157.12 Proposed Rule
Texas ~~Accreditation Process~~Air Medical Licensure Rule Draft
~~October 2009~~February 2010

(a) The Air Medical Provider seeking licensure through the State of Texas who does not wish to obtain deemed status through Commission on Accreditation of ~~Air~~ Medical Transport Services (CAMTS) Accreditation must acquire ~~Accreditation, and therefore~~ licensure, through the ~~Texas Accreditation Process~~ Licensure Rule~~(TAP)~~.

(1) Submission of the appropriate application, self assessment and supporting documents must be submitted to DSHS prior to the establishment of a new Air Medical Program.

(A) Initial applicants *may* initiate a pre-survey process with a DSHS-approved surveyor. The surveyor and applicant will undertake an evaluation of the applicant's training, resources and plans concerning Air Medical Operations to assist the program in preparation for the initial ~~TAP~~Licensure.

(B) Initial applicants will be licensed with a provisional license upon successful completion of the initial ~~TAP~~Licensure.

(C) A provisional initial license holder must complete a ~~TAP re-accreditation~~ the Licensure survey not less than 12 months or more than 15 months after the initial provisional license issuance.

(D) A provisional initial license holder who successfully completes ~~a TAP reaccreditation~~ the Licensure survey will be awarded regular license status.

(2) Established Air Medical Programs (AMP's) who wish to seek licensure through the ~~Texas Accreditation Process~~Licensure Rule- must complete their survey process and obtain re-licensure within two years after the effective date of the ~~TAP~~ Licensure Rule to remain an Air Medical Provider.

(3) The complete self assessment package with supporting documents will be completed and submitted with the application for provider license to DSHS.

(A) The self assessment, documentation and application must be submitted in electronic format as acceptable by DSHS.

(i) Documentation must include:

(aa) Current FAA Part 135 Air Carrier Certificate.

(bb) Current individual aircraft FAA Airworthiness Certificate(s).

(cc) All other documentation as required to demonstrate evidence of program components.

(A) Associated fees must be included with application.

(B) All program records that support the ASP process must be on site during the site survey.

DRAFT

(C) Established Air Medical Providers must provide a minimum of 6 months documented compliance with the ASP requirements prior to the date of application.

(D) Application for initial provider license must show documentation of protocols, policies, procedures, training, Quality Improvement (QI) and evaluation of outcomes that comply with the ASP requirements.

(4) Notification of the intent to perform a site visit will be delivered to the AMP 90 days in advance.

(A) The site visit cannot be delayed by the AMP more than 90 days after intent to visit date established by DSHS.

(B) The site visit team will be composed of DSHS department representatives along with other AMP Personnel which could include but is not limited to:

(i) Physician Medical Director

(ii) AMP Administrator

(iii) AMP Educator

(iv) AMP Nurse or Paramedic

(v) AMP Pilot

(vi) AMP Mechanic

(vii) Federal Aviation Administration (FAA) Representative

(C) The AMP is responsible for reasonable expenses incurred by Non-DSHS Department Members conducting the review.

(5) The site visit team will establish and provide a schedule to the applicant.

(A) No personnel or program component may be excluded or exempt from participation in site survey.

(B) Scheduled activities may include but are not limited to:

(i) Meeting with the AMP Medical Director and Administrator.

(ii) Interviewing staff members.

(iii) Reviewing records.

(iv) Interviewing hospitals and other appropriate regional personnel.

(v) Site visits to bases, offices and communication centers.

(vi) Preparation of initial evaluation in the form of a short oral summery of what was found by the survey team to AMP by evaluators prior to completion of survey.

(vii) Programs will provide clarification of evaluation points to evaluators.

(C) A copy of the final written report will be mailed to DSHS and the Air Medical Program Director within 30 days of the completion of the site visit.

(i) Deficiencies may result in disciplinary action as authorized by §157.16 of this title (relating to Emergency Suspension, Suspension, Probation, Revocation or Denial or a Provider License). The department may grant a reasonable period of time for the provider to correct deficiencies as defined in §157.16 . If the department must reinspect the provider because of noncompliance noted during a

DRAFT

previous inspection, the provider shall pay a nonrefundable administrative fee, if applicable.

(ii) Failure to correct identified deficiencies within a period of time determined to be reasonable by the DSHS or if the deficiencies are found to be repeated, the provider shall be subject to disciplinary actions in accordance with §157.16 of this title.

(6) If a provider changes any part of the originally completed survey process it must be reported to DSHS in writing within (XX) days with an explanation.

(A) DSHS will evaluate the change and decide if a new site visit is warranted to assure compliance with the ASP.

(7) DSHS regional office may perform or order an unannounced site visit at any time.

(8) Program renewal applications must consist of an update to the original program self assessment that addresses and documents all changes and updates to the program.

(A) DSHS requires an on-site survey to renew a provider license.

(9) A program may contest, in writing, a site survey result to DSHS no later than 30 days after the receipt of the rejection of application for initial or renewal licensing.

(A) Appeals must include either supporting documentation to refute the deficiencies or provide an acceptable plan of corrective action to correct the deficiencies.

(B) Appeals will be reviewed by DSHS with decision delivered within (XX) calendar days after receipt of appeal.

(b) The AMP must demonstrate a hiring, education and credentialing process.

(1) The AMP should be able to provide a job description for each clinical and operational position.

(A) The AMP must document a process by which air medical personnel applicants are screened to insure that they meet the minimum qualifications for the position for which they apply.

(2) The AMP must administer an employment application process that includes an assessment of the candidate's knowledge, skills and experience.

(3) After selection for employment, the AMP should have a credentialing process that incorporates the following:

(A) A defined preceptor selection process.

(i) That involves the Medical Director in the selection of appropriate preceptors.

(ii) The Medical Directors approval of the development and training of preceptors.

(B) The Medical Directors established clinical competencies.

(C) The Program Director established program competencies.

(D) New employee proficiency criteria:

(i) The new employee must attend an initial didactic training session.

(ii) The new employee must demonstrate understanding of aircraft safety, protocols, procedure manuals, and proficiency in clinical procedures to the agency's standard.

DRAFT

(aa) In accommodating airframes, new employees will ride as 3rd person until the preceptor establishes that the new employee has met pre-established competencies as defined by the Medical Director and Program Director.

(aa) In airframes that cannot accommodate a "third" person, new employees will ride as a 2nd person until preceptor establishes that the new employee meets the prerequisites for independent duty as determined by the Medical Director and Program Director.

(E) New employees must demonstrate proficiency to second evaluator.

(4) New employee clinical evaluation must be completed using:

(A) A process that allows the new employee to evaluate the new employee program.

(B) A process to promote inter-rater reliability.

(5) A process for remediation and reeducation must be defined.

(6) A representative sample of call types (minimum number to be determined by the Medical Director) of critically ill adult patients, pediatric patients and trauma patients will be correctly cared for by the new employee prior to release from new employee.

(7) Must demonstrate loop closure from preceptor to new employee and from new employee back to preceptor in evaluation.

(8) The AMP must maintain documentation that employee certifications and/or licensures are verified.

(9) The AMP must maintain documentation of a system that requires each patient care provider to demonstrate skills appropriate for their level of training to the satisfaction of the Medical Director.

(10) The AMP must have an established process for reintegration of personnel.

(11) The AMP must have an established policy for administrative personnel to remain field credentialed.

(12) The AMP must at a minimum document initial demonstration of patient care skills, scene control skills, program competencies, ethics, compliance, and to include but not be limited to:

(A) Advanced airway management.

(B) Altitude physiology.

(C) Stressors of flight.

(D) Anatomy and physiology along with assessment of adult, pediatric and neonatal patients, as appropriate, within the programs scope of care.

(E) Aircraft and ambulance orientation including safety procedures (for all crew members including specialty team members).

(F) Emergency access and egress training.

(G) Orientation to all emergency procedures.

(H) Air Medical Service Crew Resource Management including human factors, stress recognition and management.

(I) Survival training.

DRAFT

(J) Cardiac emergencies and advanced cardiac critical care.
(K) Mission specific education for patient populations encountered (i.e. environmental emergencies, high risk OB, multi-system trauma, neonatal emergencies, thermal related injuries, etc.).
(L) Disaster and triage including Hazardous Materials (Haz-Mat) recognition and response.
(M) Radio communications.
(N) Hemodynamic monitoring, pacemakers (invasive and non invasive), automatic implantable cardiac defibrillators, intra-aortic balloon pump, central lines, pulmonary artery and arterial catheters, ventricular assist devices and extracorporeal membrane oxygenation (ECMO), as appropriate, within the programs scope of care.
(O) Infectious control.
(P) Mechanical ventilation and respiratory physiology for adult, pediatric and neonatal patients, including oxygen therapy in the transport environment.
(Q) Pediatric medical and trauma emergencies.
(R) Pharmacology.
(S) Quality Management education.
(T) Respiratory emergencies.
(U) Scene management.

(c) The AMP must implement and maintain Professional Development Programs that:
(A) Reinforce and expand the knowledge base of the individual provider.
(B) Have objectives based upon quality improvement outcomes.
(C) Are designed to incorporate best practices from industry, Protocol Development Review Committee (PDRC), and Quality Improvement Committee (QIC).

(2) The AMP will maintain minimum professional requirements.
(A) Hours as required by the professional certifying or licensing authority.
(B) Consisting of at least 50% in person training.
(C) Must offer a Professional Development Program on at least a semi-annual basis.
(D) The Medical Director shall be responsible for defining and approving the objectives of the professional development hours.

(3) The AMP will provide Professional Development Training Programs that annually include:
(A) Hazardous Materials.
(B) Human Factors and Crew Resource Management (including specialty team members).
(C) Infectious Control.
(D) State EMS rules and regulations regarding ground and air transport.
(E) Stress recognition and management.
(F) Survival Training (including specialty team members).

DRAFT

(G) Medical patient transport considerations (assessment/treatment/preparation handling/equipment)
(H) Day and night flight protocols
(I) General aircraft safety including (including specialty team members): Emergency shut down and aircraft evacuation procedures.
(J) Aviation terminology and communications procedures including emergency frequency uses.
(K) In flight and ground fire suppression procedures (fire extinguishers)
(L) In flight emergency landing procedures.
(M) Safety in and around the aircraft, including FAA rules and regulations pertinent to safety for medical team members, patient(s) and lay individuals.
(N) Specific capabilities and limitations for each aircraft used, which includes backup aircraft.
(O) Use of emergency locator transmitter (ELT)
(P) Scene landing operations.
(Q) Hospital landing site changes or special needs review.
(R) Patient loading and unloading (including specialty team members)
(S) Refueling policy for normal and emergency situations.

(4) The AMP shall provide outreach professional development:
(A) That clearly identifies the FAA Part 135 Certificate Holder as the entity that is operating the aircraft.
(B) The Air Medical Provider must provide education regarding safe Ground Operations in and around the aircraft.
(C) Safety program consisting of patient preparation criteria and personal safety around the aircraft.
(i) Including landing zone (LZ) designation for rotor wing services.
(ii) Information on how to initiate a flight.
(iii) Hours of operations.
(iv) Helicopter shopping dangers.
(v) Access to services/services available from the flight program including crew composition and specialty teams.

(d) An AMP must demonstrate protocol administration and oversight.
(1) The AMP must demonstrate that the protocol is annually reviewed and updated.
(2) The AMP protocol must be executed/approved by the Medical Director.
(3) The AMP must demonstrate a process for assessing relative benefit from protocol revisions.
(4) The protocol criteria will be jointly defined by the Medical Director and by the provider's PDRC.
(5) The AMP must demonstrate protocol compliance.

DRAFT

(A) The AMP must demonstrate the level of clinical care provider proficiency as defined by the Medical Director.

(B) The AMP must demonstrate a remediation process for clinical care providers and timeline that clearly identifies the criteria for successful completion and for revocation of credentials.

(e) The AMP must demonstrate operational standards:

(1) The AMP must demonstrate aircraft design and configuration that does not compromise patient stability in loading, unloading or in-flight operations.

(A) The aircraft must have an entry that allows loading and unloading without excessive maneuvering (no more than 45 degrees about the lateral axis and 30 degrees about the longitudinal axis) of the patient, and does not compromise functioning of monitoring systems, intravenous lines, and manual or mechanical ventilation.

(B) The AMP must demonstrate that aircraft have a minimum of one stretcher/sled.

(i) The stretcher/sled must be able to be carried to the patient.

(ii) The AMP must demonstrate aircraft stretchers and the means of securing it in-flight must be consistent with FAR's.

(iii) The AMP must demonstrate a policy that indicates the maximum gross weight allowed on the stretcher (inclusive of patient and equipment) as consistent with manufacturer's guidelines.

(iv) The stretcher must be large enough to carry the 95th percentile adult patient, full length in the supine position. (The 95th percentile adult American male is 6 ft. and 212 lbs.)

(v) The stretcher should be sturdy and rigid enough that it can support cardiopulmonary resuscitation. If a backboard or equivalent device is required to achieve this, such device will be readily available.

(vi) The head of the stretcher must be capable of being elevated at least 30 degrees for patient care and comfort.

(vii) If the stretcher is floor supported by its own wheels, there must be a mechanism to secure it in position under all conditions. These restraints permit quick attachment and detachment for patient transfer.

(C) The AMP must demonstrate operational standards that require securing the patient to the stretcher/sled.

(i) Patients transported by air are restrained with a minimum of three cross straps and shoulder straps that must comply with FAA regulations including applicable STCs. (cross straps are expected to restrain the patient at the chest, hips and knees). Belt locations should be adjustable along the length of the stretcher to accommodate patients' specific medical situations (Such as pregnant patients or specific injury locations)

(ii) Patients less than 60 pounds (27kg.) ~~should be provided~~ must be secured with an appropriately sized ~~FAA approved~~ restraining device (for patient's height and weight), which ~~is further~~ must be secured by a FAA approved locking device that allows good access to the patient from all sides and permits the patients head to be raised at least 30 degrees.

~~(ii)~~(iii) Patients less than 40 pounds (18kg) must be secured in a five-point safety strap device that allows good access to the patient from all sides and permits the patients head to be raised at least 30 degrees..

DRAFT

(2) The AMP must demonstrate operational standards that address the use of an Isolette when it is part of the AMP's mission profile.
  (A) There must be a restraining device within the isolette to protect the infant in the event of air turbulence or poor road conditions.
  (B) Isolettes must be capable of being opened from its secured position in order to provide full access to the infant in the event of complicated airway problems or extrication from the isolette becomes necessary.
(3) The AMP must demonstrate an aircraft policy to address the need for supplemental lighting system installed in any aircraft in which standard lighting is insufficient for patient care.
  (A) A self-contained lighting system may be powered by a battery pack or a portable light with a battery source must be available.
  (B) In an aircraft, there must be a means to protect the pilot's night adaptation vision provided for night operations, either through the medical configuration or by a dividing curtain. (Use of adaptive lighting or low intensity lighting in the patient care area is acceptable if not able to isolate the patient care area.)
(4) The AMP must document that medical equipment complies with the applicable F.A.R. on avionics interference.
(5) The AMP Aircraft must have operational controls and communications equipment that are physically protected from any intended or accidental interference by the patient, medical transport personnel, or equipment and supplies.
(6) The AMP must demonstrate policies that address storage, maintenance, use and accessibility of inhaled gases appropriate to the AMP mission profile.
(7) The AMP must demonstrate policies that address medication:
  (A) Storage within the manufacturers recommendations
  (B) Security that complies with federal and state narcotic laws
(8) The AMP must demonstrate policies that require environmental temperature control and address the effects of hyperthermia and hypothermia extremes on patients and crew.
(9) The AMP must demonstrate that it is providing equipment to support patient care such as:
  (A) Cardiac monitor, defibrillator and external pacemaker that are secured and positioned so that displays are visible.
  (B) Ventilator capable of supporting the AMP's mission.
  (C) 3 Chamber intravenous administration device.
    (i) May not substitute mechanical metering devices for infusion pump.
  (D) Vital sign monitoring capable of non-invasive blood pressure, heart rate, external temperature, pulse oxymetry, exhaled carbon-dioxide, endotracheal end tidal CO2.
  (E) Additional devices as determined by the AMD.
  (F) Electric power outlet must be provided with an inverter or appropriate power source of sufficient output to meet the requirements of the complete specialized equipment package without compromising the operation of any electrical aircraft/ambulance equipment. (An extra battery may be the back-up power source for equipment.)
  (G) AMP must document a program of biomedical support for the devices as required by the device manufacturers.
(10) The AMP must demonstrate written operational policies to address personnel staffing:

DRAFT

(A) That demonstrates strategies to minimize duty-time fatigue, length of shift, number of shifts per week and day-to-night rotation

(B) That documents scheduled clinical personnel shift times that do not exceed 24 hours.

(i) Exceeding twenty-four hours in exigent circumstances is permitted on infrequent basis, and must be documented and evaluated by the SMSC.

(ii) During exigent shifts beyond twenty-four hours, the AMP must evaluate fitness for duty of personnel on an ongoing basis during the additional hours.

(aa) Exigent shifts beyond twenty-four hours will not be permitted to exceed thirty-six hours in total duty time.

(iii) That documents clinical personnel twenty-four-hour shifts that:

(aa) Do not include any duties beyond those associated with the transport service.

(bb) Clinical personnel are provided with access to and permission to uninterrupted rest after daily medical personnel duties are met.

(cc) The physical base of operations includes an appropriate place for uninterrupted rest.

(iv) That documents communications personnel twelve hour shifts that:

(aa) Do not include any duties beyond those associated with the transport service.

(bb) A secure environment that is free of non communications essential distractions.

(v) The AMP must demonstrate policies that require all personnel must have at least eight hours of rest with no work-related interruptions prior to any scheduled shift of twelve hours or more. Aviation and aircraft maintenance personnel must adhere to the applicable F.A.R.s.

(vi) The AMP must demonstrate policies that all personnel have the right to call "time out" and be granted a reasonable rest period if the team member (or fellow team member) determines that he or she is unfit or unsafe to continue duty, no matter what the shift length. There should be no adverse personnel action or undue pressure to continue in this circumstance.

(vii) The AMP must demonstrate policies that require management to monitor transport volumes and personnel's use of "time out" policy.

(viii) AMP must have policies that address crew interface requiring team members to stay alert on all legs of the transport, requiring at least one team member on empty legs, to assist the pilot in staying alert.

(C) The AMP must demonstrate programs to promote personnel well being through:

DRAFT

(i) Wellness programs that promote healthy lifestyles (e.g. balanced diet, weight control, no smoking).

(ii) Evidence of an injury prevention program and ergonomic strategies to reduce employee injuries.

(f) The AMP must demonstrate Program Administrative oversight.

(1) The AMP must provide an organizational chart that outlines a well defined line of authority.

(2) This reporting structure should support following chain of command when addressing or handling issues or concerns within the complexity of the air medical program.

(A) There should be a clear and direct method in place for reporting information within the organization with rapid communication throughout.

(B) There should be a mechanism in place for loop closure.

(3) The AMP must ensure that a policy manual is available and familiar to all personnel.

(A) Policies are dated and signed by the appropriate manager(s).

(B) Policies are reviewed on an annual basis.

(4) The AMP must demonstrate that all disciplines understand their role in aviation operations and Operational Control.

(A) Hospital or non-hospital based program director/administrator must be oriented to ~~Flight~~ Federal Aviation Regulations (FAR's) that are pertinent to the medical service and state ambulance rules.

(5) The AMP should have a policy in place that documents the employer's disciplinary process.

(6) The AMP will document formal, periodic staff meetings for which minutes will be kept for four years.

(A) Minutes will document attendance, base identification and who is presiding and any discussion items.

(B) The AMP must demonstrate a process for disseminating information between meetings.

(7) The AMP management must demonstrate written guidelines for media issues and marketing activities.

(8) The AMP must demonstrate a policy that addresses transfers of patient care occur from a lower level of care to an equal or higher level of care, except for elective transfers.

(9) The AMP must demonstrate an appropriate utilization review process through trending and tracking requests.

(A) The AMP must provide evidence of feedback to the requesting agents and feedback from the patient receiving facilities.

(B) The AMP must demonstrate utilization review that may be prospective, concurrent, or retrospective.

(C) The AMP's collected data must be tabulated.

(D) The AMP must establish trigger criteria for utilization review.

DRAFT

(10) The AMP must establish and demonstrate a practice of ethical conduct.

(A) The AMP must provide evidence of use of a written code of ethical conduct.

(i) The AMP must demonstrate ethical practices in business operations.

(ii) The AMP must demonstrate ethical practices in marketing.

(iii) The AMP must demonstrate ethical practices in professional conduct.

(B) The AMP must demonstrate ethical practices in clinical operations.

(C) The AMP must demonstrate a written compliance plan that is in accordance with the HHS OIG's "Compliance Guidance for Ambulance Providers".

(D) The AMP Ethical/Compliance (EC) Plan must contain the following elements:

(i) Ethical and Compliance Management Plan (EMP)

(aa) The AMP must clearly states the policies, objectives and requirements of the EMP.

(bb) The AMP's plan must define each element of the EMP.

(cc) The plan must clearly identify the responsibilities and authority of key individuals for managing the EMP.

(ii) EC Promotion

(aa) The AMP must clearly demonstrate that EC is a core value through procedures, practices and training.

(iii) Document and Data Information Management

(aa) The AMP must clearly document and publicize the organization's EC policies, objectives and EMP.

(bb) The AMP demonstrates that the organization provides change control for all applicable documents and has a process to communicate changes in documents to all personnel.

(cc) The AMP must establish periodic review of all EC documents.

(iv) Occurrence Reporting

(aa) The AMP must demonstrate procedures for New employeeal reporting of EC concerns.

(v) Occurrence Investigation and Analysis

(aa) Every EC concern must be investigated by the AMP.

(bb) All investigations must be documented with an analysis by the AMP.

(vi) EC Oversight Programs.

(aa) The AMP must demonstrate oversight programs that evaluate the effectiveness of the EMP.

(bb) The AMP's oversight programs must include New employeeal and external assessments.

DRAFT

(cc) The AMP must demonstrate that all oversight programs are integrated.

(vii) EC Training Requirements

(aa) The AMP must document that all personnel are given introductory and recurrent EC training.

(bb) The training requirements for the AMP must include:

1. An EC orientation for all new personnel, stressing the AMP's commitment to ethics and compliance including everyone's role in the EMP.
2. A tracking mechanism for training requirements.
3. Access to conferences, workshops, literature and trade journals.

(viii) Management of Change

(aa) The AMP must have a process to ensure that all personnel are made aware of and understand any changes in requirements and policies.

(ix) Key Objectives and Continuous Improvement

(aa) The AMP must identify key EC objectives.

(bb) The AMP must demonstrate EC key objectives which are tailored to the size, nature and complexity of the organization.

(cc) The AMP must demonstrate proactive and reactive monitoring of key EC objectives.

(dd) The AMP must demonstrate response to detected offenses and development of corrective action plans.

(g) The AMP will have a center to receive and coordinate all requests for the medical transport service.

(1) The center will be staffed by Communication Specialists.

(A) Communication Specialists will be utilized to maintain contact with the medical personnel for response ready status and/or patient coordination and communication of patient status change.

(2) The Communication Center shall be equipped with communication capabilities appropriate to the mission profile.

(A) The AMP should have a backup emergency power source for communications equipment, or a policy delineating methods for maintaining communications during power outages and in disaster situations.

(3) The AMP must retain paperwork/database information regarding transport requests for a period of four years.

(A) The AMP must have a method of audio recording or documenting call taking and radio traffic.

(4) The AMP will demonstrate written policies concerning communications.

DRAFT

(A) The Communications Specialist must document all aspects of the transport.

(B) The AMP shall have a written policy requiring that all transport requests are screened for turn downs by other agencies.

(i) Information obtained from flight screening shall be communicated internally and externally.

(C) The AMP shall have written policies outlining Visual Flight Rule (VFR) flight following requirements.

(D) The AMP must demonstrate policies that address post flight debriefings and shift briefings with Communication Specialist.

(E) The AMP must maintain written records collecting data as required by Federal, State and Local requirements.

(5) The AMP will provide initial training and annual competencies for Communication Specialists.

(A) Initial and recurrent training shall include:

(i) Navigation techniques and map reading skills.

(ii) Radio operations.

(iii) Telephonic equipment training.

(iv) Hazardous materials protocols and procedures.

(v) Weather interpretation training.

(vi) Stress recognition and management.

(vii) Customer service/public relations/phone etiquette.

(viii) Computer literacy and skills.

(ix) Current Post Accident/Incident Plan (PAIP).

(6) The AMP shall demonstrate participation in weather turndown notification systems and other reporting mechanisms appropriate to your region.

(7) The AMP shall have written policies regarding communication center operations during IFR flights.

(8) The AMP should have a backup system in place for the computerized systems utilized for flight following and mapping.

(h) The AMP must demonstrate an appropriate and safe work environment for all personnel.

(1) The facility must have adequate lighting, ventilation, work and rest space commensurate to mission profile and scheduled duty hours.

(2) The facility will have allocated location for storage of equipment required for patient care and care of the aircraft.

(A) The crew quarters must be in a quiet, secure, environmentally safe area away from the public.

(B) The crew quarters must accommodate:

(i) Flight planning.

(ii) Crew briefings.

(iii) Access to a weather reporting system.

DRAFT

(iv) Computer and internet access.

(v) Proper rest quarters with chairs, beds, tables and desks as appropriate for the Air Medical assignment.

(3) The AMP must demonstrate a designated medical oxygen storage location with policies for safe handling and storage.

(A) The AMP must demonstrate training on available medical oxygen systems, safe storage and handling.

(4) The AMP must demonstrate a designated biohazard storage location with policies for safe handling and disposal.

(5) The AMP must demonstrate Material Safety Data Sheets (MSDS) is accessible at every base and operational facility as appropriate.

(A) The AMP must demonstrate training on MSDS awareness and use.

(6) The AMP must demonstrate a policy to address the control of foreign object debris (FOD).

(i) An Air Medical Provider must demonstrate Safety initiatives in the workplace.

(1) The AMP must provide evidence of a Safety Management System with the following elements:

(A) SMS Management Plan

(i) The organization clearly states the policies, objectives and requirements of the SMS.

(ii) The plan defines each element of the SMS.

(iii) The plan clearly identifies the responsibilities and authority of key individuals for managing the SMS.

(B) Safety Promotion

(i) The organization clearly demonstrates that safety is a core value through procedures, practices, training and allocation of resources.

(C) Document and Data Information Management

(i) The organization clearly documents and publicizes the organization's safety policies, objectives and SMS procedures.

(ii) Demonstrates that the organization provides change control for all applicable documents and has a process to communicate changes in documents to all personnel.

(iii) The organization establishes annual review of all SMS documents.

(D) Hazard Identification and Risk Management

(i) The organization demonstrates a process to identify hazards and to manage risks.

(ii) The organization demonstrates a process to prioritize risk management.

(iii) The organization demonstrates a method to track identified hazards.

(E) Occurrence and Hazard Reporting

(i) The organization demonstrates procedures for internal reporting of hazards.

(ii) The organization demonstrates a hazard reporting form available to all employees.

DRAFT

(iii) The organization demonstrates timely collection of occurrence and hazard information.

(F) Occurrence Investigation and Analysis

(i) Every hazard, incident or accident must be investigated by the organization.

(ii) All investigations shall be documented with an analysis by the organization.

(G) Safety Assurance Oversight Programs

(i) The organization demonstrates oversight programs that evaluate the effectiveness of the SMS.

(ii) The organization's oversight programs must include internal and external assessments.

(iii) The organization's oversight programs must proactively seek out potential hazards based on available data as well as evaluating the organization's safety program.

(iv) The organization must demonstrate that all oversight programs are integrated.

(H) Safety Management Training Requirements

(i) Organization must document that all personnel are given introductory and recurrent SMS training.

(ii) Training requirements for the organization must include:

(aa) A safety orientation for all new personnel, stressing the organization's commitment to safety and everyone's role in the SMS.

(bb) Document SMS competency requirements for personnel.

(cc) Track training requirements

(dd) Provide access to conferences, workshops, literature and trade journals.

(I) Management of Change

(i) The organization must have a process to ensure that all personnel are made aware of and understand any changes in requirements, procedures and applicable maintenance and operator manuals.

(J) Emergency Preparedness and Response

(i) Organization must have a written Emergency Response Plan (ERP).

(aa) Plan must outline what should be done when an emergency occurs.

(bb) Plan must outline what to do after an accident happens.

(cc) Plan must define roles that are responsible for each action.

(ii) The organization's ERP must be readily available to staff on duty.

(iii) Organization must demonstrate that the plan is updated when information changes.

(iv) Organization must document at least annual training, review and practiced.

(K) Performance Measurement and Continuous Improvement

DRAFT

(i) Organization must identify key safety goals.
(ii) Organization must demonstrate proactive and reactive monitoring of key safety goals.
(iii) Demonstrates performance measurements that are tailored to the size, nature and complexity of the organization.

(2) The AMP must demonstrate the implementation of Personal Protective Equipment (PPE) appropriate to the environment and provider mission profile.

(A) The AMP must demonstrate appropriate outerwear for Rotor-Wing Operations

(i) Boots or sturdy ankle supporting footwear
(ii) Flame retardant clothing
(iii) Clothing must have reflective material or reflective striping on uniforms for nighttime operations
(iv) Flight helmets with visor(s) and appropriate communications capabilities.
(v) Appropriate outerwear pertinent to survival in the environment
(vi) Personnel must wear only natural fibers (i.e. cotton) under flight uniforms.
(vii) Other clothing or personal protective equipment as required for mission profile (i.e. rescue, extrication, law enforcement assist)
(viii) AMP must document a program of ongoing maintenance and replacement as required by manufacturer's recommendation for all PPE.

(3) The AMP must demonstrate an Exposure Control Plan consistent with Federal OSHA Guidelines.

(4) The AMP must demonstrate policies regarding:

(A) Dress codes.
(B) PPE use including the use of eye protection.
(C) Crew rest for medical staff that addresses maximum duty time and assurance for adequate crew rest.
(D) Safety complaint and feedback system.
(E) Fitness for duty status:

(i) Duty status during illness (i.e. sinusitis, otitis media, etc.).
(ii) Medical conditions, including pregnancy, which may cause an employee to be unable to perform job function that requires clearance to return duty by personal physician.
(iii) Duty status while taking medications which may cause drowsiness.

(j) The AMP must have a Quality Improvement (QI) Program which demonstrates an ongoing system that includes retrospective review, concurrent review, and prospective forecasting of clinical care.

(1) The AMP QI Program must be overseen by the Medical Director.
(2) The AMP QI Program must demonstrate that it is designed to be a source of Clinical Practice improvement.
(3) The AMP QI Program must demonstrate that it is designed to be non punitive.

(A) The QI program must include a remediation process.

DRAFT

(B) The AMP QI Program must demonstrate inclusion of disciplinary action as a last resort or in extreme instances of violations of protocol or policy.

(4) The AMP should be able to demonstrate an appropriate method of chart review given their resources and abilities.

(5) The AMP must demonstrate the methods used to define the review process, including the sampling methodology, filters, and triggers.

(6) The AMP must demonstrate ongoing performance improvement through direct observation and retrospective review

(A) Retrospective audits should be accomplished through chart audits or patient care records reviews.

(B) Direct observation of performance.

(7) The AMP shall demonstrate a customer service process which addresses complaints, concerns, comments, and service inquiries.

(A) The AMP shall document investigation.

(B) The AMP must document written closure.

(k) An AMP must provide evidence of Oversight Committees with the following elements:

(1) The AMP shall demonstrate the ability of all personnel to report and direct information to its committees

(A) In a defined and easily accessible method.

(B) Anonymously if the respondent so desires.

(C) That provides a recording and tracking mechanism for the report.

(2) The AMP shall demonstrate that its oversight committees publish and disseminate their meeting minutes and provide information to all levels of the organization.

(3) The AMP committee's must:

(A) Have a charter that clearly states the policies, objectives and requirements of the committee.

(B) Have representatives from all disciplines with the AMP.

(C) Must review and oversee each element of its charter.

(4) An Air Medical Provider must provide evidence that it has Oversight Committees encompassing:

(A) Safety Management Systems Committee (SMSC)

(B) Quality Improvement Committee (QIC)

(C) Education Committee (EC)

(i) The EC includes external representatives as required to review education processes.

(D) Communications Committee (CC)

(i) The CC includes external representative customers for review of external relationships as required.

(E) Public Information & Outreach Committee (PIOC) [Optional]

DRAFT

(i) The PIOC incorporates external representatives for review as required.

(F) Product Review Committee (PRC) [Ad Hoc]

(G) Protocol Development and Review Committee (PDRC)

(i) The PDRC reviews and oversees each element of the Protocol based on QIC reports and best practices within the pre-hospital environment.

(H) Customer Service Committee (CSC)

(i) The CSC incorporates external representative stakeholders as indicated by program needs.

(5) An Air Medical Provider must demonstrate its active participation with all required external committees.

(l) The AMP shall designate or employ a medical director who shall meet the following qualifications:

(1) A physician who is currently licensed in the state of Texas, in good standing with the Texas Medical Board, in compliance with the Texas Board of Medical Examiners Rules, particularly regarding Emergency Medical Services as outlined in 22 TAC 197, and in compliance with Subtitle B of Title 3 of the Texas Occupations Code;

(2) Have knowledge and experience consistent with the transport of patients by air;

(3) Be knowledgeable in aeromedical physiology, stresses of flight, aircraft safety, patient care, and resource limitation of the aircraft, medical staff and equipment;

(4) Have access to consult with medical specialists for patient(s) whose illness and care needs are outside the medical director's area of practice; and

(5) The physician shall fulfill the following responsibilities:

(A) Ensure that there is a comprehensive plan/policy to address selection of appropriate aircraft, staffing and equipment;

(B) Be involved in the selection, hiring, training, and continuing education of all medical personnel;

(C) Be responsible for overseeing the development and maintenance of a QI program;

(D) Participate in any administrative decision making processes that affect patient care;

(E) Ensure that there is an adequate method for on-line medical control, and that there is a well defined plan or procedure and resources in place to allow off-line medical control.

(F) Oversee the review, revision and validation of written medical policies and protocols annually.

(G) Knowledgeable about laws and regulations affecting local, regional, and state EMS operations.

(H) Actively involved in administrative and legislative environments affecting regional and/or state pre-hospital organizations.

(m) The AMP will be assessed as a part of the licensure process in demonstrating program components and compliance with law.

DRAFT

(1) Failure to address any of the following program components shall be considered a Critical Failure and result in loss of or denial of license.

(A) Program for credentialing of providers

(B) Program for Professional development

(C) Protocols or Standards of Care

(D) Established Operational Standards

(E) Administrative Oversight

(F) Communications Center

(G) Base or Facility Standards

(H) Program for Safety Standards

(I) Program for Quality Improvement

(J) Established Committees

(K) Medical Direction

(2) Convictions of any of the following:

(A) Violations of law regulating healthcare provider fraud, abuse, kickbacks.

(B) Management/Operator convictions of violation of laws of moral turpitude.

DRAFT