, to promulgate rules for the purpose of establishing standards and for the administration of a voluntary time sensitive emergency system of care. Sections 56-1024 through 56-1030, Idaho Code, provide requirements for the TSE Council, its membership, duties, regional TSE committees, standards criteria, and the designation of centers. The Department is authorized to charge and collect fees established by rule under Section 56-1007, Idaho Code, and to establish and collect data for a Time Sensitive Emergency (TSE) Registry under Section 57-2003, Idaho Code.

(1-1-15)T

001. TITLE, SCOPE, AND INTENT.

01. Title. The title of these rules is IDAPA 16.02.01, "Rules of the Idaho Time Sensitive Emergency System Council."

(1-1-15)T

02. Scope. These rules provide for the administration and establishment of standards for a voluntary statewide time sensitive emergency system of care that includes procedures and requirements for designation of

trauma, stroke, and heart attack centers including data reporting, fees, appeal process and enforcement procedures, determination of regions to provide an effective access to the TSE system within the state, and operational procedures for regional TSE committees. (1-1-15)T

03. Intent. With the maturation of the Time Sensitive Emergency System (TSE), the intent is for the state to have the ability to designate TSE centers without reliance on national accreditation bodies. The TSE Council, upon review of appropriate documentation, may provide reciprocity for facilities in Idaho that also choose to operate under a designation in a neighboring state's system. (1-1-15)T

002. WRITTEN INTERPRETATIONS.

In accordance with Section 67-5201(19)(b)(iv), Idaho Code, the Department may have written statements that pertain to the interpretation of this chapter, or to the documentation of compliance with these rules. (1-1-15)T

003. ADMINISTRATIVE APPEALS.

Administrative appeals and contested cases are governed by the provisions of IDAPA 16.05.03, "Rules Governing Contested Case Proceedings and Declaratory Rulings." (1-1-15)T

004. INCORPORATION BY REFERENCE.

The Time Sensitive Emergency System Standards Manual, Edition 2015-1, is incorporated by reference in this chapter of rules. Copies of the manual may be obtained online at www.tse.idaho.gov or from the Bureau of Emergency Medical Services and Preparedness located at 2224 East Old Penitentiary Road, Boise, ID 83712-8249. (1-1-15)T

005. OFFICE -- OFFICE HOURS -- MAILING ADDRESS -- STREET ADDRESS -- TELEPHONE NUMBER -- INTERNET WEBSITE.

01. Office Hours. Office hours are 8 a.m. to 5 p.m., Mountain Time, Monday through Friday, except holidays designated by the State of Idaho. (1-1-15)T

02. Mailing Address. (1-1-15)T

a. Idaho Department of Health and Welfare, P.O. Box 83720, Boise, Idaho 83720-0036. (1-1-15)T

b. Idaho Time Sensitive Emergency System Council, 2224 E. Old Penitentiary Road, Boise, Idaho 83712-8249. (1-1-15)T

03. Street Address. (1-1-15)T

a. The Idaho Department of Health and Welfare is located at 450 West State Street, Boise, Idaho 83702. (1-1-15)T

b. The Bureau of Emergency Medical Services and Preparedness is located at 2224 E. Old Penitentiary Road, Boise, Idaho 83712. (1-1-15)T

04. Telephone. (1-1-15)T

a. The Idaho Department of Health and Welfare number is (208) 334-5500. (1-1-15)T

b. The Bureau of Emergency Medical Services and Preparedness number is (208) 334-4000. The toll-free phone number is 1 (877) 554-3367. (1-1-15)T

05. Internet Websites. (1-1-15)T

a. The Department internet website is found at <http://www.healthandwelfare.idaho.gov>. (1-1-15)T

b. The Time Sensitive Emergency System Council internet website is found at <http://www.tse.idaho.gov>. (1-1-15)T

c. The Bureau of Emergency Medical Services and Preparedness internet website is found at <http://www.idahoems.org>. (1-1-15)T

006. CONFIDENTIALITY OF RECORDS AND PUBLIC RECORDS ACT COMPLIANCE AND REQUESTS.

01. Confidentiality of Records. Any disclosure of confidential information used or disclosed in the course of the TSE Council's business is subject to the restrictions in state or federal law, and must comply with IDAPA 16.05.01, "Use and Disclosure of Department Records." (1-1-15)T

02. Public Records Act. The Department will comply with Sections 9-337 through 9-350, Idaho Code, when requests for the examination and copying of public records are made. Unless otherwise exempted, all public records in the custody of the Department are subject to disclosure. (1-1-15)T

03. Public Availability of Preliminary Investigations, Site Reviews, and Survey Reports. Preliminary investigations and related documents are confidential until a notice of action is issued for survey reports and findings of complaint investigations relating to a designated center. Documents that are available for public review may be found at <http://www.tse.idaho.gov>. (1-1-15)T

007. -- 009. (RESERVED)

010. DEFINITIONS.

For the purposes of this chapter, the following terms and definitions apply. (1-1-15)T

01. American College of Surgeons (ACS). The American College of Surgeons (ACS) is a national body that sets standards and verifies compliance with published standards. (1-1-15)T

02. Department. The Idaho Department of Health and Welfare. (1-1-15)T

03. Director. The Director of the Idaho Department of Health and Welfare or his designee. (1-1-15)T

04. Division. The Division of Public Health, Idaho Department of Health and Welfare. (1-1-15)T

05. EMS Agency. Any organization licensed by the Department under Sections 56-1011 through 56-1023, Idaho Code, and IDAPA 16.01.03, "Emergency Medical Services (EMS) - Agency Licensing Requirements," that operates an air medical service, ambulance service, or non-transport service. (1-1-15)T

06. EMS Bureau. The Bureau of Emergency Medical Services (EMS) & Preparedness of the Idaho Department of Health and Welfare. (1-1-15)T

07. Facility. A health care organization that is voluntarily seeking designation from the Idaho Time Sensitive Emergency Council. A facility may be any of the following: (1-1-15)T

a. Center. A facility designated by the Idaho Time Sensitive Emergency Council is known as a center. (1-1-15)T

b. Freestanding emergency department: (1-1-15)T

i. Is owned by a hospital with a dedicated emergency department; (1-1-15)T

ii. Is located within 35 miles of the hospital that owns or controls it; (1-1-15)T

iii. Provides emergency services twenty-four (24) hours per day, seven (7) days per week on an outpatient basis; (1-1-15)T

iv. Is physically separate from a hospital; and (1-1-15)T

- v. Meets the staffing and service requirements in IDAPA 16.03.14, “Rules and Minimum Standards for Hospitals in Idaho.” (1-1-15)T
- c. Hospital. As defined in Section 39-1301, Idaho Code, is a facility which is primarily engaged in providing, by or under the daily supervision of physicians: (1-1-15)T
- i. Concentrated medical and nursing care on a twenty-four (24) hour basis to inpatients experiencing acute illness; (1-1-15)T
- ii. Diagnostic and therapeutic services for medical diagnosis and treatment, psychiatric diagnosis and treatment, and care of injured, disabled, or sick persons; (1-1-15)T
- iii. Rehabilitation services for injured, disabled, or sick persons, (1-1-15)T
- iv. Obstetrical care; (1-1-15)T
- v. Provides for care of two (2) or more individuals for twenty-four (24) or more consecutive hours; and (1-1-15)T
- vi. Is staffed to provide nursing professional nursing care on a twenty-four (24) hour basis. (1-1-15)T
- d. Rural Clinic. A health care clinic in a rural area that is located more than thirty-five (35) miles from a hospital via maintained roads and is capable of providing emergency care to patients. (1-1-15)T
- 08. Heart Attack.** STEMI, which is a common name for ST-elevation myocardial infarction, a more precise definition for a type of heart attack that is caused by a prolonged period of blocked blood supply that affects a large area of the heart and has a substantial risk of death and disability calling for a quick response. (1-1-15)T
- 09. Idaho Time Sensitive Emergency (TSE) System Council.** The Idaho Time Sensitive Emergency System Council established in Section 56-1027, Idaho Code. (1-1-15)T
- 10. National Accrediting Body.** An organization whose standards criteria is recognized by the Idaho Time Sensitive Emergency System Council and verifies compliance with those standards. (1-1-15)T
- 11. Regional Time Sensitive Emergency (TSE) Committee.** An Idaho regional TSE committee established under Section 56-1030, Idaho Code. (1-1-15)T
- 12. STEMI.** STEMI is an ST segment elevation myocardial infarction that is a particular type of heart attack, or MI (myocardial infarction), that is caused by a prolonged period of blocked blood supply. It affects a large area of the heart muscle, and so causes changes on the ECG as well as in blood levels of key chemical markers. This is considered a major heart attack and is referred to in medical shorthand as a STEMI. (1-1-15)T
- 13. Stroke.** An interruption of blood flow to the brain causing paralysis, slurred speech, or altered brain function usually caused by a blockage in a blood vessel that carries blood to the brain (ischemic stroke) or by a blood vessel bursting (hemorrhagic). (1-1-15)T
- 14. Time Sensitive Emergency (TSE).** Time sensitive emergencies specifically for this chapter of rules are trauma, stroke, and heart attack. (1-1-15)T
- 15. Trauma.** The result of an act or event that damages, harms, or hurts a human being resulting in intentional or unintentional damage to the body resulting from acute exposure to mechanical, thermal, electrical, or chemical energy, or from the absence of such essentials as heat or oxygen. (1-1-15)T
- 16. TSE Council.** The Idaho Time Sensitive Emergency System Council. (1-1-15)T
- 17. TSE Designated Center.** A facility that has voluntarily applied for TSE designation, met and is in

compliance with the designation criteria and standards of these rules when published, and that the TSE Council has designated as one (1) or more of the following: (1-1-15)T

- a. Level I Trauma Center; (1-1-15)T
- b. Level II Trauma Center; (1-1-15)T
- c. Level III Trauma Center; (1-1-15)T
- d. Level IV Trauma Center; (1-1-15)T
- e. Level V Trauma Center; or (1-1-15)T
- f. Pediatric Level I Trauma Center; (1-1-15)T
- g. Pediatric Level II Trauma Center; (1-1-15)T
- h. Comprehensive Stroke Center; (1-1-15)T
- i. Primary Stroke Center; (1-1-15)T
- j. Acute Stroke Ready Center; (1-1-15)T
- k. STEMI (Heart Attack) Receiving Center; (1-1-15)T
- l. STEMI (Heart Attack) Referring Center; (1-1-15)T

18. TSE Registry. The population-based data system that provides ongoing and systematic collection, analysis, interpretation, and dissemination of information related to trauma, stroke, and heart attack for system improvement, prevention and research activities. Elements in the registry describe the nature and scope of the injury, illness, or health condition, identify the incidence and prevalence of traumatic injury, illness, or health condition, the severity of the injury, performance of out-of-hospital and hospital emergency medical systems, patient outcome, and the impact of trauma, stroke, and heart attack on the health care system. The TSE Registry is established under Section 57-2003, Idaho Code. (1-1-15)T

19. TSE System. Under Section 57-2002, Idaho Code, the TSE System is an organized approach to treating injured patients that establishes and promotes standards for patient transportation, equipment, and information analysis for effective and coordinated TSE care. TSE systems represent a continuum of care that is fully integrated into the emergency medical services system and is a coordinated effort between out-of-hospital and hospital providers with the close cooperation of medical specialists in each phase of care. The focus is on prevention, coordination of acute care, and aggressive rehabilitation. Systems are designed to be inclusive of all patients with a TSE requiring acute care facilities, striving to meet the needs of the patient, regardless of the severity of injury, geographic location or population density. A TSE system seeks to prevent injuries from happening and the reduction of death and disability when it does happen. (1-1-15)T

011. -- 074. (RESERVED)

075. TSE COUNCIL.

Under Section 56-1027, Idaho Code, the TSE Council will consist of members appointed by the Governor of Idaho and the chair of each regional TSE committee. (1-1-15)T

076. TSE COUNCIL -- RESPONSIBILITIES AND DUTIES.

The TSE Council is responsible for the duties described under Section 56-1028, Idaho Code. (1-1-15)T

077. -- 079. (RESERVED)

080. TSE REGIONS.

Under Section 56-1028, Idaho Code, the TSE Council is required to establish TSE regions that provide more effective access to the Idaho time sensitive emergency system through education, but not for the purpose of promoting competition, restricting, or directing patient referrals within the region. The TSE Council has established six (6) regions in Idaho described in the Time Sensitive Emergency System Standards Manual incorporated under Section 004 of these rules. (1-1-15)T

081. TSE REGIONS -- REALIGNMENT OF REGION.

The TSE Council may realign a region of a county by initiation of the TSE Council, or at the request of a regional TSE committee, a county or local government entity in the county, a TSE designated center, or a licensed EMS agency in that county. (1-1-15)T

01. Requesting Entity. The requesting entity must forward correspondence to the TSE Council specifying the reason for the realignment request. The correspondence must include: (1-1-15)T

- a. Existing patient routing patterns used by both EMS agencies and health care centers; (1-1-15)T
- b. Distances and transport times involved in patient routing patterns; (1-1-15)T
- c. A list of all entities affected by the request; (1-1-15)T
- d. A list of all other licensed health care facilities and licensed EMS agencies in the county; and (1-1-15)T
- e. Documentation that all affected regional TSE committees are agreeable to the realignment. (1-1-15)T

02. Copies of Request for Realignment. The entity requesting the TSE Council for realignment must provide copies of the correspondence to all affected regional TSE committees, county and local governments, licensed health care facilities, and EMS agencies in the county. (1-1-15)T

03. TSE Decision for Realignment. The TSE Council will evaluate the request based on the impact to patient care and will notify all parties of the council's decision. (1-1-15)T

082. REGIONAL TSE COMMITTEES -- ORGANIZATION AND RESPONSIBILITIES.

The regional TSE committees' organization and responsibilities are described under Section 56-1030, Idaho Code. (1-1-15)T

083. -- 099. (RESERVED)

100. DESIGNATION OF TSE CENTERS -- CRITERIA.

Under Section 56-1029, Idaho Code, the TSE Council will designate a hospital as a trauma, stroke, or STEMI (heart attack) center when such hospital, upon proper application and verification, is found by the TSE Council to meet an applicable designation level for trauma, stroke, or STEMI (heart attack) designation criteria established in the Time Sensitive Emergency System Standards Manual incorporated under Section 004 of these rules. (1-1-15)T

101. -- 104. (RESERVED)

105. TRAUMA DESIGNATION CENTERS.

To be designated as an Idaho TSE designated Level I, II, III, IV, V, Pediatric Level I or Level II Trauma Center, a facility must meet or exceed requirement standards published for state designation in the Time Sensitive Emergency System Standards Manual incorporated under Section 004 of these rules. (1-1-15)T

106. -- 109. (RESERVED)

110. STROKE DESIGNATION CENTERS.

To be designated as an Idaho TSE designated Comprehensive Stroke Center, Primary Stroke Center, or an Acute Stroke Ready Center, a facility must meet or exceed requirement standards when published for state designation in

the Time Sensitive Emergency System Standards Manual incorporated under Section 004 of these rules. (1-1-15)T

111. -- 114. (RESERVED)

115. STEMI (HEART ATTACK) DESIGNATION CENTERS.

To be designated as an Idaho TSE designated STEMI (Heart Attack) Receiving Center, or STEMI (Heart Attack) Referring Center, a facility must meet or exceed requirement standards when published for state designation in the Time Sensitive Emergency System Standards Manual incorporated under Section 004 of these rules. (1-1-15)T

116. -- 119. (RESERVED)

120. DESIGNATION OF CENTERS -- GENERAL REQUIREMENTS.

01. Application. A hospital applying for initial designation as a TSE designated center must submit an application along with applicable fees for each designation it is requesting. Application process and requirements are provided in the Time Sensitive Emergency System Standards Manual incorporated under Section 004 of these rules. Fee requirements are provided in Section 200 of these rules. (1-1-15)T

02. Initial Designation. Initial designation requires completion of appropriate application, submission of appropriate fees, and completion of an appropriate on-site survey based on the Time Sensitive Emergency System Standards Manual incorporated by reference under Section 004 of these rules. (1-1-15)T

116. -- 119. (RESERVED)

190. TSE DESIGNATION -- LENGTH OF DESIGNATION.

A TSE center will be designated for a period of three (3) years, unless the designation is rescinded by the TSE Council for non-compliance with the designation standards of these rules or adjusted to coincide with applicable external verification timetables. (1-1-15)T

191. RENEWAL OF TSE DESIGNATION.

A TSE center's designation will not lapse when the application for renewal has been timely submitted to the TSE Council, and the application is undergoing review by the TSE Council or awaiting an on-site review through no fault of the applicant. (1-1-15)T

192. -- 194. (RESERVED)

195. NOTIFICATION OF LOSS OF CERTIFICATION OR LICENSURE.

Any TSE designated center that has a loss of certification or licensure will immediately notify the TSE Council. (1-1-15)T

196. -- 199. (RESERVED)

200. DESIGNATION AND TSE ON-SITE SURVEY FEES.

01. Application With National Verification. An applicant applying for a TSE designation that is verified by a national accrediting body must submit the appropriate designation fees with its application for initial designation and renewal. The designation fees are for a three (3) year designation and are payable on an annual basis. TSE designation fees are not to exceed those listed in Subsection 200.03 of this rule. (1-1-15)T

02. Application Without National Verification. An applicant who requires a TSE on-site survey prior to designation is required to pay the applicable on-site survey fee at the time of application. TSE designation and on-site survey fees are not to exceed those listed in Subsection 200.03 of this rule. (1-1-15)T

03. Trauma Designation and TSE On-Site Survey Fees.

TRAUMA DESIGNATIONS 200.03	DESIGNATION FEE 3-years / Annual (Not to exceed)	TSE ON-SITE SURVEY FEE (Not to exceed)
LEVEL 1	\$45,000 / \$15,000	\$3000 / Not applicable with ACS verification
LEVEL II	\$36,000 / \$12,000	\$3000 / Not applicable with ACS verification
LEVEL III	\$24,000 / \$8,000	\$3000 / Not applicable with ACS verification
LEVEL IV	\$12,000 / \$4,000	\$1500 / Not applicable with ACS verification
LEVEL V	\$3,000 / \$1,000	\$1500
PEDIATRIC LEVEL I and LEVEL II	\$36,000 / \$12,000	\$3000 / Not applicable with ACS verification

(1-1-15)T

04. Designation Fee Payment. After completion of the TSE on-site survey, the TSE Council will officially notify the facility of successfully meeting designation criteria. After this notification takes place, facility designation goes into effect upon the Department's receipt of the first year's designation fee or the entire three (3) year fee. Subsequent annual designation fees are due to the Department within thirty (30) days of receipt of invoice in order to maintain designation. (1-1-15)T

201. -- 249. (RESERVED)

250. TSE ON-SITE REVIEW.

The TSE Council will conduct an on-site review of each TSE designated center at least once every three (3) years, unless the center has been verified by a national accrediting body to meet or exceed the standards set in these rules. The TSE Council will schedule the on-site review with the designated center in a timely manner. (1-1-15)T

251. TSE ON-SITE REVIEW -- GENERAL REQUIREMENTS.

The TSE on-site review will consist of and consider each facility's application and compliance with the standards published for state designation and incorporated under Section 004 of these rules for the specific type of designation being requested. The general requirements in Subsection 251.01 through 251.04 of this rule apply: (1-1-15)T

01. Review Team Member Requirements. Review team members will meet the following inclusion criteria: (1-1-15)T

a. A physician reviewer will: (1-1-15)T

i. Be certified by the American Board of Medical Specialties or the American Board of Osteopathic Medicine; (1-1-15)T

ii. Be board certified in the specialty area he is representing on the review team; (1-1-15)T

iii. Be currently active in trauma, stroke, or emergency cardiac care at a center that is at or above the level being reviewed; (1-1-15)T

iv. Have no conflict of interest with the facility under review; and (1-1-15)T

v. Be from another state when performing a review for Level I, Level II, or Pediatric Trauma Center

designations. (1-1-15)T

b. A nurse reviewer or program manager will: (1-1-15)T

i. Be currently active in trauma, stroke, or emergency cardiac care at a center that is at or above the level being reviewed; and (1-1-15)T

ii. Have no conflict of interest with the facility under review; and (1-1-15)T

iii. Be from another state when performing a review for Level I, Level II, or Pediatric Trauma Center designations. (1-1-15)T

02. Review Team Member Notification of Potential Conflict of Interest. Upon being assigned to an on-site review team, a potential team member must notify the TSE Council of any potential conflict of interest regarding any financial, professional, or personal bias that may adversely affect the review of the applicant's facility. (1-1-15)T

03. Notification To Applicant of Review Team Members. The TSE Council will provide the applicant with the names of the on-site review team once they have been selected at least thirty (30) calendar days prior to the scheduled review. (1-1-15)T

04. Facility Notification of Potential Conflict of Interest. If the applicant believes that a potential reviewer has a financial, professional, or personal bias that may adversely affect the review, the applicant must notify the TSE Council in writing no later than seven (7) calendar days after the applicant receives the TSE Council's notification of the proposed review team. (1-1-15)T

05. Notification of Decision for Conflict of Interest. The TSE Council will consider the conflict of interest notice and make a decision concerning replacement of the review team member in question. No person who has a substantial conflict of interest in the operation of any center under review will participate in the on-site review of applicant. (1-1-15)T

252. TSE ON-SITE REVIEW -- REVIEW TEAM COMPOSITION.

The TSE Council will select an on-site review team based on the applicant's designation application and specifications provided in these rules and the standards published in the Time Sensitive Emergency System Standards Manual incorporated under Section 004 of these rules. (1-1-15)T

253. ON-SITE REVIEW -- ADDITIONAL REVIEWS.

The TSE Council may conduct additional, announced or unannounced, full or partial, on-site reviews of TSE designated centers or applicants when there is reason to believe that the center is not in compliance with the designation criteria standards of these rules. (1-1-15)T

254. -- 259. (RESERVED)

260. DESIGNATION DECISION.

01. Summary Report. The review team will present a verbal summary of the results to the applicant and the TSE Council for review team's recommendation on the center's designation at the completion of the site survey. (1-1-15)T

02. Written Report. The TSE Council will consider all evidence and notify the applicant in writing of its decision within thirty (30) calendar days of receiving the review team's recommendation. (1-1-15)T

03. Final Determination. The TSE Council's final determination regarding each application will be based upon consideration of all pertinent factors that include: (1-1-15)T

a. The application; (1-1-15)T

- b.** The evaluation and recommendations of the on-site review team; (1-1-15)T
- c.** The best interests of patients; and (1-1-15)T
- d.** Any unique attributes or circumstances that make the facility capable of meeting special community needs. (1-1-15)T

04. Denial. If the TSE Council denies an applicant a designation, the provisions of IDAPA 16.05.03, "Rules Governing Contested Case Proceedings and Declaratory Rulings," will apply. (1-1-15)T

261. -- 269. (RESERVED)

270. WAIVERS.

01. Granting a Waiver. The TSE Council may grant a waiver from one (1) or more designation criteria for a center applying for TSE designation. (1-1-15)T

02. Waiver Application. A center requesting a waiver must submit a completed waiver application on a TSE Council's form. The TSE Council may require the applicant to provide additional information, and the waiver application will not be considered complete until all required information is provided. (1-1-15)T

03. Post Notice. A center requesting a waiver must post a notice of the waiver application with a meaningful description of the substance of the request at all public entrances to the center and in at least one (1) area that is commonly used by the patients. The notice must: (1-1-15)T

- a.** Be posted on the date the waiver application is submitted; (1-1-15)T
- b.** Remain posted for a minimum of thirty (30) calendar days; and (1-1-15)T
- c.** Describe where and to whom comments may be submitted during the thirty (30) calendar days. (1-1-15)T

04. Notice Distribution. When the notice is posted, the center must also distribute copies of the notice to prehospital emergency medical service agencies active in the community served by the center. (1-1-15)T

05. Waiver Application Submission. The completed waiver application must be submitted to the TSE Council at least thirty (30) calendar days before a TSE Council meeting in order to be placed on the Council agenda. Applications completed less than thirty (30) calendar days in advance of a TSE Council meeting will be placed on a subsequent Council agenda. (1-1-15)T

06. Waiver Application Distribution. The TSE Council will distribute a copy of the public notice of the TSE Council meeting regarding the waiver application to all other TSE designated centers. (1-1-15)T

07. Waiver Application Review. The regional TSE committee will review the request and make recommendations to the TSE Council. The TSE Council will make a decision and notify the facility administrator within thirty (30) calendar days of the waiver decision. (1-1-15)T

- 08. Waiver Conditions.** When a waiver is granted, the council will: (1-1-15)T
 - a.** Specify the terms and conditions of the waiver; (1-1-15)T
 - b.** Specify the duration of the waiver, which under no circumstances is a waiver granted for a period longer than the designation cycle for that center; and (1-1-15)T
 - c.** Require the submission of progress reports from any center granted a waiver. (1-1-15)T

09. Waiver Renewal. A center that plans to maintain a waiver beyond its expiration must submit a new

waiver application to the council no less than ninety (90) days prior to the expiration of the waiver. (1-1-15)T

10. Waiver Revocation. The TSE Council may revoke or suspend a waiver when it determines: (1-1-15)T

a. That continuation of the waiver jeopardizes the health, safety, or welfare of the patients; (1-1-15)T

b. The applicant has provided false or misleading information in the waiver application; (1-1-15)T

c. The applicant has failed to comply with conditions of the waiver; or (1-1-15)T

d. That a change in federal or state law prohibits continuation of the waiver. (1-1-15)T

12. Appeals. When the TSE Council denies, revokes, or suspends a waiver, the provisions in IDAPA 16.05.03, "Rules Governing Contested Case Proceedings and Declaratory Rulings" will apply. (1-1-15)T

271. -- 279. (RESERVED)

280. DENIAL AND MODIFICATION.

01. Denial. The TSE Council may deny an initial or renewal application for a center's designation when a center: (1-1-15)T

a. Does not meet the criteria for designation required in these rules; (1-1-15)T

b. Application or accompanying documents contain false statements of material facts; (1-1-15)T

c. Refuses to allow any part of an on-site review; (1-1-15)T

d. Fails to comply with or to successfully complete a plan of correction, or (1-1-15)T

e. Is substantially out of compliance with any of TSE Council's rules. (1-1-15)T

02. Modification. When a center does not meet the level of designation criteria for which it applied or for which it subsequently surrenders its verification, the TSE Council may recommend a designation at a lesser level described in Section 290 of these rules, or a complete revocation of state designation. This action, unless agreed to by the applicant, will represent a denial of the application. (1-1-15)T

03. Notification and Appeal. When the TSE Council denies an application for designation, the TSE Council will provide the center with a written notification of the denial and the basis for the denial. The notice will inform the facility of the right to appeal and the procedure to appeal the denial under the provisions in IDAPA 16.05.03, "Rules Governing Contested Case Proceedings and Declaratory Rulings." (1-1-15)T

281. -- 284. (RESERVED)

285. REVOCATION AND SUSPENSION.

01. Revocation. The TSE Council may revoke the designation of a center or a waiver when any owner, officer, director, manager, or other employee: (1-1-15)T

a. Fails or refuses to comply with the provisions of these rules; (1-1-15)T

b. Makes a false statement of material fact about the center's capabilities or other pertinent circumstances in any record or matter under investigation for any purposes connected with these rules; (1-1-15)T

c. Prevents, interferes with, or attempts to impede in any way, the work of a representative of the TSE Council in implementing or enforcing these rules; (1-1-15)T

d. Falsely advertises or in any way misrepresents the facility's ability to care for patients based on its designation status; (1-1-15)T

e. Is substantially out of compliance with these rules and has not rectified such noncompliance; (1-1-15)T

f. Fails to provide reports required by the TSE registry or the state in a timely and complete fashion; (1-1-15)T
or

g. Fails to comply with or complete a plan of correction in the time or manner specified. (1-1-15)T

02. Suspension. The TSE Council may suspend a center's designation or waiver when it finds, after investigation, that the center has engaged in a deliberate and willful violation of these rules, or that the public health, safety, or welfare requires immediate action. (1-1-15)T

03. Notification and Appeal. When the TSE Council revokes or suspends a center's designation or waiver, it will provide the center with a written notification of the action and the basis for the action. The notice will inform the center of the right to appeal and the procedure to appeal the action under the provisions in IDAPA 16.05.03, "Rules Governing Contested Case Proceedings and Declaratory Rulings." (1-1-15)T

286. -- 289. (RESERVED)

290. DESIGNATION AT A LESSER LEVEL.

01. Inability to Meet Criteria. The TSE Council may determine to redesignate a center at a lesser level due to the center's inability to meet current designation criteria, without regard to any waiver previously granted. (1-1-15)T

02. Notification and Appeal. When the TSE Council decides to redesignate a center, it will provide the center with a written notification of the action and the basis for the action. The notice will inform the center of the right to appeal and the procedure to appeal the action under the provisions in IDAPA 16.05.03, "Rules Governing Contested Case Proceedings and Declaratory Rulings." (1-1-15)T

291. -- 999. (RESERVED)