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From:	European External Action Service (EEAS)
To:	European Union Military Committee (EUMC)
Subject:	Minimum Technical Requirements for Contracted In-Theatre Aeromedical Evacuation Services for EU Operations and Missions

Delegations will find attached document EEAS(2016) 933 REV 3.

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EUROPEAN EXTERNAL ACTION SERVICE



**EUROPEAN UNION
MILITARY STAFF**

Brussels, 22 September 2016

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REV 3**

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From: European Union Military Committee (EUMC)
To: European Union Military Committee (EUMC)

No. Prev. doc.: -

Subject: MINIMUM TECHNICAL REQUIREMENTS FOR CONTRACTED IN-
THEATRE AEROMEDICAL EVACUATION SERVICES FOR EU
OPERATIONS AND MISSIONS

Delegations will find attached the "MINIMUM TECHNICAL REQUIREMENTS FOR CONTRACTED IN-THEATRE AEROMEDICAL EVACUATION SERVICES FOR EU OPERATIONS AND MISSIONS " as agreed by EUMCWG on 16 September 2016.

MINIMUM TECHNICAL REQUIREMENTS
FOR
CONTRACTED IN-THEATRE AEROMEDICAL EVACUATION SERVICES FOR EU
OPERATIONS AND MISSIONS

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1. Introduction and Aim

- 1.1. The purpose of this document is to provide minimum Technical Requirements (TR) for contractor support to EU-led military Operations and Missions (Ops). It expands on the guidelines within EU concepts and provides guidance on requirements for contracting in-theatre Aeromedical Evacuation (AE) to Troup Contributing Nations (TCNs), Operation/Mission Headquarters (HQs) and civilian or state owned companies/organizations and service providers (Contractors) potentially offering services.
- 1.2. These standards will assist the Ops Commander or Head of Mission (Cdr) and their staff in ensuring AE support for their Ops where no participating Member State or Third State has offered this capability as part of the force generation process. This document can be used in whole or in part to prepare the necessary tendering documents for a contracted solution. It can also provide the reference standards for a structured solution such as a framework contract or other pre-mission arrangements. When applying these to a specific Ops, the relevant elements can be extracted respecting the requirements of a given Ops.
- 1.3. This document shall provide minimum standards of specifications, a guidance on responsibilities, capabilities, limits of outsourcing and versatility of contracted in-theatre AE.
- 1.4. These TRs will be applicable to all contracted services required to support AE in EU-led Ops.
- 1.5. The Contractor will provide and sustain the specific services as described within this schedule of requirements to an acceptable standard for provision to all forces as required by the Contracting Authority.

2. Reference Documents

- 2.1. Contracted support shall conform with, but is not limited to, guidance in the references' mentioned standards and directives (ANNEX VI). The latest version of the referenced documents shall be applicable including issues arising from updates. In case of conflict, EU medical standards take precedence.
- 2.2. The Contractor shall ensure all medical acts, tasks, liabilities or functions comply with the legal pre-requisites of the EU and that these are utilised as evidence-proven best practice.
- 2.3. For the duration of the contract period, the Contractor is to provide and maintain a publications library that details guidance and direction for delivery of related contract services.

3. Command and Control

- 3.1. Command and control authority is held by the Cdr.
- 3.2. The Contracting Authority will be determined in accordance with ATHENA regulations.
- 3.3. The Cdr will be supported by his staff, ATHENA and EUMS.

3.4. This support concerns the technical management of the contract, coordination with the customer and contractor, evaluation, facilitation and mediation of recommended changes in scope or deliverables and appropriate contractual modification as required.

3.5. In times of emergency response, the operational authority resides with the Cdr who may delegate authority to the Incident Commander on scene.

4. Guidelines, Constraints, Risks

- 4.1. All contracted support shall be in line with the EU Concept for Contractor Support to EU-led military operations.
- 4.2. The term Area of Operation (AOO) shall be used throughout this document to include all activities and areas required for Full Operational Capability (FOC) of the contracted services. The AOO for the contractor may be larger than the pure Ops AOO, regarding e.g. tactical AE to Role 3 in neighbouring countries. The Cdr shall provide the Contractor with a map depicting geographical area, base locations, base size, training sites, airfields and scope of response requirements.
- 4.3. The Contractor shall define standard day-to-day capabilities in number of events supportable, of operational assets, teams dispatched and ability, conditions, and terms for expanding services in response to catastrophic events.
- 4.4. Some of the many multinational force elements in the AOO may have some organic medical treatment capability for use in expeditionary missions. However, within the scope of this contract, the best possible co-operational support must be trained and co-ordinated.
- 4.5. Supply chain difficulties within the AOO and surrounding countries can occur and cause significant delays in the processing of goods to destination. These factors can be cultural, political, administrative, geographical and/or directly or indirectly related to the security situation. Problems with paperwork processing, customs clearance and physical transport due to poor roads and vehicles are common occurrences. Contractors operating within the theatre of operations must be aware of these issues and develop procedures to overcome and compensate these difficulties.
- 4.6. Seasonal variations such as flooding and snowfall may occur where the supply routes are located. Contractors must plan for this and take appropriate actions to prevent loss or damage of equipment and infrastructure to mitigate risk.
- 4.7. The Contractor is to be aware of the specific conditions in the AOO and be ready to respond to emergencies, including but not limited to: structural alarms, fires, in support of the Fire Rescue Services, that may threaten life or property, automotive, aircraft or vehicle accidents, medical emergencies, rocket or base intrusion attacks, hostilities, insurgencies, hazardous material incidents and natural disasters.
- 4.8. Even in the case of a Force Majeure the Contractor cannot stop but must plan for contingency of delivery of mission critical services as long as entitled personnel is in the AOO. During the time of a Force Majeure the Contractor is entitled for additional payment, to be defined in the contract.
- 4.9. The Contractor has to ensure medical support to its employees either through the Contracting Authority itself or by arrangements with third parties. Military medical support to non-entitled personnel in theatre is restricted to emergencies for life, limb, or eyesight and only after approval by the Cdr considering free capacities and operational restrictions.

5. Description of the Services Required

- 5.1. The Contractor has to provide an emergency physician/anaesthesiologist-led AE service throughout the AOO to all entitled personnel, supporting all activities 24 hours per day, 7 days per week for the duration of the contract. The Contractor will make every effort to accommodate the Cdr's requirements for patient evacuation. In extreme medical emergency situations, the Contractor will make every effort to evacuate the patient(s) even where adverse weather or night conditions prevail, subject always to the aircraft commander's discretion. The pilot's decision shall be final in all cases involving the safety of persons and aircraft, this provision does not extend to military security decisions and assessments, as this remains the responsibility of the military Cdr. During a medical evacuation the continuum of care must be ensured at all time.
- 5.1.1. The Contractor must respond to all medical emergencies according to the GOLDEN HOUR or at least the 10-1-2 timelines (Ref. 1), lower standards specified by the Cdr are on his responsibility. Standards are maximum 30 minutes NTM to take off for the primary and 60 minutes for the backup AE aircraft, steady or temporary higher standards must be specified by the Cdr. If unachievable, the Contractor will provide mitigation measures for approval by the Cdr.
- 5.1.2. Under the condition that the Contractor is only responsible for tactical MEDEVAC after Damage Control Surgery, the NTM can be prolonged and will be stated in the contract.
- 5.1.3. The Cdr remains responsible for decisions relating to patients emergency evacuation, noting the contractor may provide advice.
- 5.1.4. The Contractor has access to a 2 months stock of essential consumables and pharmaceutical provisions to maintain effective medical treatment during evacuations.
- 5.1.5. The Contractor is to provide aviation assets to the standards detailed at the Annexes.
- 5.1.6. The contractor is to provide a liaison officer to the HQ as agreed with the Cdr.
- 5.2. The Contractor is to provide its medical services in support of all operations and activities within the AOO operating to HQ instruction. The Contractor will:
- 5.2.1. Receive and respond to emergency services calls.
- 5.2.2. Execute triage of casualties in the event of any incident forcing one's action.
- 5.2.3. Provide emergency medical care and trauma resuscitation according to current standards of advanced cardiac and trauma life support (ACLS/ATLS).
- 5.2.4. Provide AE/patient transport to the best dedicated Medical Treatment Facility (MTF) from any point of the AOO even unprepared but suitable landing sites.
- 5.2.5. Provide reports as directed by the Cdr and participate in HQ incident/accident debriefs.
- 5.2.6. Support the Cdr with expert knowledge in contingency planning as required.
- 5.2.7. Participate in training and practical exercises.
- 5.2.8. Contribute to the Emergency Response Plan and the MASCAL Plan.

5.3. The Contractor must maintain the skillsets described in ANNEX VI.

6. Schedules, Milestones and Operating Hours

6.1. The AE service will commence FOC of its services, 24/7, continuously throughout the contract latest within 3 months after contract approval. There will be no reduction in capability for the duration of the contract for any reason.

7. Contractor Human Resources Requirements and Qualifications

7.1. The Contractor shall be responsible for continuing development training, evaluation and license endorsement, in all control disciplines for all employees with no impact to services.

7.2. The Contractor will maintain an effective number of staff in the AOO at all times, able to provide all contracted capabilities and trained, qualified and/or certified to the following minimum standards:

7.2.1. All AE personnel qualifications and/or Curriculum Vitae/Résumés shall be available to the HQ to be reviewed and validated prior to personnel deployment to theatre. This includes the right to reject personnel if qualifications are not verifiable or are not in conformity with the EU standards or in case of security concerns.

7.2.2. As a minimum, physicians shall hold a medical degree recognised or acceptable in an EU MS, paramedics/nurses shall have pre-hospital trauma training and hold a State Registration acceptable within the EU.

7.2.3. All AE personnel shall hold a certification of specific AE-training.

7.2.4. Pilots, shall hold a certification, acceptable to an EU MS, for applicable communication and flying procedures and shall be competent to achieve any operating qualification specific to the Ops.

7.2.5. All personnel must be mentally and physically fit to be able to fulfil the demanding aspects of AE.

7.2.6. The Contractor shall be responsible for obtaining all needed security clearances and validating individual clearance status with HQ prior to personnel mobilization.

7.2.7. At least two members of the staff in the AOO shall hold a valid security clearance to permit participation in base briefings and contingency planning as required.

7.2.8. Excellent language skills in the preferred language of the Op, usually but not limited to spoken and written English as well as technical English, are essential for all key personnel.

8. Provision of Infrastructure, Equipment, Tools and Supplies

8.1. The Contractor shall not assume there are existing vehicle fleet, equipment, tools or supplies but must operate with the existing infrastructure in AOO which he might enhance. Nevertheless it is not excluded that Ops can support within its means for e.g. real life support (RLS).

- 8.2. The Contractor will have to coordinate with HQ a planning for missing infrastructure and facilities. These might be provided by Ops or the contractor and shall be constructed to an approved standard regarding safety, security and hygiene. A follow on planning after termination of the contract has to be implemented in the contract.
- 8.3. The Contractor shall be responsible for provide equipment, tools, supplies, spares, personal protective equipment (PPE) and consumables required to support contractual obligations for services and maintaining all infrastructure and equipment required to support this contract.
- 8.4. The Contractor shall ensure its AE support is equipped to meet requirements also based on AOO operations, size, population, facilities and nature of operations to meet standards for continuum of care and appropriate treatment of patients during evacuation.

9. Management and Maintenance of Infrastructure, Equipment, Tools and Supplies

- 9.1. The Contractor shall ensure that all infrastructure, equipment and supplies are maintained to standard levels of serviceability in order to ensure a safe and secure work and living environment and the performance of contracted emergency services.
 - 9.1.1. All equipment, vehicles and test tools provided by the Contractor will remain as Contractor Furnished Equipment. The Contractor will maintain asset tracking and shall provide to HQ, on a quarterly basis, a management/inventory report of all assets, supporting the contract, its condition and ownership.
 - 9.1.2. It is the Contractor's responsibility to maintain, upgrade and replace infrastructure and equipment, as required, in order to ensure overall serviceability of listed items and supplies to adequately support contracted service levels throughout the contract term and into any follow-on service requirement. This includes establishing a system for calibration of equipment (including medical equipment) and recording as required. As an exception the construction of infrastructure elements may become part of the contract.
 - 9.1.3. The maintenance of infrastructure and life conditions encompasses the prevention of vermin, poisonous or dangerous animals, vectors, germs (e.g. in the water) and also hygiene inspections on a regular base.
 - 9.1.4. Any potential for failure, that impacts the contract requirements must be properly and immediately addressed with the HQ to prevent service degradation.
 - 9.1.5. The Contractor shall maintain a robust supply system and effective accounting for and correct storage of all drugs and pharmaceuticals. This will include to record adherence to EU regulation of controlled drugs and effective maintenance of the cold chain for supply, respecting SOFA/SOMA or national / host nation's regulations.
- 9.2. The Contractor shall implement a tailored Preventive Maintenance Program (PMP) for all service equipment and infrastructure in support of the contract. The contractor shall initiate corrective maintenance and storing as required to meet or exceed the recommended standards by the Original Equipment Manufacturers (OEMs).
 - 9.2.1. Infrastructure maintenance shall conform to a known nationally or internationally recognized standard. The standard to be used shall be described within the Technical Proposal.

- 9.2.2. The PMP shall include the Contractor's Operating Procedures, Maintenance/Inspection Schedules and Checklists as well as Procedures for Warranty Management and any special maintenance procedures necessary to address the impact of the harsh environmental conditions in this region on equipment and facilities.
- 9.2.3. The Contractor shall maintain asset registers and records detailing any maintenance, testing, statutory inspections or obligations, monitoring, diagnostics and analysis to include unscheduled ones outside of the PMP schedule. These records shall be used to identify any recurring defects or adverse trends. The recording and maintaining of records, stock levels/inventories etc. are a key function and shall be managed accordingly.
- 9.3. The Contractor shall be responsible for managing care, custody and control of any inventory of supplies held using proven inventory management principles and processes. A lack of availability of parts and material will not relieve the Contractor from the requirement to complete the work as required by the customer.
- 9.4. The Contractor shall work with HQ to establish a list designating Mission Essential Equipment, Supplies and Infrastructure with critical levels. This list shall consider all equipment required to meet contract service requirements. When minimum levels drop below the established critical level, the Contractor shall take immediate corrective action and provide mitigation plans to HQ to prevent disruption in services.
- 9.5. HQ can declare non full capability of the Contractor's services if non-serviceability of any essential services of the contract occurs. Consequences will be stated in the contract.
- 9.6. The Contractor shall assign a Site Manager for all facilities, infrastructure, equipment and supplies supporting this contract.
- 9.7. The Contractor shall assign a Fire Warden for each facility occupied and/or used in support of this contract. Fire Wardens shall be trained to implement and enforce local command Fire Safety standards in accordance with command guidance.
- 9.8. The Contractor shall be responsible for the repair or replacement for any losses or damage caused by misuse, neglect, bad practice, wilful harm etc. by contractor personnel.
- 9.9. The Contractor is responsible for the admission of any utilized vehicle by the Contractor on the installation.
- 9.10. The Contractor shall be responsible for transporting all his equipment and supplies in order to fulfil his obligations as defined in this document and its annexes and appendices. This shall also include all required customs clearances and exemption certificates.

10. CIS Requirements

- 10.1. Desktop and mobile phones and radio systems have to be in place to guarantee communication between AE unit, flight officer, HQ 24/7.
- 10.2. Internal computer systems must be in place for data capture and provision of reports and datasheets regarding the security level of operational data and patient information confidentiality.

- 10.3. There has to be a systems to ensure secure and confidential exchange of civilian and military health and medical data and to provide all capabilities to take part in the Ops patient regulating/patient tracking process. The system must also be able to make electronic copies of all medical records available on request from specific medical staff of the customer nations.

11. Security and Safety Requirements

- 11.1. Personnel shall hold an Authorisation to Deploy and shall be properly authorized access prior to arrival.
- 11.2. The Contractor shall develop and implement a safety program to cover all safety aspects.
- 11.2.1. The Contractor shall include a Safety Management Plan describing safety program implementation. A complete review of local conditions, policies and procedures shall be performed by the Contractor during contract mobilisation.
- 11.2.2. All elements of safety shall be implemented upon start of mobilisation and continue until the last person leaves the AOO upon end of services.
- 11.2.3. The Contractor shall provide appropriate protective, safety, and warning equipment to all his personnel. He shall ensure that personal protective equipment such as, but not limited to head, hand, foot, eye and face, anti-infective suits and hearing protection is used where it is not possible to eliminate or control a hazard by other means.
- 11.2.4. The Contractor shall train personnel in the safest way to work under AOO conditions, to conduct work and in the use and maintenance of personal protective equipment.
- 11.3. The Contractor shall inform the HQ of any accidents/incidents occurring to contractor personnel on station. This includes non-work related events as well as work related events.
- 11.4. Regarding military security and safety issues the HQ is the ultimate authority.

12. Environmental Requirements

- 12.1. The Contractor shall ensure all waste (especially medical) generated is properly disposed of.
- 12.2. Aircraft and other vehicles shall use a catch basin etc. to prevent contamination of soil (Ref. 3).
- 12.3. Upon return to the owning authority at the end of the contract, all land and facilities shall be free from any requirement for environmental cleanup and as an absolute minimum, be in the same condition as upon arrival.
- 12.4. The Contractor shall develop a program for environmental management as defined within ISO 14001.

13. Data, Reports and Plans

- 13.1. The Contractor shall be ready to provide HQ with Daily Shift Roster, Vehicle Readiness Status, weekly, monthly and annual activity reports and statistics to depict performance, actions taken,

trouble areas, and any issues requiring command guidance. The required items and format of the reports will be alterable at the discretion of Cdr.

- 13.2. The Contractor must respect the code of conduct /medical confidentiality / no passing on of medical information to non medical personnel.
- 13.3. The Contractor has to guarantee the archiving of patient's records for a time period of 30 years in an appropriate way.
- 13.4. Project Management Plan:
 - 13.4.1. The Contractor shall develop and provide to HQ, a Project Management Plan describing key program aspects and the Contractor's proposed method for project development, timeframe/milestones, implementation, execution and sustainment. This plan shall address areas such as; staffing, supply, cost control, services execution, program sustainment, milestones etc..
 - 13.4.2. The Contractor shall develop and implement a Staffing and Manning Plan including an organisational structure as well as roles & responsibilities as part of the Project Management Plan which reflects at least the requirements of this document.
 - 13.4.3. The Contractor shall provide details on the intended level of sub-contracting, if any, and the procedures to ensure sub-contractors meet the performance requirements. The sub-contracting must be authorised by the Contracting Authority.
- 13.5. Medical Plan:
 - 13.5.1. The Contractor shall develop a Medical Plan that describes how the contractor will comply with the requirements established within this document for their own employees. The plan must be available for the HQ prior to mobilization. The Contractor's employees might be treated by the Contractor itself, MTFs of Ops or through agreements with third parties.
 - 13.5.2. As a minimum the Medical Plan shall address the following areas of pre-deployment and continuous medical/dental screening, Role 1 medical and dental care support, access to Role 2/3 medical capability, arrangements for MEDEVAC/STRATEVAC, repatriation of dead, support to MASCAL Response plans and arrangements for medical health recording and maintenance.
 - 13.5.3. The Contractor shall explain the extent of health screening including pre-deployment vaccination undertaken for employees and will offer evidence.
 - 13.5.4. The Contractor shall be ready to obtain medical insurance for itself and other persons employed or contracted by it under the contract including unlimited STRATAIRMEDEVAC to the respective home country. Ops shall be under no liability in respect of the medical expenses of the Contractor.
- 13.6. Incident reports:
 - 13.6.1. The Contractor shall submit incident reports as required by local command guidance each time an incident (or accident) occurs that has the potential to result in, injury or loss of life,

damage or loss of property and any other incident which may have cause to bring either EU or the Contractor into disrepute.

13.7. Operational Reports:

13.7.1. Reporting concerning operations in general will be done by HQ. The Contractor is obliged to provide data such as times of alert and take off, flight time to the scene, flight hours, landings, transported passengers, requesting unit on a daily, weekly and monthly base as specified by HQ's Air Operation Manager.

13.8. The reports referred to above must be submitted to the respective Project Managers identified in the Contract. The Project Manager is responsible for requesting clarifications, proposing amendments, and - subsequently - approving the reports.

14. Quality Assurance and Performance Measurement

14.1. HQ will provide a regular schedule of visits to the Contractor to maintain the required levels of confidence by monitoring and evaluating services.

14.2. The Contractor shall establish an internal Quality Management Program (QMP).

14.2.1. The Contractor shall clearly define QMP policies, procedures, mode of program execution and levels of responsibility for program management, supervision, and surveillance performance by duty position.

14.2.2. This program shall implement the requirements established in the internationally recognized series of ISO standards listed in this document and as augmented by specific guidance within any Annexes, e.g. Occupational Health and Safety as defined within OHSAS 18000 series of standards.

15. Mobilisation/Demobilisation

15.1. For FOC the commissioning of vehicles, facilities and equipment for readiness and validation of manning for the contract must be completed not later than 90 days after signing the contract. The Contractor shall include his planning factors in the mobilisation plan and provide projected minimum timelines for successful implementation of mobilisation stages.

15.2. The Contractor shall provide a description of RLS requirements and specifically list requirements for housing of personnel during and after transition phases.

15.3. The Contractor shall check if Ops can provide e.g. food, laundry, electricity, water and fuel for contractor personnel and vehicles deployed in support of this contract.

15.4. The Contractor must provide a Mobilisation Plan describing milestones, strategy and approach to deploying the required resources to perform the services specified and to provide the required RLS services to personnel for the duration of the contract:

- 15.4.1. A transition plan shall describe all risk to service mitigation and actions required to mitigate service disruption including primary and alternative shipping proposals to address both cost and timeliness.
- 15.4.2. Any preparatory inspections, surveys, etc. must be detailed.
- 15.4.3. Facility development and/or construction requirements, equipment, supply and facility inspection requirements and proposed timeline shall be described.
- 15.4.4. The Contractor shall provide weekly mobilisation reports to the HQ describing mobilisation status for all key areas mentioned in the Mobilisation Plan. The Contractor shall identify significant problems that may cause a slippage in key mobilisation milestone activities. The report shall include a summary of corrective action.
- 15.5. Demobilisation includes all actions required to achieve successful contract close down. Demobilisation may support transfer to the follow-on contractor (including incumbent winning follow-on contract), transfer of activities to Ops, end of service requirements, or withdrawal of forces and assets from AOO.
- 15.5.1. Demobilisation requirements include all activities required to dispose of equipment and infrastructure, repatriate employees and render the site suitable for return to local authorities. Therefore a Demobilisation Plan shall be sent and agreed with the HQ 3 months before contract closure, defining all inherent issues.
- 15.5.2. The Contractor must take all actions required to perform a smooth and orderly transition or completion of services. There shall be no interruption or degradation of services during transition periods. Handover/takeover activities shall start, at a minimum of 90 days prior to the end of the contract service period.

ANNEX I - REQUIREMENTS FOR PERSONNEL

1. General Requirements

- 1.1. All requirements mentioned below shall be considered as minimum.
- 1.2. The Contractor has to provide personnel to fulfil all tasks as described in para 5 main document.
- 1.3. The Contractor is responsible for the safe accommodation of flight crews, medical crews, mechanics, site manager and any other personnel. The location must also be suitable to fulfil required timelines.
- 1.4. The Contractor is responsible for transfer flights and/or shipping in and out of the AOO of the Contractor's personnel.
- 1.5. The Contractor must provide liability insurance in accordance with EU commission Regulation No 785/2004. The Insurance provider also has to certify that this liability will stay in place even if the Contractor will be asked to countersign a waiver of responsibility to exclude Ops from responsibility where the Contractor will be operating on Ops facilities and Contractor's use of airspace.
- 1.6. Aircraft will be engaged in day and night flight operations. For night flight operations both pilots of the helicopter crew have to be equipped with adequate Night Vision Goggles (NVG). For flight operations under Instrument Flight Rules (IFR)-weather conditions both pilots of the aircraft crew have to be IFR-rated and meet the respective currency requirements.
- 1.7. The AE aircraft will be permanently on standby and 'ready for take-off' within at least 30 minutes during daytime and within 45 minutes during night-time after receiving an alert call unless otherwise specified by HQ.
- 1.8. In case of temporary and sudden unavailability of any crew member, especially key personnel, due to unforeseen reasons (sickness or other), an equivalent replacement must be available on the site within 48 hours. Such unavailability has to be reported without delay to the HQ.

2. Specific Requirements

- 2.1. Key personnel – General
 - 2.1.1. The Contractor has to submit all relevant documents for key personnel such as CVs , certificates, licenses, diplomas, working records, logbooks in original with a certified translation at least in English or Ops specific language.
 - 2.1.2. All staff/personnel appointed for the Contract must hold all necessary licences/certificates which have to be valid during the period of their deployment.
 - 2.1.3. All staff/personnel, especially key personnel and pilots, appointed by the Contractor must have sufficient professional/working experience in international operations or with international organizations.
 - 2.1.4. All staff members must be physically and mentally fit for the AOO. This includes preparatory measures (necessary vaccinations) and medical check before deployment to the AOO;
 - 2.1.5. All medical staff shall be fluent in spoken and written English at least comparable to Common European Framework of Reference for Languages (CEFR) level B2. Preferably physicians shall be capable of level C1 and all medical staff of level B1 in case of an Ops

specific language. Knowledge of any other EU language would be an obvious benefit for operating within this multinational environment. Pilots have to meet the requirements of International Civil Aviation Organisation (ICAO).

- 2.1.6. All medical staff dedicated to AE shall hold a certification of specific AE-training, approved by an EU MS or recognizable as EU equivalent.
- 2.1.7. Pilots should hold certificates/licenses at least acceptable by EU MSs, ICAO or European Aviation Safety Agency (EASA) to perform all service tasks.
- 2.1.8. Working hours and shift schedules have to be in accordance with European law. For pilots current ICAO regulations apply.

2.2. Site Manager

- 2.2.1. At least 5 years of relevant working experience in a managing position of an aviation company or a commercial operator including AE operations;
- 2.2.2. At least 2 years of relevant working experience in international operations or with international organizations.

2.3. Chief Pilot/ Flight Operations Manager (helicopter)

- 2.3.1. At least 2500 Flight Hours as Pilot In Command (PIC) in helicopters;
- 2.3.2. Minimum Flight Hours in Make/Model of deployed aircraft 200 or 50 as PIC;
- 2.3.3. Minimum Flight Time as Night PIC of 100 hrs;
- 2.3.4. Minimum Flight Time in Night Vision Imaging System (NVIS) Operations of 50 hrs;
- 2.3.5. Minimum Flight Time under IFR of 75 hrs as PIC;
- 2.3.6. Holder of Air Transport Pilot License (ATPL) (H);
- 2.3.7. At least 5 years of working experience in the field of helicopter flight operations;
- 2.3.8. At least 3 years of working experience in a supervisor position.

2.4. Captain/Commander/Pilot (helicopter)

- 2.4.1. At least total logged Flight Time in helicopter of 2000 hrs;
- 2.4.2. At least total logged Flight Time as PIC of 1000 hrs;
- 2.4.3. Minimum Flight Hours in Make/Model of deployed aircraft 200 or 50 as PIC;
- 2.4.4. At least total logged Flight Time as Night PIC of 100 hrs;
- 2.4.5. At least total logged Flight Time in NVIS Operations of 50 hrs;
- 2.4.6. At least total logged Flight Time under IFR of 75 hrs as PIC; and
- 2.4.7. Holder of ATPL (H).

2.5. Co-Pilot (helicopter)

- 2.5.1. At least total logged Flight Time in helicopter of 1000 hrs;
- 2.5.2. At least total logged Flight Time as PIC of 250 hrs;
- 2.5.3. Minimum Flight Hours in Make/Model of deployed aircraft 100 or 20 as PIC;
- 2.5.4. At least total logged Flight Time in NVIS Operations of 20 hrs;
- 2.5.5. At least total logged Flight Time under IFR of 30 hrs as PIC; and

- 2.5.6. Holder of ATPL (H) or CPL (H) with IR.
- 2.6. Chief Pilot/ Flight Operations Manager (airplane)
 - 2.6.1. At least 5000 Flight Hours as PIC in airplanes;
 - 2.6.2. Minimum Flight Hours in Make/Model of deployed aircraft 200 or 50 as PIC;
 - 2.6.3. Minimum Flight Time as Night PIC of 200 hrs;
 - 2.6.4. Minimum Flight Time in NVIS Operations of 50 hrs;
 - 2.6.5. Minimum Flight Time under IFR of 150 hrs as PIC;
 - 2.6.6. Minimum Flight Time Multi Crew of 500 hrs as PIC;
 - 2.6.7. Holder of Air Transport Pilot License (ATPL) (A);
 - 2.6.8. At least 5 years of working experience in the field of airplane flight operations;
 - 2.6.9. At least 3 years of working experience in a supervisor position.
- 2.7. Captain/Commander/Pilot (airplane)
 - 2.7.1. At least total logged Flight Time in airplane of 3000 hrs;
 - 2.7.2. At least total logged Flight Time as PIC of 1000 hrs;
 - 2.7.3. Minimum Flight Hours in Make/Model of deployed aircraft 200 or 50 as PIC;
 - 2.7.4. At least total logged Flight Time as Night PIC of 100 hrs;
 - 2.7.5. At least total logged Flight Time in NVIS Operations of 50 hrs;
 - 2.7.6. At least total logged Flight Time under IFR of 75 hrs as PIC;
 - 2.7.7. Minimum Flight Time Multi Crew of 500 hrs as PIC and
 - 2.7.8. Holder of ATPL (A).
- 2.8. Co-Pilot (airplane)
 - 2.8.1. At least total logged Flight Time in airplane of 1500 hrs;
 - 2.8.2. At least total logged Flight Time as PIC of 250 hrs;
 - 2.8.3. Minimum Flight Hours in Make/Model of deployed aircraft 100 or 20 as PIC;
 - 2.8.4. At least total logged Flight Time in NVIS Operations of 20 hrs;
 - 2.8.5. At least total logged Flight Time under IFR of 75 hrs as PIC; and
 - 2.8.6. Holder of ATPL (A) or CPL (A) with IR.
- 2.9. Maintenance Manager
 - 2.9.1. At least 10 years of working experience in the field of aircraft maintenance;
 - 2.9.2. Holder of an Aircraft Maintenance License Category B1.3 in accordance with EU Commission Regulation no. 2042/2003 (Part-66) or an equivalent by a national aviation authority in accordance with ICAO standards and recommendation practices;
 - 2.9.3. A member of a Maintenance Organization in accordance with EU Commission Regulation no. 2042/2003 (Part-145) or an equivalent by a national aviation authority in accordance with ICAO standards and recommendation practices.
- 2.10. General requirements for medical personnel

2.10.1. All staff members appointed by the Contractor must be holders of the necessary licenses and medical clearances, from or accepted or at least with the possibility to be accepted by one EU Member State, which have to be presented to the HQ;

2.10.2. Medical personnel must be fit to perform as described in capability matrix ANNEX V.

2.11. AE Physician:

2.11.1. Anaesthetist or Emergency Medicine Physician specialized in transport medicine aspects of high dependency and Intensive Care.

2.11.2. University degree in Medicine in accordance with EU Commission directive 2005/36/EC or acceptable to an EU recognized equivalent;

2.11.3. Minimum 2 years of relevant professional experience after being certified as specialist;

2.11.4. General professional experience: at least 1 year of work in the context of international crisis management, humanitarian aid, natural disaster sites, post conflict areas, other emergency fields, or equivalent is an advantage;

2.11.5. Specific professional experience: at least 2 years as a specialist in the context of emergency medicine and its pre-hospital and transportation aspects (AE); “medical currency”, i.e. proven record of working in AE within the last twelve (12) months prior of a deployment to the Mission, demonstrating involvement in at least ten (10) relevant emergency cases per month, on average, during this period.

2.12. AE Nurse:

2.12.1. Nurse specialized in Anesthesia, Intensive Care or Emergency Medicine.

2.12.2. Registered Nurse in accordance with EU Commission directive 2005/36/EC or acceptable to an EU recognized equivalent;

2.12.3. Minimum 2 years of relevant professional experience after certification as registered nurse;

2.12.4. Knowledge and working experience in clinical nursing, including emergency medicine services, pre-hospital care and transportation medicine;

2.12.5. General professional experience: at least 1 one year as nurse in the context of international crisis management, humanitarian aid, natural disaster sites, post conflict areas, other emergency fields, or equivalent is an advantage; and

2.12.6. Specific professional experience: at least 2 years of nursing in the context of emergency medicine and its pre-hospital and transportation aspects (AE); “medical currency”, i.e. proven record of working in AE within the last twelve (12) months prior of a deployment to the Mission, demonstrating involvement in at least ten (10) relevant emergency cases per month, on average, during this period.

2.13. AE Paramedic:

2.13.1. State approved licence as paramedic by an EU MS or recognized as EU equivalent;

2.13.2. Minimum 3 years of professional training and 2 years of relevant professional experience after being certified as registered paramedic, advantageously including Helicopter Emergency Medical Services (HEMS) Crew Member training;

2.13.3. Knowledge and working experience in emergency medicine services, pre-hospital care and transportation medicine;

- 2.13.4. General professional experience: at least 1 year as paramedic in the context of international crisis management, humanitarian aid, natural disaster sites, post conflict areas, other emergency fields, or equivalent is an advantage; and
- 2.13.5. Specific professional experience: at least 2 years of serving in the context of emergency medicine and its pre-hospital and transportation aspects (AE); “medical currency”, i.e. proven record of working in AE within the last twelve (12) months prior of a deployment to the Mission, demonstrating involvement in at least ten (10) relevant emergency case per month, on average, during this period.
- 2.14. Two out of AE physicians, AE nurses or AE paramedics are considered as 1 AE team. Generally a physician should be in the AE team, but for more routine and non-life threatening AEs it is sufficient that any 2 out of the above mentioned medical staff categories are in the AE team. In the case of no AE physician in the AE team an AE physician has to be in direct communication with the AE team and the AE team must be able to perform all duties considering the skill set in ANNEX V. The Contractor has to show the ability to deploy at least 2 AE teams for the deployment period.
- 2.15. CVs and proof of respective qualifications for additional personnel other than the key personnel described within the document must not be submitted in the tender, but provided upon request by HQ. The Contractor shall select and hire additional experts as required according to the needs. The selection procedures used by the Contractor to select other experts shall be transparent and shall be based on pre-defined criteria, including professional qualifications, language skills and work experience. Cost for backstopping and support staff are considered to be included in the financial offer of the tenderer.

ANNEX II - REQUIREMENTS FOR HELICOPTERS

1. General Requirements

- 1.1. All requirements mentioned below shall be considered as minimum.
- 1.2. The Contractor has to provide vehicles to fulfil all tasks as described in para 5 main document.
- 1.3. The helicopters have to be operated in accordance with EU Commission Regulation no. 965/2012, JAR-OPS 3 or an equivalent by a national aviation authority in accordance with International Civil Air Organisation (ICAO) standards and recommendation practices.
- 1.4. The helicopters and all equipment have to be certified in accordance with EU Commission Regulation no. 216/2008 or an equivalent by a national aviation authority in accordance with ICAO standards and recommendation practices.
- 1.5. The Successful Tenderer has to submit evidence before signing the contract that he has obtained all required permissions of the respective Civilian Aviation Authority of his Home State to operate the helicopters including all required equipment without limitations or restrictions inside the AOO.
- 1.6. The Successful Tenderer has to submit evidence before signing the contract that he is permitted by the respective Civilian Aviation Authority of his Home State as well as the Host Nation (HN) to land and take off also outside certified airports and heliports in the AOO during day and night.
- 1.7. Maintenance for the helicopters shall be conducted in according with EU Commission Regulation no. 2042/2003 (Part-145) or an equivalent by a national aviation authority in accordance with ICAO standards and recommendation practices. Maintenance staff shall be certified in accordance with EU Commission Regulation no. 2042/2003 (Part-66) or an equivalent by a national aviation authority in accordance with ICAO standards and recommendation practices.
- 1.8. The Contractor is responsible for the provision of the equipment for the ground handling of the aircraft according to the applicable law in the AOO and international regulations.
- 1.9. The Contractor is responsible to ensure availability of necessary facilities such as hanger facility, office space and storage required to accommodate aircraft operations according to the applicable law in the AOO and international regulations.
- 1.10. The Contractor must ensure at all times security of the aircraft and provide a point of contact – a Site Manager must be designated. This person has to be reachable on a 24/7 base at least by telephone. For absences more than 24 hours the Contractor has to replace the Site Manager with a person approved by HQ.
- 1.11. The Contractor is responsible for transfer flights and/or shipping in and out of the AOO of the Contractor's helicopter, equipment, spare parts and supplies.
- 1.12. The Contractor must provide liability insurance in according with EU commission Regulation No 785/2004. The Insurance provider also has to certify that this liability will stay in place even if the Contractor will be asked to countersign a waiver of responsibility to exclude Ops from responsibility where the Contractor will be operating on Ops facilities and his use of airspace.
- 1.13. One AE Helicopter will be permanently on standby and 'ready for take-off' within at least 30 minutes during daytime and within 45 minutes during night-time after receiving an alert call unless otherwise specified by HQ. As soon as the first one is activated the second one has to go straight into the first ones standby status.

- 1.14. In case of breakdown/Aircraft On Ground (AOG) this has to be reported without delay to the HQ. It has to be ensured that at least one helicopter is permanently available and operational. In case of breakdown of one helicopter the Contractor is obliged to provide a spare helicopter with similar characteristics within an appropriate timeline to be determined by HQ.
- 1.15. The contractor shall be allowed a certain downtime per month per aircraft, depending on flight hours, for servicing and maintenance, but shall deconflict these with predicted Ops needs.

2. Specific Requirements

- 2.1. All helicopters shall meet the requirements in the relevant parts of following regulations:
 - 2.1.1. EU Commission Regulation no. 965/2012;
 - 2.1.2. EU Commission Regulation no. 2042/2003;
 - 2.1.3. EU Commission Regulation no. 216/2008;
 - 2.1.4. JAR-OPS 3; or
 - 2.1.5. Equivalent issued by a national aviation authority in accordance with ICAO standards and recommendation practices.
 - 2.1.6. The aircraft must have an endurance of 2 hours and speed of 200km/hours or more in configuration with ICU for at least one littered patient (always optional second seated or littered) transport with at least 3 cabin crew;
 - 2.1.7. In any case the aircraft must be able to continue the flight after failure of one engine.
 - 2.1.8. The aircraft should be marked with special markings for AE helicopter with symbols of the Geneva convention (e. g. Red Cross, Red Crescent) on both sides according to Ops regulations;
 - 2.1.9. For flight operations under Instrument Flight Rules (IFR)-weather conditions the helicopter has to be IFR-equipped and meet the respective requirements with GPS and a satellite tracking system;
 - 2.1.10. The helicopter must be equipped with Night Vision Goggles (NVG) for both pilots for Night Vision Imaging System (NVIS) operations without limitations or restrictions;
 - 2.1.11. The helicopter must have certified AE equipment as specified in ANNEX IV;
 - 2.1.12. The helicopter must have an intercom system for communication between the cockpit and at least one passenger in the cabin, communication between medical staff itself and the Patient Evacuation Coordination Cell (PECC) or equivalent must be ensured;
 - 2.1.13. The helicopter must have passenger safety/briefing cards and cabin safety signs in English;
 - 2.1.14. The helicopter has to be equipped with very high frequency/ultra high frequency (VHF/UHF) radios for Air Traffic Control (ATC) communication in accordance ICAO standards and VHF-FM equipment for tactical communication in accordance with the HQ.

1. General Requirements

- 1.1. All requirements mentioned below shall be considered as minimum.
- 1.2. The Contractor has to provide vehicles to fulfil all tasks as described in para 5 main document.
- 1.3. The airplanes have to be operated in accordance with EU Commission Regulation no. 965/2012, JAR-OPS 3 or an equivalent by a national aviation authority in accordance with International Civil Air Organisation (ICAO) standards and recommendation practices.
- 1.4. The airplanes and all equipment have to be certified in accordance with EU Commission Regulation no. 216/2008 or an equivalent by a national aviation authority in accordance with ICAO standards and recommendation practices.
- 1.5. The Successful Tenderer has to submit evidence before signing the contract that he has obtained all required permissions of the respective Civilian Aviation Authority of his Home State to operate the airplanes including all required equipment without limitations or restrictions inside the AOO.
- 1.6. The Successful Tenderer has to submit evidence before signing the contract that he is permitted by the respective Civilian Aviation Authority of his Home State as well as the Host Nation (HN) to land and take off from certified airports in the AOO during day and night.
- 1.7. Maintenance for the airplanes shall be conducted in according with EU Commission Regulation no. 2042/2003 (Part-145) or an equivalent by a national aviation authority in accordance with ICAO standards and recommendation practices. Maintenance staff shall be certified in accordance with EU Commission Regulation no. 2042/2003 (Part-66) or an equivalent by a national aviation authority in accordance with ICAO standards and recommendation practices.
- 1.8. The Contractor is responsible for the provision of the equipment for the ground handling of the aircraft according to the applicable law in the AOO and international regulations.
- 1.9. The Contractor is responsible to ensure availability of necessary facilities such as hanger facility, office space and storage required to accommodate aircraft operations according to the applicable law in the AOO and international regulations.
- 1.10. The Contractor must ensure at all times security of the aircraft and provide a point of contact – a Site Manager must be designated. This person has to be reachable on a 24/7 base at least by telephone. For absences more than 24 hours the Contractor has to replace the Site Manager with a person approved by HQ.
- 1.11. The Contractor is responsible for transfer flights and/or shipping in and out of the AOO of the Contractor's airplane, equipment, spare parts and supplies.
- 1.12. The Contractor must provide liability insurance in according with EU commission Regulation No 785/2004. The Insurance provider also has to certify that this liability will stay in place even if the Contractor will be asked to countersign a waiver of responsibility to exclude Ops from responsibility where the Contractor will be operating on Ops facilities and his use of airspace.
- 1.13. The AE airplane will be permanently on standby and 'ready for take-off' within at least 30 minutes during daytime and within 45 minutes during night-time after receiving an alert call unless otherwise specified by HQ.
- 1.14. In case of breakdown/Aircraft On Ground (AOG) this has to be reported without delay to the HQ. It has to be ensured that at least one airplane is permanently available and operational. In case of

breakdown of one airplane the Contractor is obliged to provide a spare airplane with similar characteristics within an appropriate timeline to be determined by HQ.

1.15. The contractor shall be allowed a certain downtime per month per aircraft, depending on flight hours, for servicing and maintenance, but shall deconflict these with predicted Ops needs.

2. Specific Requirements

2.1. All airplanes shall meet the requirements in the relevant parts of following regulations:

- 2.1.1. EU Commission Regulation no. 965/2012;
- 2.1.2. EU Commission Regulation no. 2042/2003;
- 2.1.3. EU Commission Regulation no. 216/2008;
- 2.1.4. JAR-OPS 3; or
- 2.1.5. Equivalent issued by a national aviation authority in accordance with ICAO standards and recommendation practices.
- 2.1.6. The airplane must be able to perform flight operations in configuration with ICU for at least one littered patient (always optional second seated or littered) transport with at least 3 cabin crew;
- 2.1.7. In the contract specific details related to the AOO must be mentioned like Take-Off distance and Load Classification Number (LCN) according to the available airports.
- 2.1.8. In any case the aircraft must be able to continue the flight after failure of one engine.
- 2.1.9. The airplane should be marked with special markings for AE airplanes with symbols of the Geneva convention (e. g. Red Cross, Red Crescent) on both sides according to Ops regulations;
- 2.1.10. The airplane must be IFR equipped with GPS and a satellite tracking system;
- 2.1.11. The airplane must have certified AE equipment as specified in ANNEX IV;
- 2.1.12. The airplane must have an intercom system for communication between the cockpit and at least one passenger in the cabin, communication between medical staff itself and the PECC or equivalent must be ensured;
- 2.1.13. The airplane must have passenger safety/briefing cards and cabin safety signs in English;
- 2.1.14. The airplane has to be equipped with very high frequency/ultra high frequency (VHF/UHF) radios for Air Traffic Control (ATC) communication in accordance ICAO standards and VHF-FM equipment for tactical communication in accordance with the HQ.

ANNEX IV – REQUIREMENTS FOR AIRCRAFT MEDICAL EQUIPMENT SETUP

1. General

- 1.1. Medical devices shall, when stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, cause no safety hazard which could be foreseen using risk analysis procedures in accordance with EN ISO 14971, which is connected with their intended application, in normal condition and in single fault condition.
- 1.2. Medical devices with alarms and signals shall provide a clear visual signal and buttons, switches, indicators, controls etc. shall be easily accessible and clearly readable under all conditions.
- 1.3. When markings and instructions for the use of medical devices are present they shall conform to EN 1041 and EN 980. Graphical symbols shall be derived from Harmonized Standards when available. Any other symbols used shall be clear in their intentions and there shall be a description of their meaning on the label or associated literature.
- 1.4. The medical devices shall function throughout the temperature range from 0 °C to 45 °C and shall function for at least 20 min when placed in an environment at -5 °C to 50 °C after storage at room temperature (20 ± 5) °C. Medical devices shall function as intended between 5 % to 95 % relative humidity within the temperature range of 0 °C to 45 °C.
- 1.5. The medical equipment shall function and present correctly at variable atmospheric pressures. The operating range shall be stated, and if readings or performance vary, a table of correcting values shall be attached. The table shall state, in accordance with the prevailing atmospheric conditions, the extent of discrepancy between the actual values and the values indicated by the device. It is desirable to have an altitude meter or GPS in cabin.
- 1.6. Interior lighting shall be provided in accordance with (except in the case of NVIS operations):

Type	Air ambulances
Patient area, minimum (lux)	200 ^a
Surrounding area, minimum (lux)	50
^{a)} Means shall be provided to switch the lighting level down to 10 lux.	

- 1.7. The aircraft shall have the technical option to install an isolator to transfer infectious patients.

2. Electrical power driven medical devices

- 2.1. Electrical power driven medical devices shall conform to EN 60601-1. Medical devices shall be IPX4 rated according to EN 60529. Life supporting devices shall be capable of operating with 12 V and/or 24 V DC power input.
- 2.2. Medical equipment, essential for the treatment or safety of the patient, shall function as intended during the entire transport. Essential medical equipment shall be provided with batteries and electrical connector(s) in order to prevent interruption of the power supply (EN 13718-2 clause 4.3).
- 2.3. The patient compartment shall have available a minimum of four 12/24 V DC outlets. Optionally one additional outlet may be supplied by a separate battery, dedicated to medical devices. The outlets shall be available for medical equipment and located in the area of storage and/or use of the medical device. The outlets for the medical devices shall be labeled with the nominal voltage and current rating. Outlets should have a visible indication under intended operational conditions in order to show if the power is switched on.

- 2.4. Main voltage (AC) should be provided by an inverter and available for use with medical device. The requirements on the AC and the inverter are to be found in EN 13718-1. The inverter is considered as an accessory to the medical device and shall therefore be CE-marked MDD 93/42 EEC.
- 2.5. Connectors shall be designed to prevent short-circuiting under the environmental conditions prevailing in the air ambulances. There shall be an externally mounted connector to enable charging of rechargeable batteries of all medical devices.
- 2.6. When the aircraft is connected to mains on the ground means should be provided to prevent earth leak currents. If internal power supply of the aircraft is used the device requires airworthiness assessment and certification.
- 2.7. The electromagnetic emission and susceptibility of medical devices shall conform to RTCA DO-160D section 20 and 21 or ISO 7137 clause 3.6 and 3.7.

3. Gas supply

- 3.1. The medical device shall conform to the requirements for gas installation in EN 13718-2. Pressure regulators and pressure regulators with flow metering devices shall conform to EN ISO 10524-1 or EN ISO 10524-3. The pressure regulators shall be directly connected to the source of supply. Flow metering devices for connection to terminal units shall conform to EN 13220.
- 3.2. The range of the nominal distribution pressure for medical gases shall be 400 kPa; the pressure measured at the terminal units (if fitted) shall be within $\pm 10\%$ of the nominal distribution pressure at a test flow of 40 l/min. For vacuum the nominal distribution pressure shall be 60 kPa absolute pressure; the pressure measured at the terminal units (if fitted) shall not rise to more than 60 kPa absolute pressure at a test flow of 25 l/min. It shall be possible to see the remaining amount of oxygen in the cylinder in the patient compartment
- 3.3. Cylinder valves shall conform to EN ISO 10297. If pin-index valves are used, their outlet connection shall conform to EN ISO 407. All sections of pipeline distribution systems for compressed medical gases shall withstand a pressure of 1,43 times the maximum pressure which can be applied to that section in single fault condition. The medical equipment shall function during single fault condition in the gas installation i.e. 10 Bar.
- 3.4. A filter having a pore size no greater than 100 μm shall be provided between the cylinder(s) and the first pressure regulator.

4. Installation/Fixation of medical equipment/devices in AE helicopter

- 4.1. All medical devices shall be either fitted to or stowed in the aircraft securely. The mounts for fixation of medical device shall conform to EASA part 21. If rail clamps are used they shall conform to EN ISO 19054 with additional fixation requirements according to EASA part 21. The devices shall be restrained within the aircraft and g-load requirements shall be in accordance with the particular class or certification of the aircraft. (e.g. EASA CS-27, EASA CS-29).
- 4.2. Manufacturers of the aircraft installation and/or of the medical devices intended for transport and use within air ambulances shall provide recommendations for the proper attachment of the medical device. The manufacturer of the medical device has to declare the maximum weight for the device.
- 4.3. A location in the aircraft shall be specified for the stowage and efficient use of medical devices. Essential medical devices for the management of vital functions, including airway management and ventilation shall be in reach of the medical personnel whilst seated. Medical devices required for use outside the aircraft shall be easily accessible.

5. Patient compartment

- 5.1. The patient compartment shall be designed to enable free access by the medical personnel to the patient(s)'s vital body parts, (e.g. including head, chest, abdomen and pelvis), in order to ensure adequate treatment, monitoring and care. Cardiopulmonary resuscitation must be possible during the flight. A possibility to elevate the patient's upper body and/or legs would be of advantage.
- 5.2. The medical device and its position in the patient compartment shall allow free access and interaction by medical personnel in a treatment, monitoring and care situation. The positioning of medical devices shall allow the operation of the device without obstructing aisles, emergency exits or patient loading and unloading sites.
- 5.3. There shall be a fixed lockable container available for the storage of controlled drugs. Means shall be provided for keeping temperature sensitive drugs cool (6 ± 2 °C) and to warm up infusion bags (38 ± 2 °C).
- 5.4. It is desirable to have windows in the patient compartment being positioned or screened to ensure the privacy of patients when required. Secure fixation of the patient on the litter and secure fixation of the litter to the aircraft is mandatory. For patient and crew comfort means for regulation of cabin temperature to 18 - 28 °C should be in place at all times.
- 5.5. The interior of the patient compartment shall be designed to minimize the risk of injury. Drawers shall be secured to prevent self-opening. The ceiling, the interior walls and the doors of the patient compartment shall be fully lined with hygienic surfaces. The edges of surfaces shall be designed and/or sealed in such a way that no fluid can infiltrate.
- 5.6. The floor shall be sealed to the structure of the aircraft and designed to allow fluids to drain. Floor coverings, also when wet, shall provide adequate grip for the attendant and shall be durable and easy to clean and disinfect.
- 5.7. The patient compartment shall have at least two seats for the medical personnel allowing direct access to the stretcher patient. If more than one stretcher patient is being carried, it shall be possible to provide at least basic treatment to all patients transported.
- 5.8. The minimum dimensions of patient treatment area shall be: Height: 1150 mm; Length: 2400 mm; Width: 1200 mm
- 5.9. The safe loading and unloading of patients shall be possible under all operational conditions, even by running rotors. The doors to the patient compartment must be big enough to ensure easy loading of littered patients on stretchers. There shall be a sufficient space from the top of the stretcher mattress to the top of the door opening where the patient is loaded to avoid implications to the patient.

6. Information to be supplied by the manufacturer

- 6.1. User manuals in English must be provided for all equipment, electronically and/or in printing. User instructions shall include information of products intended use and the environmental conditions.
- 6.2. Instructions for use shall contain all information necessary to use the product in accordance with its specification and shall include an explanation of the function of controls, the sequence of operation and connection and disconnection of detachable parts and accessories.
- 6.3. Instructions for use shall give detailed instructions for the safe performance of cleaning, inspection and preventative maintenance to be performed by the operator or by authorized persons, and shall indicate the recommended frequency or interval of such activities.

6.4. A list of recommended spare parts shall be provided.

7. Testing

7.1. Medical devices shall be tested according to ISO 7137:1995. The tests have to be carried out at 23 ± 2 °C. The manufacturer of fixed installations and fixed medical devices shall conform to the strength test procedures of EASA part 21 for the particular aircraft. With regards to vibration, bump and free fall medical devices shall conform ISO 7137 clause 2.2 and IEC 60068-2-32, Procedure 1.

8. Medical devices, products and equipment in AE aircraft

8.1. Tables A.1 to A.10 list the recommended minimum number of medical devices, products and equipment to be available inside the ambulance for the appropriately medical personnel in order to provide treatment, monitoring and intensive care of one patient in one aircraft for the continuum of care during transfer. The devices shall be usable for all sizes and ages of patients.

A.1 Patient transfer devices

Generic device group	Examples of European Standards	No	Proposals for type
Main stretcher	EN 1865	1	
Undercarriage	EN 1865	1	
Vacuum mattress	EN 1865	1	Not too fluffy for fitting on the stretcher. Straps must be attached permanently to the mattress. Flame resistant
Carrying sheet or Transfer mattress	EN 1865	1	
Long spinal board with head immobilizer and securing straps.	EN 1865	1	Backboard with pins and with the Speed-Clip Restraints system. Flame resistant
Break-away stretcher	EN 1865	1	With pins and with the Speed-Clip Restraints system, e.g. Ferno Scoop EXL Stretcher

A.2 Isolated extremity and upper spinal immobilization devices

Generic device group	Examples of European Standards	No	Proposals for type
Traction device		1	e.g. Kendrick Traction Device (KTD)
Immobilisation set for fractures		1	e.g. Hartwell Medical Evac U-Splint
Cervical upper spinal immobilization devices/Cervical collar-set		1	
Extraction upper spinal immobilization device or Extension devices/Short spinal board		1	e.g. Kendrick Extraction Device (KED)

A.3 Ventilation and respiration devices

Generic device group	Examples of European Standards	No	Proposals for type
Stationary oxygen, with a quick-connection Appropriate amounts for refill must always be available on ground	EN 737-series EN ISO 15002 EN 739 EN 737-1 EN ISO 10524-1	1	Oxygen system with 2 flow controlled patient- outlet (2-15 L/min) and quick-connection to the portable ventilator Min. 2000 L in Hcp.
Portable oxygen, min. 400 l, with a quick-connection and a carrying system	EN 737-1 EN ISO 10524-1	1	2 oxygen cylinder/each set with flow controlled patient outlet (2-15 L/min)
Nebulisation device		1	Oxygen driven
Transport ventilator for controlled and assisted ventilation with adjustable PEEP-valve ^a / CPAP- function ^b .	EN 794-3	1	
Stationary suction device ^c	EN ISO 10079-1 EN ISO 10079-3	1	e.g. Laerdall LSU suction
Portable suction device	EN ISO 10079-2	1	
Intubation devices set including laryngoscope handle (-s) with suitable blades	EN 1819 EN 1281-2 EN ISO 5356-1 EN 12342	1	Can be included in Major Trauma Kit (in Emergency Bag)
Endotracheal tubes set with connectors	EN 1282-1 EN 1782	1	
Oropharyngeal airways set	EN 12181	1	
Intubation cuff manometer		1	
Nasopharyngeal tubes		1	
HME-filter ^d		1	
Tube fixing materials		1	
Tracheostomy kit ^e		1	See A 6
Pleurocentesis kit		1	See A 6
<p>a) Positive End Expiratory Pressure. b) Continuous Positive Airway Pressure. c) Stationary non-manual suction device with a minimum negative pressure of 40 kPa, with a collection container with a minimum capacity of 1 l, can be portable. d) Heat and Moisture Exchange e) Insertion stylets, inflation tube clamp, inflation syringe, Magill forceps etc.</p>			

A.4 Medical devices for diagnosis and monitoring

Generic device group	Examples of European Standards	No	Proposals for type
Monitor/Defibrillator with non-invasive pacing providing us with all vital parameters (minimum): SPO2, ETCO2, RR,		1	e.g. Philips Heart Start MRx or Physio-Control LIFEPAK 15 or Propac

HR, NIBP, IBP, ECG12, and Temperature. etc			
Invasive BP monitor	EN 60601-2-30	1	See monitor above
Non-invasive BP Monitor	EN 1060-1 EN 1060-2	1	See monitor above
Pulse oximeter	EN ISO 21647	1	See monitor above
Capnometer	EN 864	1	See monitor above
Stethoscope		1	
Ear thermometer (15-42 °C)		1	
Diagnostic light		1	
Glucometer		1	
Power pack, spare batteries for medical equipment	1		

A.5 Devices for injection and infusion

Generic device group	Examples of European Standards	No	Proposals for type
Devices for injections and infusions	EN 1707 EN 20594-1 EN ISO 7886-1,-2 EN ISO 7864 EN ISO 10555-1,-3,-5 EN ISO 6009 EN ISO 8537 EN 11070	1	Isolation cover for infusion bag and line.
Infusion container temperature regulator 38 ± 2 °C		1	Not required to be portable.
Volumetric infusion device	EN 60601-2-24	2	Syringe driver
Automatic infusion device with volumetric properties		1	For secondary transport
Pressure infusion device		1	

A.6 Devices for managing life-threatening problems

Generic device group	Examples of European Standards	No	Proposals for type
Defibrillator with rhythm display, recording, and documentation of patient data	HD ^a 395.2.4 = EN 60601-2-4	1	See monitor above A 4
External pacing facility		1	See monitor above A 4
Portable Advanced Resuscitation System (PARS): Manual resuscitators Airways, Aspirator, and Suction catheters		1	
Haemostatic control		1	e.g. Combat Application Tourniquet (CAT)
Medical Anti-Shock Trousers (MAST)		1	
Tracheostomy kit		1	

Pleurocentesis kit		1	
Surgical cut-down kit		1	For vascular access and hemostasis
Injector for intraosseous infusion		1	e.g. Vitaid Ltd. EZ-IO G3 + accessories
Arterial lines		1	e.g. Luerlock
Central venous catheters		1	e.g. Luerlock

A.7 Bandaging and nursing devices

Generic device group	Examples of European Standards	No	Proposals for type
Wound treatment materials/haemostatic dressing		1	e.g. CAT, ChitoFlex [®]
Treatment materials for wounds caused by burns and corrosives		1	
Fracture stabilising/immobilisation		1	e.g. SAM-Sling
Spinal stabilising/immobilisation			e.g. Kendrick's extraction device
Adhesive fixing materials		1	
Kidney bowl set		1	
Gastric tube with accessories	EN 1618	1	
Sterile surgical glove, set of pairs.	EN 455 -1, -2 and -3	2	
Small surgical kit ^a		1	
Skin cleaning and disinfection material set	Standards from CEN/TC 216 <i>Chemical disinfectants and antiseptics</i>	2	

^a E.g. scalpels, suture holder, stitch cutter, forceps, scissors, clamps etc.

A.8 Medicinal products (drugs)

Groups according to the ATCC system ^a	No	Proposals for type
General anaesthetics	2	
Local analgesics (N 01 B) and general analgesics (N 02)	2	
Infusion solutions (B 05 B B)	2	Intravenous solutions in soft pouches
Resuscitation/Emergency drugs/equipment (ATLS)	2	

^a Anatomical Therapeutic Chemical Classification System for pharmaceuticals

A.9 Rescue and protection equipment etc.

Type	No	Proposals for type
Light rescue tools, set ^a	1	e.g. Paratech [®] Highway Hooligan tool 36" or 42" + Saw, hammer and multi-tool handset
Seat belt cutter (number per crew member)	1	Pre-hospital pocket-tool including belt cutter, window

		punch and a knife
Warning lights	2	
Fire extinguisher	2	
Spotlight (number per crew member)	1	Headlight
Basic protective clothing including safety/flight helmets (with communication headset) and safety gloves	1	
Vomiting bag set	2	
Sharps container	2	
Blankets and pillows	2	
Waste box/bag	1	
Urinal	1	

A.10 Communication equipment for medical personnel

Type	No	Proposals for type
Fixed mobile radio transceiver and/or portable transceiver	1	
Portable alerting system. This could be included in the portable radio receiver (number per crew member)	1	
Access to the public telephone network e.g. via the normal radio transmitter or by mobile telephone that can be connected to the cabin communication system	1	
Internal communication between the medical personnel, the pilots and the patient(-s) under conditions of high ambient noise levels, e.g. over 85 dB A.	1	

Module	Capability	Skill Set
Aeromedical Casualty Staging	Manage patient care	<ol style="list-style-type: none"> 1. Manage patient care including: <ol style="list-style-type: none"> 1.1. Maintain short term ventilated patients 1.2. Survey dressings (i.e. abdominal vacuum pack, bandages, limb dressings) 1.3. Survey plastered and splinted limbs 1.4. Ensure cleanliness and comfort of patient 2. Provide general ward clinical support on request 3. Basic knowledge of decontamination procedures (contaminated and infectious)
	Supervise stock levels	<ol style="list-style-type: none"> 1. Control stocks of drugs and other material stock 2. Control oxygen stocks 3. Manage clinical waste
	Prepare patient for transfer	<ol style="list-style-type: none"> 1. Knowledge of the use and limitations medical transport (ground, air and sea) 2. Explain transport procedures to patient 3. Prepare the patient for transfer (in-hospital and/or inter-hospital) 4. Preparation of equipment for casualty evacuation 5. Inform higher MTF level and commanders (MEDEVAC procedure, 9-liner) 6. Complete medical records and transfer documentation to ensure proper handover
	Respond to MASCAL	<ol style="list-style-type: none"> 1. Be able to act IAW the established MASCAL plans and procedures
In-Theatre AE	Manage pre hospital care and life support	<ol style="list-style-type: none"> 1. Pre-hospital trauma life support principles 2. Knowledge of: triage, radiation, decontamination procedures (radio contamination and infectious) and (aero) medevac 3. Record and update patient related observations and treatment
	Manage severe casualties (trauma and wound injuries)	<ol style="list-style-type: none"> 1. Manage a patient according to ATLS or Battle ATLS procedures 2. Conduct triage in order to determine the patient loading order 3. Stopping of (catastrophic/severe) bleeding 4. Care of burn wounds 5. Initial stabilization of fractures including spinal 6. Administration of fluids, drugs (including pain relieve by high potential drugs) 7. Securing of airways (by tubes – intubation, cricotomy or Rapid Sequence intubation RSI) 8. Administration of oxygene and inhalatives / nebulized drugs 9. Thorax puncture (valve and drainage)
	Manage patient tracking and transfer	<ol style="list-style-type: none"> 1. Inform higher MTF level and commanders (IAW medical evacuation procedures) 2. Prepare equipment for patient evacuation/transfer 3. Know and be able to apply techniques for immobilisation, mobilisation and transport of patients 4. Prepare patient for transfer and explain transport procedure to the

		<p>patient</p> <p>5. Complete medical records and transfer documentation to ensure a proper handover</p> <p>6. Be familiar with procedures to be followed in case of death</p>
	Manage nursing care.	<p>1. Assess patient and deliver nursing care</p> <p>2. Dress and bandage wounds</p> <p>3. Ensure or maintain haemorrhage control</p> <p>4. Prepare and administer medication (including pain relief)</p> <p>5. Check proper application of plasters and splints</p> <p>6. Ensure continuous monitoring, cleanliness and comfort of patient</p>
	Ensure transport	<p>1. Check and maintain the proper configuration of the airframe and aeromedical equipment</p> <p>2. Knowledge of the (aero) medevac organisation and structure</p> <p>3. Record medical activities</p> <p>4. Manage patient handover procedures</p> <p>5. Know command procedures according the appropriate SOP's</p> <p>6. Ensure communication with the appropriate elements</p> <p>7. Be aware of and know how to use the appropriate Lines of Communication</p> <p>8. Be able to use maps, GPS and communication system</p>
	Be trained in Survival aircraft (AC) mishap	<p>1. Be able to execute airframe emergency procedures</p> <p>2. Be able to utilise survival equipment</p> <p>3. Be able to use maps, GPS and communication system</p>
	Control stock levels in transport assets and manage stores	<p>1. Control stock of drugs</p> <p>2. Control medical oxygen stock and other medical material</p> <p>3. Be able to verify availability of the required electrical supply/connections and access for the medical equipment</p> <p>4. Manage stores</p> <p>5. Manage clinical waste</p>
	Respond to MASCAL	<p>1. Be able to act IAW the established MASCAL plans and procedures</p>
AE flight procedures	Communication with HQ/PECC	<p>1. Inform HQ about status of operations</p> <p>2. Respond to AE requests and orders</p> <p>3. Information exchange and requests IAW ICAO</p>
	Flight procedures	<p>1. Follow procedures IAW civilian and Ops</p> <p>2. Coordination with HQ and personnel on ground for patient pickup and delivery</p>
	Respond to MASCAL	<p>1. Be able to act IAW the established MASCAL plans and procedures</p>

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4. EUMC Glossary of Acronyms and Definitions, EEAS (2015) 216, 13. February 2015
5. EU Commission - Medical Device Directive 93/42/EEC
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15. EASA CS-27 Certification Specification for Small Rotorcraft
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21. ISO 2631-1 Evaluation of human exposure to whole-body vibration – Part 1: General requirements
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29. EN 3-3 Portable fire extinguishers - Construction, resistance to pressure, mechanical tests
30. EN 3-6 Portable fire extinguishers - Part 6: Provisions for the attestation of conformity of portable fire extinguishers in accordance with EN 3 part 1 to part 5
31. EN 3-7 Portable fire extinguishers - Part 7: Characteristics, performance requirements and test methods to pressure and mechanical tests for extinguishers with a maximum allowable pressure equal to or lower than 30 bar
32. EN 3-9 Portable fire extinguishers - Part 9: Additional requirements to EN 3-7 for pressure resistance of CO2 extinguishers
33. EN 340 Protective clothing – General requirements

34. EN 737-1 Medical gas pipeline systems – Part 1: Terminal units for compressed medical gases and vacuum
35. EN 738-4 Pressure regulators for use with medical gases - Part 4: Low-pressure regulators intended for incorporation into medical equipment
36. EN 739 Low pressure hose assemblies for use with medical gases
37. EN 794-3 Lung ventilators – Part 3: Particular requirements for emergency and transport
38. EN 864 Medical electrical equipment – Capnometers for use with humans – Particular
39. EN 980 Graphical symbols for use in the labeling of medical devices
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41. EN 1281-2 Anesthetic and respiratory equipment – Conical connectors – Part 2: Screw-threaded weight-bearing connectors (ISO 5356-2:1987 modified)
42. EN 1707 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Lock fittings
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44. EN 1789 Medical vehicles and their equipment – Road ambulances
45. EN 1865 Specifications for stretchers and other patient handling equipment used in road ambulances
46. EN 13220 Flow-metering devices for connection to terminal units of medical gas pipeline systems
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68. EN ISO 407:2004 Small medical gas cylinders - Pin-index yoke-type valve connections
69. EN ISO 10524-1:2006 Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices
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