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From:	European External Agency Service (EEAS)
To:	European Union Military Committee (EUMC)
Subject:	Minimum technical requirements for contracted in-theatre Role 2 Basic services for EU Operations and Missions

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Delegations will find attached document EEAS(2018) 17 REV3.

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**EUROPEAN EXTERNAL ACTION SERVICE**



European Union Military Staff

**Working document of the European External Action Service  
of 13/03/2018**

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<b>Title / Subject</b>	<b>Minimum technical requirements for contracted in-theatre Role 2 Basic services for EU Operations and Missions.</b>
<b>[Ref. prev. doc.]</b>	-

Delegations will find attached the Minimum technical requirements for contracted in-theatre Role 2 Basic services for EU Operations and Missions, which was agreed by EUMC on 13 March 2018, by silence procedure.

**MINIMUM TECHNICAL REQUIREMENTS  
FOR  
CONTRACTED IN-THEATRE ROLE 2 BASIC SERVICES FOR EU OPERATIONS AND  
MISSIONS**

*DRAFT Version 3*

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### 1. Introduction, Aim and Scope

- 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 the guidelines within EU concepts and provides guidance on requirements for contracting in-theatre Role 2 Basic (B) Medical Treatment Facility (MTF) to Troup Contributing Nations (TCN), Operation/Mission Headquarters (HQ) and civilian or state owned companies/organizations and service providers/contractors who might potentially offer services.
- 1.2. 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 or Mission, the relevant elements can be extracted respecting the requirements of a given Ops or Mission. These TRs will be applicable to all contracted services required to support Role 2 in EU-led Ops/Missions.
- 1.3. A contracted solution for a Role 2 B MTF is a last resort for the preferred Force Generated Military Role 2 B MTF. This solution has to be in line with the EUMS Health and Medical Concept for EU-led Crisis Management Missions and Operations EEAS 00559/6/14, and meet the operational requirements. A civilian Role 2 B MTF shall only be contracted when the Ops or Mission is in a permissive environment. In reality this comes down to the non-executive EU missions.
- 1.4. The scope of this requirement is to provide a description of a commercial Role 2 B MTF with the core function to deliver Damage Control Resuscitation (DCR) and Damage Control Surgery (DCS) capability.
- 1.5. This document shall provide minimum standards of specifications, guidance to responsibilities, capabilities, and limits of outsourcing and versatility of contracted in-theatre Role 2. These TRs will be limited to a static Role 2 B MTF on a base. The size of Role 2 facilities and the resources required, need to be mission-tailored. And be able to add extra modules or attach to a higher Role 2 E MTF if needed by the mission.
- 1.6. Definition of a Role 2 B MTF, as accepted by the Surgeon Generals of the Member States. A Role 2 B MTF (Initial surgery response capability) is characterized by its ability to perform surgical interventions, including DCS and surgical procedures for emergency surgical cases, to deliver life, limb and function saving medical treatment, in addition to perform reception / triage of casualties; DCR and treatment of shock on a higher level than Role 1. It is also responsible for the preparation of casualties for evacuation to a higher level MTF, including patient tracking, evaluating and reporting.
- 1.7. These Minimum Technical Requirements will focus on the Role 2 B MTF. Role 2 B MTF medical services are defined as providing Core Modules (Point 4.3.), but can be tailored to the mission, the theatre or component for which it is planned. Depending on requirements with regards to operational needs, host nation support, climatic and epidemiological circumstances, planned duration, geographic and environmental situation of a mission a specific Role 2 Enhanced (E) Medical Treatment Facility can be created, with adding one or more enhancing Modules (Point 4.5.).

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1.8. The scope of the service. The Role 2 B MTF is required to be available on a 24/7 basis. Following principal capabilities are required:

- Triage, resuscitation and stabilization
- Life, Limb and Function saving surgical interventions
- Anaesthesia (general and regional)
- Advanced Life Support (ALS) and intensive care (inter alia, for non-surgical emergencies), including ventilation
- Detection, treatment and observation of invasive infectious diseases and its septic complications
- Basic treatment of contagious diseases and implementing of all necessary isolation measures
- Essential pharmaceutical support at commensurate level
- Diagnostic radiography and laboratory facilities at commensurate level
- Sufficient internal control system ('Clinical Governance program') under Project Manager's supervision
- Stock of medical supplies, fluids and consumables for minimum 2 months
- Emergency blood transfusion
- Patient documentation

1.9. The Medical capabilities at Role 2 level will vary considerably, depending on the type of Operation or Mission as well as national policies and resources but always have to be mission tailored. Therefore the end composition has to respond to the medical risk assessment for the Operations and Missions, considering its needs and all environmental aspects e.g. including medical personnel with specific training in medical challenges of a tropical or arctic environment or high-altitude conditions.

1.10. The contracted requirement for the Role 2 B MTF will incorporate the delivery of the medical infrastructure and the service provision for the patients. Additionally, it will address the mobilisation and demobilisation of the contracted support, and will consider the environmental impact of the facility.

1.11. Medical support must meet standards of medical care acceptable to both, the participating nations and the receiving country. The aim is to provide treatment outcome comparable, but not lesser, to the normal peacetime standards of the country of origin.

1.12. Role 1 and Role 2 B MTF provide different levels of care requiring different medical personnel and equipment. A Role 1 MTF can be collocated with the Role 2 B MTF resulting in no efficiencies regarding medical personnel and equipment. Efficiencies

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would be mainly related to logistical requirements such as maintenance, fuel, facility manager, etc.

- 1.13. The final decision on the location of the facility has to be agreed by the mission commander as it will have impact on patient evacuation and planning. This will include identifying the access routes to the Role 2 B MTF by road or by air (close proximity to a helipad is essential). The selection of the plot should be based on the mission strategic plan and the engineering or infrastructure assessment of the location.
- 1.14. Set-up of the Role 2 MTF, including installation of all necessary fittings and connection to life support items should be provided by the Contractor, this means connection with the local electricity grid and water supply network.  
This includes the installation of all necessary medical equipment and personnel, stocking up with appropriate disposable items required for the operation of the Role 2 facility and adherence to appropriate hygienic standards, including provision of sewage, waste disposal and cleaning services. Specific details on the clinical capabilities and skill set associated with these core modules are provided within Annexes III and V.
- 1.15. Accommodation of the staff of contracted Role 2 is the responsibility of the contractor. It should be made in accordance and with guidance of the base commander in advance.
- 1.16. Population at risk (PAR): Role 2 B MTF is implicit understanding to provide service to the hiring Organisation military personnel. However, consideration should also be given to the hiring Organisations civilians, to International Civilian Contractor (ICC) or other missions, linked or in the vicinity of the theatre, visiting guests of the bases or local diplomatic representatives from national embassies. Taking the Hippocratic Oath and the Declaration of Geneva into consideration, in some cases life, limb and function saving medical treatments to non-primary defined casualties might be necessary. Rules of Medical Eligibility and Entry Requirements will be defined in the Mission or Operation Plan (MPLAN/OPLAN)
- 1.17. The Contractor will provide and sustain the specific services as described within these technical requirements to an EU acceptable standard as further defined for provision to all patient population as required by the Contracting Authority.

## 2. Major applicable 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. The EU standards required within the hiring Organisations contracts are binding.
- 2.2. The Contractor shall ensure all medical acts, tasks, liabilities or functions comply with the legal pre-requisites of the EU medical standards, and that these are utilised as evidence-proven best practice, including the security, occupational and environmental regulations. This means also compliance with applicable European Directives,

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Regulations and healthcare standards, such as (indicatively) for occupational and patient safety, pharmacovigilance, storage, safety and quality of blood and blood products.

- 2.3. For the duration of the contract period, the Contractor is to provide and maintain a publication library that details guidance and direction for delivery of related contract services within 30 days of contract award and for the duration of the contract period.

### **3. Command and Control**

- 3.1. Command and Control authority is held by the Ops Commander for Operations, Director Military Planning and Conduct Capability (MPCC) for non-executive military missions. In this document he/she will be addressed as Commander (Cdr).
- 3.2. The Cdr will be supported by his staff, ATHENA, MPCC, EUMS and others. This support includes at least the technical management of the contract, coordination with the customer and contractor, evaluation, certification, facilitation and mediation of recommended changes in scope or deliverables and appropriate contractual modification as required.
- 3.3. The facility would be under the functional authority of the Ops Force Commanders designated Medical Advisor (MEDAD) in theatre, in regard of quality assurance standards and direct reporting.
- 3.4. The Contracting Authority will be determined in accordance with ATHENA regulations. Medical advice is mandatory by MEDAD of the Operation or Mission in consultation with MPCC/ EUMS MEDAD.
- 3.5. The Ops MEDAD has a role in advising the Force Commander in the development of the medical plan for support of the operation/mission. The Role 2 will at all times report to the Medical Advisor about the aspects that will have an impact on the level of service of the Role 2.
- 3.6. The Cdr will provide a permanent, regular and independent schedule of inspections to the contracted Role 2 to establish the required levels of confidence in medical governance for the participating Member States. These inspections will have an evaluation and audit task with military medical experts from Member States, participating nations or the EUMS. Recommendations and tasks from these inspections will have to be respected and implemented by the Contractor.

### **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.



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- 4.2. The contractor has to prove experience with the deployment and management of medical facilities (like a Role 2 MTF or higher echelon) of at least 5 years within the last 7 years in more than 3 countries or enlarged experience in a country of equivalent environmental conditions.
- 4.3. Role 2 B MTF shall include at least the following modules; enhancement might be necessary due to the needs of Ops and Missions. Personnel requirements for the modules are defined in ANNEX I.

### 4.3.1. Operating Theatre (OT).

The surgical capability defines the function of a Role 2 Basic MTF provided on a continuous 24 hrs/ 7 days.

There shall be minimal one Operating Theatre with one operating table with a capacity of 8 surgical operations per day (4 critically wounded patients and 4 CAT B/C patients), and an additional Damage Control Resuscitation (DCR) capability within the Emergency Room and Reception Area (ER). This permits both routine and rapid response requirements. The OT shall have access to central medical gases and be appropriately staffed with the necessary specialist medical staff. The OT shall be equipped for surgical and anaesthesia procedures to provide trauma surgery, abdominal surgery, thoracic surgery, and with mobile digital X-ray, ultrasound and also including required technical elements, such as mobile laminar airflow. There must be place for preoperative handwashing facilities, storage capacity and changing rooms (pre- & post- operating room (OR)).

The teams will operate in shift patterns provided by the contracted management, which would incorporate any needs for leave. An on-call cascade capability would be managed for MASCAL or similar incidents. The team should incorporate abdominal/thoracic and trauma surgeon, anaesthetist and OR nurse. The Surgical Module must be able to manage a trauma patient, pre and post-operative care, an anaesthetised patient, and provide Advanced Life Support and surgical care for critically injured trauma patients. In addition, it may be able to deliver emergency and/or elective surgery, manage the OR and patient transfer. It is able to respond to MASCAL.

### 4.3.2. Emergency Room and Reception Area (ER).

This unit shall have 2 ER bays which include ultrasound capability and minor surgical and emergency procedures, especially for infected wounds. The ER area shall provide an intermediate capability for the reception and triage of an increased number (8 stretchers) of casualties. The ER shall provide a broad spectrum of initial treatments for various clinical conditions and be capable of performing minor and emergency damage control resuscitative surgical procedures. The ER team shall incorporate an emergency physician and 2 emergency nurses (ER nurse). A physician's assistant shall not be considered acceptable as a substitute for a physician.

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### 4.3.3. High Dependency Unit (HDU).

4 High Dependency monitoring beds with ventilator that can be used in emergency situations for a short period as a bed for a ventilated patient. The holding capacity in the unit is to treat 2 ventilated and 2 high dependent patients at the same time and for up to three days, until an evacuation is arranged. These beds will be appropriately staffed with the necessary medical professionals.

The capability shall be managed by the anaesthetist of the surgical team (dual hatted). In addition 1 HDU nurse per ventilated patient and 1 HDU nurse per 2 high dependent patient beds. Post-Op/HDU must be able to manage post-operative patients, including the provision of sedative care and pain control. The HDU module is able to prepare the patients for Strategic Aeromedical (STRATAE) Evacuation. It controls stock levels and is able to respond to MASCAL.

### 4.3.4. Clinical Laboratory.

The laboratory shall be capable of the following test capabilities:

#### 4.3.4.1. Haematology.

Full blood count, erythrocyte sedimentation rate (ESR), blood film review, and platelet counts. Blood grouping and cross-matching.

#### 4.3.4.2. Clinical Chemistry.

Electrolytes, Liver functional test (LFT), cardiac enzymes, renal function tests, C-reactive protein (CRP), lactate, glucose, urinalysis, and blood gas analysis.

#### 4.3.4.3. Clinical Microbiology.

Plate culture and antibiotic assessment, basic clinical microscopy, thick or thin blood smear (Malaria).

#### 4.3.4.4. Other laboratory

E.g. serotyping, immunoassay investigations, biochemical analysis tests the company deems necessary to perform the tasks.

### 4.3.5. Medical Imaging/Radiology Unit.

Broad range of medical imaging capability (head, backbone, chest, limbs, abdomen, pelvis) shall be provided with image interpretation in-house or as a telemedicine solution. The imaging shall include mobile digital x-ray, ultrasound and video laryngoscopy.

### 4.3.6. Wards.

There will be 2 wards of 6 beds each. These beds are intended for post-operative care and short-term admission patients. One of the wards shall also be used for separation of possible contagious patients (with dedicated ablution unit), the other ward shall provide surge capacity with 2 additional respirators, monitors etc. for post-operative care. It conducts administrative tasks and controls stock levels. It is able to prepare patients for intra-hospital or inter-hospital transfer as well as Aeromedical Evacuation (AE).

The MTF should provide additional, stand-by contingency capacity with 9 beds in the case of a small infectious outbreak, where provisions for an ad hoc isolation ward must be foreseen.

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### 4.3.7. Medical Supply Unit.

This unit shall provide the pharmaceuticals, medical consumables and medical gas supply as well as blood bank management including transfusion services to cover all Role 2 requirements. Medical supply Unit shall be responsible for the storage, handling and disposal of all pharmaceuticals, medical products and blood/ blood products. The coordination and distribution must be under supervision of a pharmacist technician or pharmacist (if applicable for example in larger contingents) in accordance with Good Distribution Practice (GDP). Specifications are defined in Annex III.

### 4.3.8. Ambulance vehicle.

There shall be minimal 1 ambulance vehicle, operational 24/7, provided for any transfer of patients e.g. to the meeting point for Aeromedical Evacuation or specialised examinations and care in a higher level facility. The ambulance will be manned with a driver and nurse. The transport of a high dependent patient has to be accompanied by a physician.

### 4.3.9. Medical Administration Cell.

This section shall provide maintenance of medical records, MTF security, coordination and management of the facility. This section is also responsible for archiving the patient records and managing the confidential medical data according to the hiring Organisations regulations.

### 4.3.10. Mortuary Capability.

A cooled container in coordination with J4 Mission must be provided.

## 4.4. Blood Products.

Blood products have to meet the minimum requirements of the EU Directives 2002/98/EC, 2001/83/EC, 2003/94/EC, 2004/33/EC, 2016/1214/EC and Council Recommendation 98/463/EC.

## 4.5. In addition enhanced modules, dependent on the operations' or missions' needs might be mandatory:

- 4.5.1. Extended Surgery
- 4.5.2. Imagery
- 4.5.3. Computer Tomography (CT) Scan
- 4.5.4. Intensive Care Unit
- 4.5.5. Extended Laboratory
- 4.5.6. Dental Care
- 4.5.7. Mental Health
- 4.5.8. Internal Medicine
- 4.5.9. Hospital Management
- 4.5.10. Sterilisation
- 4.5.11. Primary Healthcare

## 4.6. The infrastructural requirements for Role 2 are defined in Annex II and III.

## 4.7. The term Base shall be used throughout this document to include all activities and areas described above and included within the perimeter fence since the date the contract

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starts. The Cdr shall provide the Contracting authority with a map depicting base locations, base size, training sites, airfields and scope of response requirements since the date contract starts. All changes to the base perimeter from this baseline shall constitute a change in contracted requirements. All infrastructure and base activities shall be coordinated with the Base manager.

- 4.8. Contractors will be self-sustainable. The contracted requirements for the Role 2 B MTF will incorporate the delivery of the medical infrastructure and the service provision for the patients. Additionally, it will address the mobilisation and demobilisation of the contracted support, and will consider the environmental impact of the facility. Consideration would also be given to staff accommodation and all associated Real Life Support requirements to maintain an effective workforce.
- 4.9. Any services for Real Life Support will be negotiated on case by case basis when this framework contract (FWC) is activated with for example the following Real Life Support (RLS):
- An area of at least 90m x 70m will be required by the Role 2 B MTF , without parking spaces
  - It should be noted that the dimensions of the hiring organisations' ambulances vary and provision shall be made for the largest armoured ambulances
  - A power source and reserve
  - Fresh water, sewage treatment and waste removal
  - Vehicle fuel
  - Food and laundry services
  - Clinical waste capability
  - Domestic accommodation.
- 4.10. The Contractor shall establish emergency support services to provide a recall capability to extend/expand medical support in response to MASCAL and medical peaks.
- 4.11. 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 disaster events.
- 4.12. Coordination with other force generated or contracted medical capabilities should take place in coordination with the Medical advisor of the operation or mission. Especially regular recalls and training in regard to mass casualty incidents.

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- 4.13. Supply chain difficulties within the Area of Operation (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, meteorological and/or directly or indirectly related to the security situation. Problems with paperwork processing, customs clearance and physical transport due to poor maintained roads and vehicles are common occurrences. Seasonal variations such as flooding and snowfall may occur where the supply routes are located. Contractors must be aware of these issues and develop procedures to overcome and compensate for these.
- 4.14. 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 may be entitled for additional payment, to be defined in the contract.
- 4.15. The Contractor has to ensure medical support to its employees supporting this contract. Medical support to non-entitled personnel in theatre is restricted to emergencies for life, limb and function saving when the Role 2 is directly confronted, or requested by the Cdr.
- 4.16. Intellectual and industrial property rights.
- 4.16.1. The Contractor and contracted personnel shall treat all documents and information received in connection with the contract as private and confidential. The Contractor shall save information only in so far as it may be necessary for the purposes of the performance thereof. The Contractor shall not publish or disclose any particulars of the contract without the prior consent in writing of the Contracting Authority or the Project Manager after consultation with the Contracting Authority. If any disagreement arises as to the necessity for any publication or disclosure for the purpose of the contract, the decision of the Contracting Authority shall be final.
- 4.16.2. All reports and data such as maps, diagrams, drawings, specifications, plans, statistics, calculations, databases, software and supporting records or materials acquired, compiled or prepared by the Contractor and contracted personnel in the performance of the contract shall be the absolute property of the Contracting Authority unless otherwise specified. The Contractor shall, upon completion of the contract, deliver all such documents and data to the Contracting Authority. The Contractor and contracted personnel may not retain copies of such documents and data and shall not use them for purposes unrelated to the contract without the prior written consent of the Contracting Authority. Notwithstanding is the storage of medical data as required by law following medical confidentiality.
- 4.16.3. The Contractor and contracted personnel shall not publish articles relating to the services or refer to them when carrying out any services for others, or divulge information obtained from the Contracting Authority, without the prior written consent of the Contracting Authority in accordance with Article 4.16.1.

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- 4.17. Any results or rights thereon, including copyright and other intellectual or industrial property rights, obtained in performance of the contract, shall be the absolute property of the Contracting Authority, which may use, publish, assign or transfer them as it sees fit, without geographical or other limitation, except where intellectual or industrial property rights already exist.
- 4.18. Patient Rights are to be consistent with overarching EU and international medical standards and regulations for patient care.

The Role 2 shall inform the patient of his rights as a patient, and ensure that these rights are upheld. The list of patient rights shall include the following:

- (i) To be fully informed of his medical health status in a language he can understand
- (ii) To refuse treatment, except of a life-threatening event.
- (iii) To express complaints regarding the care received and to have these complaints resolved when possible;
- (iv) To refuse to participate in experimental treatment or research;
- (v) To be examined and treated in surroundings designed to give visual and auditory privacy.

#### 4.19. Patient Complaints Management

4.19.1. The Role 2 shall be required to have in place patient complaints management system. The Role 2 patient complaints management system shall ensure:

- Early identification and clarification of complaints
- Cost-effective resolution of complaints in a timely manner.

4.19.2. The Role 2 shall design and operate a patient complaints management system that:

- Is readily accessible to the Contracting Authority
- Identifies every complaint and enables timely retrieval of documentation
- Ensures that all aspects of the complaint are documented and dated.

4.19.3. The Role 2 shall ensure all complaints are:

- Recorded within 24 hours of receipt
- Immediately notified to the Contracting Authority
- Acknowledged by the Role 2 to the patient making the complaint, upon recording;
- Patient given full cooperation as required by the Contracting Authority

4.19.4. The Role 2 and the Contracting Authority shall conduct monthly reviews of patient's complaints to identify and mitigate system and practice deficiencies, through periodic monthly performance meetings as established and agreed by both parties during the life of the relationship.

## 5. Description of the Services Required

5.1. The Contractor has to provide a Role 2 (B) MTF as defined in the contract using core and if required additional enhanced modules.

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- 5.1.1. All patients requiring Role 2 and other medical levels of care will be coordinated according to the Operations and Missions Standard Operating Procedures (SOP's).
- 5.1.2. The manning for this contract should be maintained at the lowest effective level to undertake the requirement.
- 5.1.3. These minimum requirements will be suitable for a contingent up to 5000 pax depending on the Ops Risk assessment.
- 5.1.4. The contractor is to provide a liaison officer to the HQ as agreed with the Cdr.
- 5.2. The Contractor is responsible, including but not limited, to:
  - 5.2.1. Pharmaceutical provisions will be included in the all-in costs applicable to the treatment of entitled personnel. The overall requirement will consist of essential emergency and prescribed requirements for the clinician. The contractor should maintain at least 2 months stock of essential consumables and pharmaceutical provisions to cover all common medical conditions, sufficient to maintain effective medical treatment delivery. Blood should be at least 1 month stock.
  - 5.2.2. The Contractor shall monitor re-order levels and track expiry dates of all drugs or blood. Reports should be provided to the MEDAD of the Operation or mission. The Contractor shall ensure that expired drugs or blood are not given to patients.
  - 5.2.3. The Contractor will provide a list of basic medical instruments and diagnostic devices that will be used to fulfil the Role 2 B MTF services.
- 5.3. The patients should be offered regular meals throughout their stay within the Role 2. Contractual arrangements for routine and "special" hospital meals (dietary considerations), including the provision of irregular hours' duty meals will have to be arranged by the Contractor.
- 5.4. The Contractor has to respond to emergencies, including but not limited, to:
  - 5.4.1. All medical emergencies within the timelines established in EU Health and Medical Concept for EU-led Crisis Management Missions and Operations (10-1-2 rule). If standards are unachievable, due to conditions beyond the Contractor's control, the Contractor shall develop a risk analysis with appropriate mitigation measures. This must be approved by the Cdr in consultation with the Member States (MS).
  - 5.4.2. The patients shall be prioritised and treated within established timelines and clinical guidelines and agreed parameters accepted by the hiring Organisations regulations. The concept of Good Medical Practice (GMP) would apply whenever there is doubt regarding any medical activity for which clear guidance is not provided. The final arbitrator of medical care delivery would be the MEDAD.
  - 5.4.3. Execute triage of casualties in the event of any incident and/or medical problems and execute the transport to the meeting point for Aeromedical Evacuation.

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- 5.4.4. Prepare the patient for Aeromedical Evacuation (AE) to a higher treatment facility according to the current standards and in consultation with the responsible Aeromedical Expert/ PECC. Strategic Aeromedical Evacuation (STRATAE) is a national responsibility that shall be executed in tense coordination with (Joint Medical) JMED/ MEDAD of the Operations and Missions.
- 5.5. The Cdr remains responsible for decisions relating to patients emergency evacuation, depending on the operational security situation. Medical consequences for the emergency evacuation should be clearly communicated with the Cdr by the Contractor.
- 5.6. The Contractor is to provide medical services in support of all operations and activities within residential and industrial areas of the base:
- 5.6.1. Receive and respond to casualties brought to the Role 2 B MTF.
  - 5.6.2. Establish and maintain emergency reporting reports recording key details of calls and casualties received.
  - 5.6.3. Provide reports as required to support accident investigations and reporting.
- 5.7. The Contractor is to provide technical guidance and expert knowledge to support the base emergency services.
- 5.7.1. Develop and maintain relevant emergency response plans for contract services provided, coordinated and developed in cooperation with the Fire Services.
  - 5.7.2. Support the Contracting Authority in developing contingency, crisis response and emergency action plans and checklist.
  - 5.7.3. Describe the capabilities, response actions, procedures, responsibilities and interaction with military personnel in details.
  - 5.7.4. Planning has to be in line, but is not limited to Base Emergency Response Plan, Mass Casualty Response Plan (MASCAL), Outside Perimeter Response Planning and Emergency Route Plan.
  - 5.7.5. Participate in training, table-top and local exercises. Participate in accident reporting, investigation and mitigation planning. Attend and participate in Command incident/accident debriefs.
- 5.8. Supply, Equipment and Vehicle Maintenance:
- 5.8.1. All equipment, vehicles and test tools will remain as Contractor Furnished Equipment (CFE) excepting any specific items of Furnished Equipment provided with the infrastructure on arrival. 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.



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- 5.8.2. The Contractor shall take all actions required to coordinate and track maintenance of vehicles to ensure serviceability supports performance of contracted emergency services.
- 5.8.3. The Contractor is responsible for repair and maintenance of all equipment and infrastructure related to this contract outside routine infrastructure maintenance. This includes establishing a system for calibration of equipment (including medical equipment) and recording as required.
- 5.8.4. The Contractor shall establish a medical supply account to provide all supplies required to meet the contract, including pharmaceutical supplies and blood products. A 2-month supply of clinician-led pharmaceutical stocks is to be held on stock. For blood this is 1 month. Additionally, all clinical waste containers are the Contractor's responsibility. Medical waste management shall be arranged in line and coordinated with the missions SOPs.
- 5.8.5. Any potential for failure to meet contractual obligations for supply and equipment/vehicle maintenance, that impacts the contract requirement within this TRs must be properly and immediately addressed with the Contracting Authority to prevent service degradation.
- 5.8.6. The Contractor shall maintain effective accounting for and storage of all blood and pharmaceuticals. This will include adherence to EU regulation of controlled drugs and effective maintenance of the cold chain for supply, respecting Status of Forces Agreement (SOFA) / Status of Mission Agreement (SOMA) or national / host nation's regulations.
- 5.9. Preventive and Corrective Maintenance Program:
- 5.9.1. The Contractor shall implement a 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 Original Equipment Manufacturers (OEMs) recommended Operation and Maintenance (O&M) program.
- 5.9.2. Infrastructure maintenance shall conform to a known EU nationally or EU recognized standard. The standard to be used shall be described within the Technical Proposal. The Contractor shall hold/have access to this standard and make it available for the Contracting Authority review upon request.
- 5.9.3. This program shall cover all infrastructure and equipment used to support this contract. This includes all assets provided to the contractor as well as contractor procured assets.
- 5.9.4. The PMP shall include the Contractor's Operating Procedures, Maintenance / Inspection Schedules and Checklists.
- 5.9.5. The PMP shall address Contractor support of Warranty items. Any equipment or infrastructure under warranty shall be maintained in such a manner to sustain the warranty terms and conditions. The Contractor must notify the Contracting Authority if warranty terms and conditions cannot be maintained due to operating location, lack of local service provider, etc.
- 5.9.6. The PMP shall include the Contractor's Operating Procedures for Warranty Management and any special maintenance procedures necessary to address the impact of the harsh environmental conditions in the particular region on equipment and facilities.

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5.9.7. The Contractor shall track maintenance schedules and document all maintenance activities to include unscheduled repairs performed outside of the PMP schedule.

### 6. Schedules, Milestones and Operating Hours

- 6.1. The Contractor will commence Full Operational Capability (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.
- 6.2. The Contractor will guarantee a 24/7 coverage based on shift-work system. Working hours of the contracted personnel shall not exceed the working hours applicable to the military personnel in the Operation or Mission. (That adheres to EU Working Time Directive (2003/88/EC) in the context of a low-caseload environment.)
- 6.3. The Mobilisation section (para 15) shall provide further details.

### 7. Contractor Human Resources Required and Qualifications

- 7.1. The Contractor shall provide any necessary licenses, permits, visas required to perform this contract and comply with EU laws, codes and regulations, as applicable.
- 7.2. 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. A plan on regular rotation to maintain specific skills shall be provided by the Contractor.
- 7.3. 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:
  - 7.3.1. All employees for the Role 2 B MTF shall be recognised by a competent authority in regard to the EU Directive 2005/36/ EC. The Contractor shall be responsible to demonstrate the qualifications of its medical and technical personnel. Specific requirements are defined in Annex I and Annex V.
  - 7.3.2. All proposals for appointment should be vetted for acceptability by the Contracting Authority medical staff, the right to perform a peer-to-peer assessments and the right to reject personnel in case of qualification or security concerns shall be reserved.
  - 7.3.3. Ambulance driver(s) shall be familiar with applicable radio and driving procedures for medical ambulances and competent to achieve any operating qualification specific to the base.
  - 7.3.4. All personnel shall be mentally and physically fit to be able to fulfil the demanding physical aspects of emergency response. Paragraph 13.9 elaborates the further medical requirements.

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- 7.3.5. The Contractor shall be responsible for obtaining all needed security clearances and validating individual clearance status with HQ prior to personnel mobilisation.
- 7.3.6. All personnel shall be cleared and security screened prior to arrival and in accordance with the base procedures.
- 7.3.7. If necessary valid security clearances have to be held at least for one physician at Role 2 to permit participation in base briefings and contingency planning, one physician and ambulance driver in order to access the airfield security area. This requirement has to be fulfilled regardless of personnel rotations and other absences.
- 7.3.8. Malpractice insurance for all medical personnel to cover liabilities must be ensured and proved by the Contractor.
- 7.3.9. Excellent language skills in the preferred language of the Ops, usually but not limited to spoken and written English as well as technical English, are essential for all key personnel. Specific requirements for medical personnel are fixed in Annex I Paragraph 1.12.
- 7.3.10. The Contractor shall not make changes to the agreed personnel without the prior written approval of the Contracting Authority. The Contractor must on its own initiative propose a replacement in the following cases: in the event of death, illness accident, during leave or resignation of a member of staff.

### **8. Provision of Infrastructure, Equipment, Tools and Supplies**

- 8.1. There is no plan to furnish equipment, tools or support this contract by external sources.
- 8.2. The Contractor shall not assume there are existing vehicle fleet, equipment, tools or supplies or existing Role 2 infrastructure. Nevertheless it is not excluded that Ops can support within its means for e.g. Real Life Support (RLS).
- 8.3. Equipment can be any tools, vehicles, test stands or other items used to support activities to fulfil contract requirements. Supplies can be items such as spare parts and consumables used to support contract infrastructure and equipment assets as listed above. Supplies can also be the spares parts and consumables to include medical items used to provide the contracted service requirements.
- 8.4. The age of vehicles to be provided for this contract must be stated with the expected and planned lifespan and serviceability. Vehicles older than 5 years will not be considered acceptable for this contract. The vehicles should be in good condition and able to drive on the local or base provided fuel.
- 8.5. The Contractor has ultimate responsibility for provisioning equipment, tools, supplies, spares, personal protective equipment (PPE) and consumables required to support

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contractual obligations for services and maintaining all infrastructure and equipment required to support this contract.

- 8.6. Any facility/infrastructure construction, whether temporary or permanent, shall be coordinated through the Contracting Authority prior to execution in order to obtain proper authorisation from the Base Authorities.
- 8.7. Contractor provided infrastructure and facilities shall be constructed to an approved standard and shall remain the property of the Contractor. They shall be removed by the Contractor at their expense upon termination of the contract unless otherwise specified by the Contracting Authority.
- 8.8. The Contractor will have to coordinate with HQ a planning for mission 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. Follow on planning after termination of the contract has to be implemented in the contract.
- 8.9. These facilities will conform to basic safety, security and hygiene standards as established by the HQ and records maintained of all checks.
- 8.10. The Contractor shall provide planning to meet all infrastructure requirements within the technical proposal. This planning shall describe the facility; purpose/proposed use, structural design and method of construction.
- 8.11. The Contractor shall supply all tools, general and special test equipment and calibration equipment, and vehicles required in the performance of the services specified in these technical requirements.
- 8.12. General terms for management, maintenance, tracking and documentation of all infrastructure, equipment and supplies are described in paragraph 9 below.
- 8.13. The Contractor shall ensure the Role 2 is equipped to meet requirements established in standards listed in Paragraph 2 based on base operations' size, population, facilities and nature of operations. This includes but is not limited to:
  - 8.13.1. Ambulances fully equipped to meet standards for continuum of care and appropriate treatment of patients during evacuation to a higher level of care or AE meeting point, depending on the situation.
  - 8.13.2. Proof of appropriate vehicle insurance shall be provided for the ambulance.
  - 8.13.3. All required personnel protective equipment including medical gowns and eye protection.

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- 8.13.4. All other associated tools, equipment, supplies, medical supplies, items required for administrative support, and items required for user maintenance of facilities.
- 8.14. The Contractor shall ensure its Role 2 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 the patients.

### **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. This will be accomplished by developing a tailored program to cover the type and quantity of assets involved.
- 9.2. The Contractor shall establish a preventative maintenance regime for all equipment and infrastructure used in support of this contract. Apply the preventative maintenance planning, program and document requirements in paragraph 5 and 13 to this regime.
- 9.3. 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.
- 9.4. The Contracting Authority, the Operation Headquarters (OHQ), Local Command Safety and the Base Fire Marshall hold the right to inspect facilities periodically at any time with no prior announcement, with respect to patient rights.
- 9.5. Arrangements have to be provided to establish storage for weapons with guidance of the base commander and security manager.
- 9.6. The Contractor shall establish a Site Manager for all facilities, infrastructure, equipment and supplies supporting this contract. This manager shall provide oversight to ensure the requirements in paragraph 13 are accomplished. Designate the Site Manager not later than start of services.
- 9.7. 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.
- 9.8. 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.

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- 9.9. 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 on any infrastructure, equipment or supplies for which the Contractor has control and accountability.
- 9.10. The Contractor shall provide a management / inventory report of all equipment and infrastructure supporting the contract to the Contracting Authority regularly, on a quarterly basis as a minimum.
- 9.11. The Contractor shall work with the HQ to establish a list designating mission essential equipment and infrastructure including critical levels. This list shall consider all equipment required to meet contract service requirements.
- 9.12. When actual levels of serviceable mission essential equipment drops below the established critical level, the Contractor shall take immediate corrective action and provide mitigation plans to prevent disruption in services.
- 9.13. The Contractor shall brief the Contracting Authority on status and progress of corrective actions for any equipment remaining down for maintenance for more than two days.
- 9.14. HQ can declare non full capability of the Contractor's services if non-reparability of any essential services of the contract occurs. Consequences will be stated in the contract.
- 9.15. The Contractor shall operate all systems inclusive of equipment, instruments and interfaces in accordance with Original Equipment Manufacturers (OEM) specifications and recommendations.
- 9.16. The Contractor shall establish a calibration program for all items requiring calibration. This may require use of a certified calibration laboratory and/or certification of contractor personnel to perform required calibrations. The Contracting Authority Quality Management System (QMS) shall review this program for compliance with applicable technical standards.
- 9.17. The Contractor shall ensure that all spares and materials maintained in stock are stored and protected in accordance with OEM specifications and in such a way as to minimize loss, theft or degradation due to environmental conditions.
- 9.18. The Contractor shall maintain asset registers and records detailing any testing, statutory inspections and/or obligations, monitoring, diagnostics and analysis. These records shall be used to identify any recurring defects or adverse trends. The

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recording and maintaining of records, stock levels/inventories etc. are a key function and shall be managed accordingly.

- 9.19. The Contractor is responsible for the admission of any utilized vehicle by the Contractor on the installation. The Contractor shall provide a vehicle license plate for each vehicle utilized by the Contractor on the installation. These license plates shall conform to local command requirements.
- 9.20. Any cross utilisation or sharing of equipment amongst contractors or service areas shall be approved by the Contracting Authority prior to transfer/loan.
- 9.21. Inventory Management. The Contractor shall be responsible for managing care, custody and control of any inventory of supplies held using proven inventory management principles and processes. The Contractor shall record and maintain records, consumption, demand history, material purchases; stock levels/inventories etc. lack of availability of parts and material will not relieve the Contractor from the requirement to complete the work as required by the Contracting Authority.
- 9.22. The Contracting Authority shall audit/inspect all infrastructure, equipment and supply management, maintenance and associated documentation in coordination with trained experts. The contractor will make equipment available for inspection by the Contracting Authority personnel on request without prior notice.
- 9.23. The contractor shall be responsible for transporting all his equipment and supplies in order to fulfil his obligations as defined in these Technical Requirements and its annexes. This shall also include all required Customs clearances and exemption certificates.

### **10. CIS Requirements**

- 10.1. The Role 2 B MTF should ensure they deliver a communications plan that clearly describes how they will maintain effective communications with the patients, the parent units, the mission medical authority/MEDAD team and any other designated and authorised entity. Lines of communication shall be demonstrated that insure medical confidentiality whilst transferring medical data to organising structures (e.g. Patient Evacuation Cell, statistical data). The hiring Organisation would provide Communication and Information Systems (CIS) and intelligence database equipment for connectivity with the responsible HQ.
- 10.2. The Contractor should provide effective communication and coordination with all the contributors to the contract such as airfield management, ground transports and ambulances, all ground support activities and destination medical facilities to coordinate the safe patient handling and movement.
- 10.3. The contractor should equip the Role 2 B MTF with standard Information Technology (IT) and communications capabilities, which shall be compatible and interoperable to

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exchange selected data with the hiring Organisations' -IT and communications infrastructure. Any connectivity has to be approved in regard to IT and information security by the hiring Organisation.

10.4. As a minimum, the Contractor shall equip and maintain:

10.4.1. Desktop telephones as part of the base telephone network, and mobile phones and radio systems, to guarantee secure and reliable communication, are to be in place. These are to be interoperable with the force communications network.

10.4.2. 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.

10.4.3. There has to be a system 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.

10.4.4. If the security situation allows it, open internet access can be installed by the Contractor for Role 2 personnel.

10.5. The Contractor should provide digital patient data handling including one telemedicine workstation (internet access, secure external data exchange).

10.6. Medical Records

10.6.1. All treatment received, including medications, are to be fully documented in the patient's medical records.

10.6.2. The Role 2 B MTF shall have an established system for maintaining of medical records, including the administration, custody and safekeeping.

10.6.3. Original medical records are the property of the Role 2 B MTF and shall not be removed unless by court order or subpoena.

10.6.4. The Contractor is to make available the copies of all medical records on request from specific medical staff of the customer civilian or military medical service with due regard to the rules of medical confidentiality.

10.6.5. Upon completion, each treatment must be followed by a complete original signed report containing the essential medical components of the diagnosis, diagnostics and procedures, as well as additional therapeutic recommendations provided to the medical personnel of the receiving nation.

10.6.6. All medical records are to be treated as "Medical-in-confidence" and shall not be released to any unauthorized persons.

10.6.7. All medical records shall reflect the name of the patient, diagnosis, procedure(s) performed treatments and medications prescribed, and the name of the physician or licensed health practitioner.



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- 10.6.8. All medical record entries shall be legible, complete and dated by the person responsible for ordering the service, providing or evaluating the service.
- 10.6.9. Each medical record shall contain documentation of any complications, acquired infections, and adverse reactions to medical treatment and care.
- 10.6.10. Security of Medical Records. The medical records fall under medical confidentiality due to their sensitive nature and are under uniform protection of medical records and personal information. The medical records are to be held in a secure filing or electronic system and will only be seen and used by authorised medical staff, for purposes directly related to the treatment of entitled members. The medical records service shall provide secure storage, controlled access, prompt retrieval, and resources to review medical records.
- 10.6.11. Disclosure of Medical Records. Mission members will be furnished with a copy of their individual medical records, if a mission member so requests.
- 10.6.12. New Contractor. If there is a change of the Medical Contractor during treatment, the predecessor shall hand over copies of all medical records to the successor on signature that are necessary to continue treatment.
- 10.7. Any processing and movement of personal data must be in line with EU Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016.

### **11. Security and Safety Requirements**

- 11.1. Personnel shall attend a newcomer briefing within 30 days of arrival, subject to availability of the courses.
- 11.2. Personnel shall hold an Authority to Deploy.
- 11.2.1. All Contractor personnel shall be properly authorized base access prior to arrival on station. Complete request for deployment in accordance with guidance provided by the Contracting Authority and local command security guidance pertaining to installation access.
- 11.2.2. There can be no exceptions to this policy in order to sustain installation personnel safety and security.
- 11.3. The Contractor shall develop and implement a safety program to cover all safety aspects.
- 11.3.1. The Contractor shall include a Safety Management Plan (SMP) describing safety program implementation with the technical proposal. A complete review of local conditions, policies and procedures shall be performed by the Contractor during contract mobilisation. Provide the Contracting Authority with an updated safety program upon start of services. Continue to review and provide updates to this document throughout the contract performance period.

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- 11.3.2. All elements of safety shall be implemented upon start of mobilisation and continue until the last person leaves the installation upon end of services.
- 11.3.3. This safety plan shall be tailored to local operations.
- 11.3.4. The contractor shall ensure the health, safety, and welfare of workers and minimize the risk of injury, illness and property damage by permanently monitoring the application of the safety rules and instructions for job specific safe work practices.
- 11.3.5. The Contractor shall train and guide personnel in the safest way to conduct the work.
- 11.3.6. The Contractor shall provide appropriate protective, safety, and warning equipment for hazardous material (HAZMAT) situations to all personnel. He shall ensure that personal protective equipment such as, but not limited to head, hand, foot, eye and face, and hearing protection is used where it is not possible to eliminate or control a hazard by other means.
- 11.3.7. All persons needing to wear personal protective equipment shall be instructed in its proper use, and where appropriate, in its service and maintenance.
- 11.3.8. All personal protective equipment shall be inspected routinely, kept in good working condition, and maintained in accordance with the manufacturer's instructions.
- 11.4. Any personal protective equipment found to be of questionable reliability, damaged, or in need of service will be removed from use, reported to the supervisor, and repaired by a qualified person or replaced.
- 11.5. The Contractor shall inform the Base Safety Officer and the Contracting Authority of any accidents/incidents occurring to contractor personnel on station. This includes non-work related events as well as work related events. Timelines of report shall conform to installation Safety Office directives based on severity of event. This will be supplemented with weekly written reports to the Contracting Authority.
- 11.6. Regarding military security and safety issues the HQ is the ultimate authority. Security issues concerning obligatory care of Prisoner of War (POW) and other Detainees need to be clarified before the mission/operation starts.

## **12. Environmental Requirements**

- 12.1. The Contractor shall ensure all waste and especially medical waste generated is properly disposed of and in accordance with the base SOP and EU Directive 2008/98/EC.
- 12.2. The provision of medical incineration is outside the scope of this document and would form part of the mobilisation considerations for the Base Support Services at the designated location, under due consideration of Host Nation (HN) regulations. However, the Contractor will remain responsible for appropriate processing and disposal of clinical waste.

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- 12.3. Protection from unintended and accidental radiation exposure from medical devices in regard to adjoining infrastructure has to be taken into consideration according to Council Directive 2013/59/ EURATOM. Relating documents have to be provided to the Contracting Authority and its Medical Advisers.
- 12.4. Ambulances and other vehicles of the Contractor shall use a catch basin to prevent (Petroleum, Oil, and Lubricants) POL products contaminating the soil.
- 12.5. All land and facilities shall be returned to the Base on demobilisation, free from any requirement for environmental clean-up and as an absolute minimum, in the same condition as received.
- 12.6. The Contractor shall develop a program for environmental management as defined within International Organization for Standardization (ISO) ISO 14001.

### **13. Data, Reports and Plans**

- 13.1. The Contractor shall provide transparency to the customer nation/Contracting Authority in all its operations. Contracting Authority shall provide the Contractor with periodic reports to review performance, area of concern and issues requiring guidance; the format of which will be defined in the Statement of Work (SOW). Contracting Authority shall also provide the customer representatives and MEDAD with regular updates on the performance of the contract facility.
- 13.2. The Contractor shall provide Base Fire Officer, Base Commander and his Medical Adviser, HQ and the Contracting Authority Point of Contacts (POCs) 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.
- 13.3. The Contractor must respect the code of conduct /medical confidentiality / no passing on of medical information to non-medical personnel. Request for medical information for non-treatment reasons can only be given by written request and consent of the patient. Transfer of medical confidential information has to be restricted to a need to know basis.
- 13.4. The Contractor has to guarantee the technical equipment to archive patient's records for a time period of 30 years in an appropriate way.
- 13.5. The Contractor has to provide Commanders staff/Medical Adviser and Ground Safety with immediate feedback on detected health and safety issues and accident response.
- 13.6. The required items and format of the reports specified above will be alterable at the discretion of Base Commander.
- 13.7. Project Management Plan (PMP):

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- 13.7.1. The Contractor shall develop and provide to the Contracting Authority, a Project Management Plan describing key program aspects and the Contractor's proposed method for project development, timeframes, implementation, execution and sustainment. This plan shall address areas such as staffing, supply, cost control, services execution, program sustainment, milestones and goals, etc.
- 13.7.2. Provide this plan within the Technical Proposal. Update the plan upon contract award and provide the updated plan to the Contracting Authority not later than 30 days after contract award notice.
- 13.7.3. 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.
- 13.7.4. This plan shall include, as a minimum, an organisational chart, and position descriptions, qualification requirements for key positions as well as for positions requiring specific technical skills or professional certification.
- 13.7.5. Clearly identify operational skills sets and/or positions that shall be staffed at all times.
- 13.7.6. Identify means of providing back-up/redundant personnel to cover all required skills and/or duty positions during personnel leave or during absence.
- 13.7.7. Provide nomination of the key personnel and submission of Curriculum Vitae (CVs) to the Contracting Authority for review within the Technical Proposal and prior to personnel deployment for the duty positions.
- 13.7.8. As an integral part of the Project Management Plan, organisation structure shall be formalised and approved by the Contracting Authority 30 days after contract award. A final review 45 days after start of services shall be conducted to evaluate any situational changes required by issues or customer demand.
- 13.7.9. Adjustments within the first 45 days shall not incur additional cost in terms of service provision or Real Life Support. These adjustments also shall not dilute the proposed qualifications or skill levels of personnel.
- 13.7.10. Any organization structure changes resulting in personnel transfer or personnel level adjustments after this point require written justification and approval by the Contracting Authority.

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- 13.7.11. Projected personnel levels and skills requirements associated with position shall remain stable throughout the contract.
- 13.7.12. Ensure all required duty positions, designed in accordance with the Staffing and Manning Plan, are filled at all times. Personnel levels shall be developed in a manner to compensate for Rest and Recuperation (R&R) schedules, providing redundancy of skills to ensure adequate capability exist. The contractor will immediately notify the Contracting Authority's Technical Officer in the case unforeseen personnel shortfalls occur. The Contractor is responsible to assure, that shortfalls do not affect the operational planning at any time.
- 13.7.13. The Contractor shall clearly describe the personnel sourcing and hiring process within the Technical Proposal.
- 13.7.14. Describe necessary steps taken to ensure recruitment and hiring practices employed conform to the requirements by the Contracting Authority.
- 13.7.15. Describe use of hiring agencies (if any) to include third party agencies contacted or used by the primary hiring agency.
- 13.7.16. Define corporate level support offered or required to sustain project activities.
- 13.7.17. Provide outline of support capability in terms of skills and personnel available for this support.
- 13.7.18. Define how support will be obtained and expected amount of hours support can be provided.
- 13.7.19. The Contractor shall develop and implement a cost control and cost tracking program to assist the Contracting Authority. The Contractor shall include in the Project Management Plan the Operating Procedures (OPs) for the provisioning of supplies including acquisition procedures to ensure timely as well as cost effective provisioning of supplies and spares to support the equipment and facilities specified in this TR.
- 13.8. 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.
- 13.9. Medical Plan:

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- 13.9.1. As a minimum the Medical Plan shall address continuity of patient handling from and to Role 1 access to Role 3 medical capability, continuity of patient handling from and to Medical Evacuation (including Aeromedical Evacuation) and repatriation of dead, implementing MASCAL Response plan and arrangements for medical health recording and maintenance.
- 13.9.2. Medical Records. The Plan should describe what records are being maintained to support the healthcare of the employees. The security and property rights of the information should also be noted.
- 13.9.3. Provide a final update to the Contracting Authority prior to mobilizing personnel to theatre and review/update every six months. The details of support will change and should be amended during the semi-annual Medical Plan review.
- 13.9.4. Pre-Deployment Health Checks. The Contractor shall offer a health screening and vaccination regime to its employees as applicable to the deployed staff of European Union operations and missions. Hepatitis B vaccination to Medical Staff is mandatory.
- 13.9.5. The Contractor shall be ready to obtain medical insurance for its employees including medical repatriation to the respective home country if needed. Ops shall be under no liability in respect of the medical expenses of the Contractor.
- 13.10. Incident reports:
- 13.10.1. 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.
- 13.11. Operational Reports:
- 13.11.1. Reporting concerning operations in general will be done by HQ. The Contractor is obliged to provide data if asked by the MEDAD of the HQ and within the legal restraints concerning medical information and patient confidentiality.
- 13.12. All reports shall be submitted in the English language or as defined by the Contracting Authority.

### **14. Quality Assurance and Performance Measurement**

- 14.1. Response times in accordance with the Health and Medical Concept for EU-led Crisis Management Missions and Operations. Maintain acceptable levels of manning.
- 14.2. Medical evaluation, certification and re-evaluation costs are supposed to be included in the calculation for Role 2 expenses and have to be scheduled on a regular, at least

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annual base. In general military medical evaluation will be applicable unless otherwise agreed by the Contracting Authority.

- 14.3. Vehicle serviceability shall be guaranteed to support the capability at any time.
- 14.4. Meet established levels of supplies/ consumables in accordance with mission requirements at all times.
- 14.5. The Contractor shall establish an internal Quality Management Program.
- 14.5.1. The Contractor shall clearly define policies, procedures and mode of program execution within a Quality Management Plan (QMP). The QMP shall define levels of responsibility for program management, supervision, and surveillance performance by duty position and physical location/office of individual performing these duties.
- 14.5.2. Include a draft of the QMP with the technical proposal. Submit a final plan within 20 days after contract award with updates/reviews upon start of services and annually thereafter or any time a modification/revision is made. The QMP must be submitted to the Contracting Authority Quality Manager (QM) for review and approval.
- 14.5.3. The QMP shall be specifically tailored to operating location and direct work centre requirements. It must not merely reflect large scale company processes and procedures.
- 14.5.4. Develop Operating Procedures (OPs), Policies, Checklists, inspection/surveillance schedules, etc. to support all local program elements. Identify document requirements within the mobilisation period and coordinate development and review of these documents with the Contracting Authority QM not later than 20 days prior to start of service. Provide copies of these documents to the Contracting Authority QM for review and approval.
- 14.5.5. 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 in this document.
- 14.5.6. This program shall include Occupational Health and Safety as defined within Occupational Health and Safety Assessment Series (OHSAS) OHSAS 18000
- 14.5.7. This program shall include environmental management as defined within ISO 14001 series of standards.

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- 14.5.8. Applicable QMP elements (such as safety) shall be implemented upon contract award. All stages of program implementation and execution shall be monitored for health, safety and quality.
- 14.6. Monitoring criteria and Evaluation criteria: the Contracting Authority shall carry out monitoring and evaluation by in house or external expertise. Performance measures are to provide valid, useful practical and comparable measures of progress towards achieving expected results.

### 14.6.1. Monitoring criteria:

- 14.6.1.1. Quality of implementation: the appropriateness of the consultant activities/methodology in addressing the real problems, needs and priorities of the mission as required within the contract mandate, as well as the physical and policy environment within which it operates.
- 14.6.1.2. Efficiency of implementation: assessment of how well means and activities are converted into results and of the quality of the results achieved. This will be carried out also by comparing alternative approaches to achieving the same results, to see whether the most efficient approach has been adopted.
- 14.6.1.3. Effectiveness of implementation: Analysis of the contribution made by the obtained results to the achievement of the contract purpose. This includes an assessment of the benefits accruing to the mission and how assumption/risks affect the contract achievements and objectives.
- 14.6.1.4. Corrective measures will be identified with the consultant and shall be put into practice within an agreed timeline.

### 14.6.2. Evaluation criteria.

Role 2 medical facility services can be evaluated through the following indicative list of Performance Indicators per expected result:

#### 14.6.2.1. Design of the Role 2 medical facility:

1. Quality and applicability of the final design; measured by means of an on-off evaluation report to be carried out by the Base Commanders designated personnel; indicators may include the completeness and functionality of the designs, as well as the time and effort it took to reach consensus.

#### 14.6.2.2. Structure and fittings of the Role 2 medical facility, including their maintenance



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- Quality of assembly of the Role 2 MTF; measured by means of an on-off audit report to be carried out by the Base Commanders designated personnel; indicators may include the completeness and integrity of works, smooth integration with a Role 1, if applicable.
- Maintenance service level; measured on an on-going basis; indicators may include the number of maintenance issues reported by Project Manager and not resolved within reasonable timeframe.
- User satisfaction level; measured on an on-going basis; indicators may include the number of complaints / remarks / concerns of visitors and eligible patients

### 14.6.2.3. Connection with, and uninterrupted access to utility services, as required

- Availability of key utilities; measured on an on-going basis; main indicator is the number and duration of power and water outages within the Role 2 facility.
- Quality of waste removal services; measured on an on-going basis; main indicator is the number of complaints from the mission staff members regarding the Role 2 level of hygiene in the surrounding / open-space areas.

### 14.6.2.4. Equipment to be used in the Role 2 medical facility, including their maintenance

- Maintenance service level; measured on an on-going basis; main indicator is the number of maintenance issues reported by Project Manager and not resolved within reasonable timeframe.
- Functionality and hygiene of medical equipment; measured through internal audit report to be carried out by Project Manager (e.g. every six months); main indicator is number of failures or negative incidents.
- Appropriateness, completeness, functionality and hygiene of medical equipment; measured by external audit report to be carried by a qualified external consultant (e.g. annually); main indicator is number of failures or negative incidents.

### 14.6.2.5. Disposable items to be used in the Role 2 medical facility

- Functionality and Hygiene; measured by internal audit report to be carried out by Project Manager, as regards medical disposable items (every six months); main indicator is number of failures or negative incidents.
- Appropriateness, completeness, functionality and hygiene of medical disposable items; measured by external audit report to be carried by a qualified medical military expert (annually); main indicator is number of failures or negative incidents.

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### 14.6.2.6. Specialised medical personnel to staff the Role 2 medical facility

- Service Quality; patients will participate in quality evaluation surveys; through a questionnaire to be filled out by patients, the following indicative issues can be covered: respect for patients' needs and preferences, courtesy and helpfulness of medical staff, provision of emotional and physical comfort.
- Service Output; Contractor is expected to submit an annual statistical report based on response times, caseload, referrals to other hospitals.
- Service Compliance; to be evaluated by means of external audit reports to be carried out periodically by a qualified external consultant, concerning personnel adequacy and service level of medical care, as well as compliance with relevant directives (e.g. through analysis of duty scheduling, real-time observation, etc.).
- Service Effectiveness; (so called 'Clinical Governance') measured through internal audit report to be carried out by Project Manager on a monthly basis; main indicator is number of failures or negative incidents (e.g. erroneous diagnosis, delayed medical response, etc.).

## **15. Mobilisation/Demobilisation**

- 15.1. Planning factors for mobilisation milestone development include but are not limited to:
- 15.1.1. Management deployment and delivery of required plans.
  - 15.1.2. Facilities development and/or construction requirements completed.
  - 15.1.3. Initial Operational Capability (IOC). Personnel in place providing medical services capability Damage Control Surgery (DCS) and Advanced Life Support (ALS) as soon as possible, but not later than contractually agreed.
  - 15.1.4. Full Operational Capability (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, and a declaration made that all services are fully deployable and operational to support complete contracted capability. FOC is scheduled for not later than 14 days after arrival at the Base and within 30 days of Notice to Proceed (NTP). The Contractor shall include these planning factors in the mobilisation plan and provide projected minimum timelines for successful implementation of these mobilisation stages.
- 15.2. Provision of Real Life Support (RLS) Facilities and Services are outlined below. The statements below provide general guidance for planning considerations.

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- 15.2.1. The Contractor shall obtain formal approval from Cdr for all use of facilities and land required to support contract activities. The Contractor shall conduct all operations within the confines of the areas authorized/approved by the Commander or the Contracting Authority.
- 15.2.2. All construction shall conform to an established standard with approval from Base Authorities prior to construction start up. This includes meeting Force Protection requirements. Identify standards to be used within the Technical Proposal.
- 15.2.3. The Contractor must identify power requirements. The Contracting Authority shall verify power availability based on this information.
- 15.2.4. Water and sewer lines are fully developed throughout the installation.
- 15.3. The Provision of RLS during mobilisation, in-service and demobilisation phases:
- 15.3.1. The Contractor shall provide a description of RLS requirements within the technical proposal. Specifically list requirements for housing of personnel during and after transition phases.
- 15.3.2. The Contractor shall check with the Contracting Authority if the Cdr can provide RLS such as food, laundry, electricity, water and fuel for contractor personnel and vehicles deployed in support of this contract.
- 15.3.3. The Contractor shall identify other RLS costs and include them within the mobilisation and demobilisation pricing.
- 15.4. The Contractor shall provide all required Personnel and Administrative Equipment
- 15.4.1. Provide personnel protective equipment as required by health, safety and hygiene standards to support task accomplishment.
- 15.4.2. The Cdr will inform the Contractor if there will be a Chemical, biological, radiological and nuclear (CBRN) threat to be able to issue personnel CBRN gear and antidotes. Responsibility for the provision of CBRN medical devices might have to be shifted to Force generated MTF.
- 15.4.3. Provide all office furniture and supplies as required to provide services
- 15.5. Mobilisation Plan:
- 15.5.1. The Contractor shall include a Mobilisation Plan in the bid proposal describing the strategy and approach to deploying the required resources to perform the services

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specified and to provide the required Real Life Support (RLS) services to personnel for the duration of the contract.

15.5.1.1. Identify equipment and supply requirements.

15.5.1.2. Provide primary and alternative shipping proposals to address both cost and timeliness

15.5.1.3. Outline personnel housing requirements in terms of number of bed spaces required and timing of these requirements.

15.5.1.4. Detail any preparatory inspections, surveys, etc. required.

15.5.1.5. Facility development and/or construction requirements, equipment, supply and facility inspection requirements and proposed timeline shall be described.

15.5.1.6. Describe transition plan, risk to service mitigation and actions required to mitigate service disruption.

15.5.2. All mobilisations plans shall establish tangible milestones with dates for milestone achievement. Each milestone shall be agreed upon and established in the final contract mobilisation plan.

15.5.3. Once agreed upon, milestone achievement dates shall be directive in nature and monitored to ensure mobilisation success.

15.6. Mobilisation Reports:

15.6.1. The Contractor shall provide Weekly Mobilisation Reports to ATHENA/Contracting Authority 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 the Corrective Action (CA) and a revised schedule to ensure that the agreed upon performance start date is met.

15.6.2. The Contractor shall mobilise in an orderly and effective manner to ensure they are able to start the delivery of all the services on the given date.

15.6.3. The Contractor shall perform internal audits to evaluate level of readiness to provide services. A formal report of this evaluation shall be provided to the Contracting Authority Site Office no later than ten (10) working days prior to start of service.

15.7. Demobilisation:

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- 15.7.1. 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 from theatre.
- 15.7.2. The Contractor shall include a draft Demobilisation Plan in the proposal describing the strategy and approach for demobilizing the resources used in service provision. This plan must be updated and formalized not later than 6 months after start of services. This plan shall be fully coordinated through the Contracting Authority and reviewed annually at contract anniversary.
- 15.7.3. Demobilisation requirements include all activities necessitated to dispose 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.
- 15.7.4. Demobilisation plans shall address the areas of:
- 15.7.4.1. Project Management for demobilisation actions.
  - 15.7.4.2. Provision of Services until the end of contractual commitments.
  - 15.7.4.3. Infrastructure to include receiving disposition instructions which may include transfer of ownership, removal and return to source of origin, or destruction and disposal of all infrastructures.
  - 15.7.4.4. Vehicle and equipment disposition to include return to source of origin, transfer of ownership, sale, removal from country and/or destruction and disposal.
  - 15.7.4.5. Supply until end of contractual commitments and transfer / disposition of all stocks on hand.
  - 15.7.4.6. Human Resources to include Real Life Support requirements beyond end of contract service commitments and repatriation of employees.
  - 15.7.4.7. Communications Equipment disposal, closure of accounts and disposition of any classified items.
  - 15.7.4.8. Base Camp Issues to include environmental assessment and site remediation.
  - 15.7.4.9. Customs/Taxations issues arising from the sale, transfer, or disposal of assets.
  - 15.7.4.10. Force Protection requirements from end of service provision until last employee leave theatre.

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15.7.5. Specific demobilisation actions required include but are not limited to:

15.7.5.1. Performance of an environmental assessment in order to determine what changes have occurred to the site environmental baseline. The study shall as a minimum determine the changes to the environment due to contract activities.

15.7.5.2. Proposing a remediation plan to identify and address environmental issues that occurred or developed due performance of contract activities.

15.7.5.3. Performing all required remediation activities to address the environmental impact which was attributable to the contractor.

15.7.5.4. Demobilising of any associated sub-contractors,

15.7.5.5. Validation of asset registers and provision of an asset condition (serviceability) reports.

15.7.5.6. Providing Rough Order of Magnitude (ROM) for demobilisation activities.

15.7.5.7. Providing verification of asset disposition.

15.7.5.8. Providing verification of Human Resources demobilisation,

15.7.5.9. Management, tracking and transfer of open work orders,

15.7.5.10. Asset transfer between contractor and follow-on service provider or national authority,

15.7.5.11. Data transfer and sharing between contractor and follow-on service provider or activity,

15.7.5.12. Performance of all contract requirements until termination of contract,

15.7.5.13. Validation of demobilisation expenses and reimbursement of invoiced allowable costs.

15.7.5.14. Providing handover briefings and job-shadowing to follow-on service provider outlining established procedures, policy and routine practices.

15.7.5.15. Development and coordination of handover-takeover plan.

15.7.6. The Contractor shall 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.

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## Templates and Forms

0.1. To be developed in cooperation with the Base Commander and the Contracting Authority:

- 0.1.1. Manning Report: listing people by qualification.
- 0.1.2. Asset Register: identifying all assets, with condition and ownership.
- 0.1.3. Activity Log: record of incidents, training, repairs and deficiencies.
- 0.1.4. Medical Report: status of vaccinations, sickness and MEDEVACs.
- 0.1.5. Shift Report: list of personnel manning and stations.
- 0.1.6. Drug/Consumables List: itemising usage and retained stocks.
- 0.1.7. Vehicle Maintenance Log: checks, inspections, maintenance.
- 0.1.8. Facility Custodian Log: record all accommodation/station infra issues.
- 0.1.9. Health & Safety Accident Log: record all accidents/incidents.

## Summary of Plans, Reports and Delivery Dates

Reference	Description	First Delivery	Remarks (and subsequent deliveries)
Para 2.3	Publications Library	30 days after Start of Services	Updates as required
Para 5.6.2	Emergency Log	Mobilisation	Update as required
Para 5.6.3	Accident Investigation Log	Mobilisation	
Para 5.7.1	Emergency Response Plan	20 weeks after NTP	
Para 5.7.4	MASCAL Plan		
Para 5.7.4	External Response Plan		
Para 5.7.4	Emergency Route Plan	Mobilisation	
Para 5.8.2	Vehicle Tracking/Maintenance Plan	Mobilisation	
Para 5.8.3	Calibration Recording	Mobilisation	Monthly thereafter
Para 5.8.4	Medical Supply Account	Mobilisation	Monthly thereafter
Para 5.8.6	Cold Chain Records	Mobilisation	Monthly thereafter
Para 5.9	Preventive Maintenance Plan	30 days after NTP	
Para 2.1.1	Staff CV's and Resumes	2 months before signing contract and 2 months before replacement	As required thereafter
Para 7.3.5	Security Clearances	Mobilisation	As required

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<b>Reference</b>	<b>Description</b>	<b>First Delivery</b>	<b>Remarks (and subsequent deliveries) thereafter</b>
Para 1.12	EU Standard Language Check	2 months before signing contract and 2 months before replacement	As required thereafter
Para 16.1.8	Facilities Custodian	Mobilisation	As required thereafter
Para 9.3	Fire Warden(s) and Commodity Manager	Mobilisation	As required thereafter
Para 8.12	Property Accounts	Quarterly	
Para 5.8	Equipment Replacement Plan	20 weeks after NTP	Quarterly thereafter
Para 9.10	Inventory of Assets	Mobilisation	Quarterly thereafter
Para 11.3.1	Safety Management Plan	Technical Proposal	Provide final at start of service date. Review and update as required by ISO standards
Para 11.5	Safety Report	Weekly	
Para 13.2	Daily Shift Roster Vehicle Readiness Activity Report	Weekly/Monthly	Annual Report also
Para 13.7	Project Management Plan	Technical Proposal	Final 30 days after contract award
Para 13.7.3	Staffing / Manning Plan (Integral part of Project Management Plan)	Technical Proposal	Final 30 days after contract award. Formal review 45 days after start of services.
Para 13.9	Medical Plan	Technical Proposal	Reviewed at 6 months
Para 13.1	ATHENA Progress & Performance Report	3 months after Mobilisation	Update 6 monthly
Para 14.5	Quality Management Plan (QMP)	Technical Proposal	Final 30 days after Contract award and update 90 days after start of service
Para 15.5	Mobilisation Plan	Technical Proposal	Final upon contract award
Para 15.7.2	Demobilisation Plan	Technical Proposal	Update 6 months prior to end of service



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### Glossary

A(C)LS	Advanced (Cardiac) Life Support
AE	Aeromedical Evacuation
ALS	Advanced Life Support
AOO	Area of Operation
ATHENA	Mechanism established by Council Decision 2004/197/CFSP to administer the financing of common costs of Union operations having military or defence implications
ATLS	Advanced Trauma Life Support
BATLS	Battlefield Advanced Trauma Life Support
CA	Corrective Action
CBRN	Chemical, biological, radiological and nuclear
CDIP	Concept Development Implementation Programme
CIS	Communication and information Systems
Cdr	Commander
CFE	Contractor Furnished Equipment
CRP	C-reactive protein
CSDP	Common Security and Defence Policy
CT	Computer Tomogram
CV	Curriculum Vitae
DCR	Damage Control Resuscitation
DCS	Damage Control Surgery
eFast	extended Focused Abdominal Scan for Trauma
EMA	European Medicines Agency

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ER	Emergency Room and Reception Area
ER nurse	Emergency nurse
ESR	Erythrocyte Sedimentation Rate
EUMC	European Union Military Committee
EUMS	European Union Military Staff
FFP	Fresh Frozen Plasma
FOC	Full Operational Capability
FWC	Framework Contract
GDP	Good Distribution Practice
GMP	Good Medical Practice
HAZMAT	Hazardous Material
HDU	High Dependency Unit
HN	Host Nation
HQ	Operation/Mission Headquarters
ICC	International Civilian Contractor
IOC	Initial Operational Capability
ISO	International Organization for Standardization
IT	Information Technology
JMED	Joint Medical (Officer)
LFT	Liver functional test
MASCAL	Mass Casualty
MEDEVAC	Medical Evacuation
MEDAD	Medical Advisor

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MI(M)MMS	Major Incident (Military) Medical Management and Support
MS	Member States
MPCC	Military Planning and Conduct Capability
MPLAN	Mission Plan
MTF	Medical Treatment Facility
NTP	Notice to Proceed
OEMs	Original Equipment Manufacturers
OHQ	Operation Headquarters
OHSAS	Occupational Health and Safety Assessment Series
O&M	Operation and Maintenance
OPs	Operating Procedures
Ops	Military Operations and Missions
OPLAN	Operations Plan
OR	Operating room
OT	Operating Theatre
PAR	Population at Risk
PMP	Project Management Plan
POC	Point of Contact
POL	Petroleum, Oil, and Lubricant
Post-Op	Post-Operative
POW	Prisoner of War
PPE	Personal Protective Equipment
PSDC	La politique de sécurité et de défense commune

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QM	Quality Manager
QMP	Quality Management Plan
QMS	Quality Management System
RLS	Real Life Support
Role 2 B MTF	Role 2 Basic Medical Treatment Facility
R&R	Rest and Recuperation

## 10-1-2 Timelines

Common agreed minimal standard:

**First 10 minutes** — enhanced first aid (Immediate life saving measures applied by personnel having received a tactical combat casualty care course or comparable civilian training. Bleeding and airway control for the most severely injured casualties to be achieved within 10 minutes of wounding);

**Within 1 hour** — damage control resuscitation (DCR: resuscitative measures commenced by emergency medical personnel within 1 hour of wounding);

**Within 2 hours** — Damage control surgery (DCS: depending on the specific and individual requirement, the aim is to be able to provide DCS within 1 hour but no later than 2 hours of wounding).

RLS	Real Life Support
ROM	Rough Order of Magnitude
SMP	Safety Management Plan
SOFA	Status of Forces Agreement
SOMA	Status of Mission Agreement
SOP	Standard Operating Procedures
SOW	Statement of Work
STRATAE	Strategic Aeromedical Evacuation
TR	Technical Requirements

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TCN

Troup Contributing Nations

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### ANNEX I - REQUIREMENTS FOR PERSONNEL

#### 1. General Requirements

- 1.1. All requirements mentioned below shall be considered as minimum.
- 1.2. The Contractor is responsible for the safe accommodation of all contracted personnel in the AOO (Area of Operation). The HQ will denominate the location of the accommodation and Role 2.
- 1.3. The Contractor is responsible for transfer flights and/or shipping in and out of the AOO of the Contractor's employees.
- 1.4. The Contractor must provide full liability insurance. 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.
- 1.5. The Role 2 will be permanently on standby and ready for all casualties.
- 1.6. In case of temporary and sudden unavailability of any employee, especially key personnel, due to unforeseen reasons, an equivalent replacement must be available on the site within 24 hours. Such unavailability has to be reported without delay to the HQ.
- 1.7. All employees appointed by the Contractor must be holders of the necessary clearances and medical licences, from or accepted by at least one EU Member State, which have to be presented to the Contracting Authority Project Manager, and must be valid while the staff members are deployed in the Mission.
- 1.8. All employees must be healthy, physically, dentally and mentally fit for the Area of Operation. This includes preparatory measures (including necessary vaccinations) and a medical check before deployment to the AOO.
- 1.9. It should be planned to have the same staff on duty rosters not more than 3 months before rotating them.
- 1.10. Personnel have to wear suitable clothes for the designated tasks as advised by Project Manager in accordance with infection prevention and control guidelines.
- 1.11. Working hours and shift schedules have to be in accordance with European law and regulations.
- 1.12. 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. Furthermore at least 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.

#### 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 unless otherwise stated.

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- 2.1.2. 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
- 2.1.3. Professional/working experience in a national military role 1/2/3 or military training could be of advantage.
- 2.1.4. The Contractor is responsible for the Continuous Medical Education and other necessary training and meetings to maintain the licenses of the medical personnel. To maintain clinical currency, clinical personnel deployed will undertake duties for maximum of 4 months period only on rotation. Role 2 management personnel is excluded from this rule.
- 2.1.5. Medical personnel must be fit to perform as described in the SKILL SET ANNEX V.
- 2.2. If the population that needs to be treated by far exceeds 12500 persons then the Staff should be added with extra surgical teams.

### 3. Staff Requirements

#### 3.1. Physicians

- 3.1.1. University degree in Medicine in accordance with EU Commission directive 2005/36/EC or equivalent recognised by a EU member State;
- 3.1.2. Physician with a current EU Member states medical licence in their specialisation or equivalent officially recognised by a EU member State
- 3.1.3. Minimum 5 years of relevant professional experience after being certified in their specialisation; “medical currency”, and proven record of working in their specialisation in a hospital setting within the last twelve (12) months prior of a deployment to the Mission, demonstrating involvement, on average, at least 3 (three) days a week.
- 3.1.4. General professional expeditional experience: work in the context of a military role 1/2/3, UN level 1/2/3/4, humanitarian aid, natural disaster sites, post conflict areas, or equivalent is an advantage.

#### 3.1.5. Table Physicians

Physicians	Number	Specific requirement
Surgeon	2	Current and experienced in A(C)LS or equivalent, ATLS/BATLS or equivalent, MIMMMS or equivalent Certificate to execute and diagnose emergency X-Ray

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Anaesthesiologist	1 (+1)	Current and experienced in A(C)LS or equivalent, ATLS/BATLS or equivalent, MIMMMS or equivalent (pending on risk assessments two (2) Anaesthesiologist)
ER Specialist/ Ward	1	Current and experienced in A(C)LS or equivalent, ATLS/BATLS or equivalent, MIMMMS or equivalent
Physician	1	ER Experience and e.g. expertise in tropical medicine, CBRN, internal medicine, aviation medicine

### 3.2. Nurses:

- 3.2.1. EU Member State Registered Nurse in accordance with EU Commission directive 2005/36/EC or equivalent recognised by a EU member State;
- 3.2.2. Knowledge and working experience in a hospital, clinical nursing, operation theatre, HDU, including emergency medicine services and pre-hospital care;
- 3.2.3. Minimum 5 years of relevant professional experience after certification as registered nurse; “medical currency”, i.e. proven record of working as a nurse in their hospital setting within the last twelve (12) months prior of a deployment to the Mission, demonstrating involvement in at least 3 days a week, on average, during this period.
- 3.2.4. General professional expeditional experience: at least 1 month as nurse in the context of a military role 1/2/3, UN level 1/2/3, humanitarian aid, natural disaster sites, post conflict areas, or equivalent is an advantage.

### 3.2.5. Table Nurses

Nurses	Number	Specific requirement
HDU	3	Intensive care specification (one nurse per ventilated patient, one nurse per 2 (High Dependency) HD patients)
Operating theatre	3	At least: one specialised as nurse anaesthetist ; two specialised as Surgical nurse
Emergency Room	1	Current and experienced in emergency practice such as Immediate/Advanced Life Support; Trauma Nursing Core Course / Advanced Trauma Care for Nurses, etc.
Ward	1	

### 3.3. Paramedic ambulance driver:

- 3.3.1. State approved licence as paramedic ambulance driver by an EU Member State;
- 3.3.2. Minimum 2 years of relevant professional experience after being certified as registered paramedic ambulance driver;
- 3.3.3. Knowledge and working experience as an ambulance driver in emergency medicine services, pre-hospital care and transportation medicine;



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3.3.4. General professional experience: experience as paramedic ambulance driver in the context of military ambulance, UN level 1, 2 or 3, humanitarian aid, natural disaster sites, post conflict areas, or equivalent is an advantage;

3.3.5. Specific professional expeditional experience: at least 2 years of serving paramedic ambulance driver; “medical currency”, i.e. proven record of working as a paramedic ambulance driver within the last twelve (12) months prior of a deployment to the Mission, demonstrating involvement in at least 3 days a week as an paramedic ambulance driver , on average, during this period.

### 3.4. Technicians (laboratory/ pharmaceutical/ radiologist-diagnostic assistant)

3.4.1. State approved certificate in the required profession by a EU Member State;

3.4.2. Knowledge and working experience in a hospital or a medical practice including experience in the fields of hygiene and safe practice of the profession

3.4.3. Minimum 5 years of relevant professional experience after certification; “medical currency”, i.e. proven record of practical working in their profession within the last twelve (12) months prior of a deployment to the Mission, demonstrating involvement in at least 3 days a week, on average, during this period.

3.4.4. General professional expeditional experience: at least 1 month as an assistant/ technician in the context of a military role 1/2/3, UN level 1/2/3, humanitarian aid, natural disaster sites, post conflict areas, or equivalent is an advantage.

### 3.4.5. Table Technicians

Technicians	Number	Specific requirement
Laboratory Assistant	1	Including certified briefing on the laboratory devices to be used
Pharmaceutical Assistant	1	Including safe management of blood products
X-Ray technician (Operateur)	1	Including certified briefing on the radiologic devices to be used

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### ANNEX II - REQUIREMENTS FOR ROLE 2 INFRASTRUCTURE

#### 1. General Requirements

- 1.1. All requirements mentioned below shall be considered as minimum.
- 1.2. The contractor shall arrange rooms and units related to the Real Life Support to the hospital staff and segregate the needs of the patients from the staff (sanitation, kitchen area, social and meeting rooms, changing rooms (beginning & end of shift / work hours, separate WC / restrooms / showers for staff & patients, ).
- 1.3. Walls, floors and ceilings in cleanrooms and in clean zones should be designed and constructed in such a way that the surfaces are accessible for cleaning. In a room, this generally includes the walls, floors, ceilings and doors, the inlet side of air diffusers and floor drain, etc.
- 1.4. Construction and materials are to be conform to ISO 14644-4 Cleanrooms and associated controlled environments – part 4: Design, construction and start-up. All exposed materials should be suitable for effective and frequent cleaning and disinfection, and offer no surface asperities or porosity which is likely to allow retention of particulate and chemical contamination, or the development of microbiological contamination. Methods for selecting, applying and controlling suitable procedures for cleaning and disinfection are indicated in ISO 14698-1 and ISO14698-2. All walls should have approved insecticide treatment.
- 1.5. The flooring of the Role 2 should be:
  1. Nonslip/hardwearing,
  2. Vinyl/resin/polyurethane type flooring,
  3. Seamless and edged up the wall by at least 200mm,
  4. Resistance to solvents,
  5. Resistance to detergents,
  6. Anti-static
- 1.6. The most essential rooms should be made to give collective CBRN protection. Evacuation precautions have to be prepared in case of a CBRN incident.
- 1.7. All infrastructure units allow for internal power distribution module, air-conditioning, lockable hard touch-free/handle-free doors, raised floors, noise protection, and illumination. Passage ways are included in the infrastructure architecture; delivering a closed path system for patients and medical staffs. All examination rooms and wash rooms with sinks and no touch taps.
- 1.8. Role 2 climate control:
  7. Heating,
  8. Cooling,
  9. HEPA filtered climate control in the treatment area.

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- 1.9. Interior lighting shall be provided at a minimum of 500 lux 75cm above ground. The examination and treatment area will be a minimum of 1000 lux.
- 1.10. The mains shall be installed secure including prevention to earth leak currents.
- 1.11. The Role 2 deployment includes the following infrastructure and utility services:
  10. Communications (radio and internet connectivity)
  11. Climate control in all rooms
  12. Power and electric system in all rooms, back-up power system to maintain live saving devices
  13. Potable water system, purification and reticulation
  14. Water distribution and collection system
  15. Waste management system
  16. Incinerator
  17. Fire extinguishers
  18. Emergency lighting
- 1.12. An adequate hygiene plan has to be established according to national law and guidelines in one of the Member States of the European Union.

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### ANNEX III - REQUIREMENTS FOR ROLE 2 MEDICAL EQUIPMENT SETUP

#### 1. General Requirements

- 1.1. All requirements mentioned below shall be considered as minimum.
- 1.2. 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.
- 1.3. Medical devices with alarms and signals shall provide a clear visual and auditive signal and buttons, switches, indicators, controls etc. shall be easily accessible and clearly readable (English unless otherwise defined) under all conditions.
- 1.4. 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.
- 1.5. 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 -20 °C to 60 °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.
- 1.6. 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.
- 1.7. The Role 2 needs to have a patient transport bag for CBRN patients after decontamination or for severe contagious patients for transport in an ambulance and MEDEVAC.

#### 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. Essential medical equipment shall be provided with batteries and electrical connector(s) in order to prevent interruption of the power supply.
- 2.3. 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.

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### 3. Gas supply

- 3.1. Pressure regulators with and without 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. 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  $\mu\text{m}$  shall be provided between the cylinder(s) and the first pressure regulator.
- 3.5. Compability to the systems used in medical evacuation assets (ambulances, MEDEVAC) in the Area of Operation should be taken into account.

### 4. Role 2 surgical, treatment and emergency rooms

- 4.1. The treatment and emergency rooms, 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. A possibility to elevate the patient's upper body and/or legs needs to be considered.
- 4.2. The medical device and its position in the treatment and emergency room 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.
- 4.3. There shall be a fixed lockable container available for the storage of controlled drugs. Means shall be provided for medical pharmaceutical and human blood (whole blood and plasma) to be stored uninterrupted at the necessary temperature range. Temperature control tables should be provided for quality management unless an automatic temperature control is implemented.
- 4.4. It is desirable to have windows in the patient compartment being positioned or screened to ensure the privacy of patients when required. To prevent hypothermia the regulation of the room temperature to 18 - 28  $^{\circ}\text{C}$  should be in place at all times.

### 5. Medical Supply Unit

- 5.1. The infrastructure for the Medical Supply Unit must provide sufficient capacity and capability to safely store pharmaceuticals and medical consumables and avoid contamination, mix-up or cross-contamination. They should be designed and maintained to ensure good storage conditions within acceptable environmental limits.

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This includes not exclusively room temperature control, cool, cold, freezer capabilities and humidity.

- 5.2. Precautions must be taken to unauthorized access. Narcotics and other hazardous, sensitive and/ or dangerous material and pharmaceutical products, as well as substances presenting a special risk for abuse, fire or explosion, should be stored in a dedicated area that is subject to appropriate additional safety and security measurements.
- 5.3. Storage conditions for pharmaceutical products and materials should be in compliance with the labelling specifications of the manufacturer. Special storage conditions required on the label should be provided, checked, monitored and recorded.
- 5.4. Adequate hygiene measurements have to be applied to all storage facilities.
- 5.5. Materials and pharmaceutical products should be transported not impairing their integrity and maintaining the storage conditions.
- 5.6. Quality Management should include the regular and up-to-date monitoring of in and outgoing materials and pharmaceuticals. Special attention must be paid to the special requirements for the handling of blood and blood products.
- 5.7. All stock must be regularly controlled for outdated or obsolete material or pharmaceutical products.
- 5.8. Equipment used to control or to monitor the environment where the medicinal products are stored should be calibrated at defined intervals based on a risk and reliability assessment.
- 5.9. Medical Waste shall be handled according to Directive 2008/98/EC and the Guide for sustainable waste management in the Health-care sector.
- 5.10. Premises should be designed and equipped so as to afford protection against the entry of insects, rodents or other animals. A preventive pest control programme should be in place.

### **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.

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### 7. Medical devices, products and equipment for Emergency's Role 2 and ambulance

- 7.1. Ambulance is defined as a vehicle equipped for supportive medical care.
- 7.2. Ambulance equipment to provide resuscitative care, administer basic drugs and administration of intravenous fluids during transport of the patient to a higher level of medical care or from or to an Aeromedical Evacuation.
- 7.3. The ambulance shall be in good working condition and capable of transferring at least 2 stretcher patients at a time, including all medical equipment for monitoring to ensure continuum of care for ventilated patients. Storage conditions for stored medical products should be regularly controlled.
- 7.4. Advanced communication capability for coordination with PECC and accompanying units.
- 7.5. The vehicle shall be maintained, and kept serviceable through a system of proactive scheduled management. Effective procedures and decontamination regimes shall be provided by the contractor for the vehicle.
- 7.6. Ambulances with their personnel of the Role 2 B MTF in the camp or in the surrounding camps would provide additional support in an emergency or a MASCAL situation as per the particular mission Standard Operating Procedures (SOP) describes

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### ANNEX IV – PHARMACEUTICAL STOCK HOLDINGS AND BLOOD/PLASMA

#### 1. General

- 1.1. Shipping and transport of all medical consumables and pharmaceuticals, including blood and blood products must apply to the labelled conditions for storage. Cold chain integrity shall be preferably controlled by means of electronic loggers that are shipped with the items.
- 1.2. The Contractor is to provide all pharmaceuticals relevant to the achievement of Role 2 and ambulance responsibilities. The Contracting Authority shall be able to inspect the Supplier's pharmaceutical stock to ensure the minimum contracted capability and the inventory readiness are guaranteed as specified in the agreed Inventory List.
- 1.3. The Stock should support at minimum 10 inpatients for 2 months.
- 1.4. All drugs should be approved by the European Medicines Agency (EMA) Medical with an instruction in English.
- 1.5. Storage of pharmaceuticals and consumables has to follow the manufacturer specification and be controlled and documented according to European Commission Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01), EU Directive 2011/62/EU and WHO Guide to Good Storage Practice for Pharmaceuticals.
6. Blood products managements have to be at least applicable to EU Directive 2002/98/EG.
7. At each storage site there should be an adequate number of qualified personnel to achieve pharmaceutical quality assurance objectives. National regulations on qualifications should be followed; in case of doubt the national law of the place of jurisdiction should be applied.
8. Medical Waste management should be applicable to Directive 2008/98/EC.
9. Table of Drugs and Blood products

<b>Groups of Medicinal products (Drugs) and Blood products</b>
Analgetics, general and local
Antipyretics
Antibiotics, antiparasitic, antiviral, including malaria prophylaxis
Respiratory drugs
Cardiovascular drugs (including Thrombolytica)
Gastro-intestinal drugs
Musculo-skeletal drugs
Anti-anxiety drugs
Ophthalmology drops and ointment
ENT drugs
Topical drugs



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Resuscitation drugs
Anaesthesia drugs
Narcotics
Intravenous infusion fluids
Vaccines and Immunoglobulines (including Human Rabies HRIG)
Antidotes: against local venoms, CBRN antidotes according to lead nation
CBRN decontamination products for patients (in cooperation with military authorities)
Blood and Plasma, transfusion services. Whole blood, packed cells - as a minimum 30 Red Cell concentrates (minimum 15 Blood Group 0 and Rhesus negative) – 20 units of fresh frozen plasma (FFP))
Refrigerator, Freezer, Pharmaceutical Storage

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**ANNEX V - SKILL SET**

<b>Module</b>	<b>Capability</b>	<b>Skill Set</b>
<b>Surgical</b>	Deliver surgical care according to damage control resuscitation principles and/or emergency and/or elective surgery	The Surgical Module must be able to manage a trauma patient (Blast, Burns, etc.), manage pre and post-operative care, anaesthetise a patient, provide Advanced Life Support and surgical care for critically injured trauma patient. In addition it may be able to deliver emergency and/or elective surgery, manage the OR and patient transfer.
	Manage trauma patients	<ul style="list-style-type: none"> <li>- Perform triage</li> <li>- Manage a patient (including CBRN) according ATLS or Battle ATLS principles (i.e. conduct Damage Control Resuscitation; perform general anaesthesia, analgesia, immobilisation, etc.)</li> <li>- Perform eFAST</li> <li>- Dress and bandage wounds</li> <li>- Check plasters and splints</li> <li>- Ensure cleanliness and comfort of patient</li> <li>- Manage post-operative trauma ward care</li> <li>- Prescribe medical treatment</li> </ul>
	Anaesthetise a patient	<ul style="list-style-type: none"> <li>- Perform pre-operative assessment</li> <li>- Perform general anaesthesia</li> <li>- Perform local anaesthetic technique</li> <li>- Perform regional anaesthesia</li> <li>- Manage care in the recovery area</li> <li>- Prescribe medical treatment</li> </ul>

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	<p>Manage peri-operative care and Advanced Life Support</p>	<ul style="list-style-type: none"> <li>- Perform basic airway techniques and provide support for advanced airway techniques and casualty resuscitation</li> <li>- Prepare and/or supervise the preparation of the operating room</li> <li>- Manage pre and post-operative care</li> <li>- Manage the provision of analgesia and assessment of its efficiency</li> </ul>
	<p>Deliver Surgical Care</p>	<ul style="list-style-type: none"> <li>- Perform pre-operative assessment</li> <li>- Perform damage control surgery including:             <ul style="list-style-type: none"> <li>o Insertion of thoracic drain</li> <li>o Control of thoracic hemorrhages</li> <li>o Perform tracheotomy</li> <li>o Hemorrhage control (temporary hemostasis, limb vascular shunts etc.)</li> <li>o Intestinal exclusion, bile and pancreatic drainage, drain for pancreatic and/or hepatic secretion</li> <li>o Solid organ inspection and abdominal packing (liver, splenic, retroperitoneal and pelvic hemorrhage), splenectomy, nephrectomy.</li> </ul> </li> <li>- Laparotomy</li> <li>- Perform abdominal revision surgery</li> <li>- Damage Control orthopedic Surgery:             <ul style="list-style-type: none"> <li>o limb (debridement and external fixation)</li> <li>o spine (debridement and spine stabilization)</li> <li>o external bone fixation</li> <li>o amputation</li> </ul> </li> </ul>

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	Deliver Surgical Care	<ul style="list-style-type: none"> <li>- Escharotomy</li> <li>- Perform surgery: <ul style="list-style-type: none"> <li>o Soft tissue</li> <li>o Abdominal</li> <li>o Thoracic</li> <li>o Vascular</li> <li>o Uro-genital</li> <li>o Limb debridement and external bone fixation or amputation</li> <li>o Spine (debridement and spine stabilization)</li> <li>o Brain trauma (trepanation for epidural or subdural hematoma) when a specialized surgeon is not available</li> </ul> </li> <li>- Manage post-operative ward care</li> <li>- Prescribe medical treatment</li> </ul>
	Manage operating room (OR)	<ul style="list-style-type: none"> <li>- Organize OR equipment and stores</li> <li>- Prepare specific equipment for casualty treatment</li> <li>- Control and dispose of contaminated waste and equipment</li> <li>- Maintain and clean OR</li> <li>- Maintain stock levels (drugs, blood and materials)</li> </ul>
	Prepare patient for transfer	<ul style="list-style-type: none"> <li>- Knowledge of the use and limitations medical transport (ground, air and sea)</li> <li>- Explain transport procedures to patient</li> <li>- Prepare the patient for transfer (in-hospital and/or inter-hospital)</li> <li>- Preparation of equipment for casualty evacuation</li> <li>- Inform higher MTF level and commanders (MEDEVAC procedure)</li> <li>- Complete medical records and transfer documentation to ensure proper handover</li> <li>- Include procedures to be followed in case of death</li> </ul>
	Respond to MASCAL	<ul style="list-style-type: none"> <li>- Be able to act IAW the established MASCAL plans and procedures</li> </ul>

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Module	Capability	Skill set
<b>Emergency Area</b>	It ensures the emergency management of critically ill or trauma patients	The module must be able to assess and manage critically ill or trauma patients. Maintain stock levels and be able to prepare patients for transfer and perform administrative tasks. It must be able to manage infectious and CBRN contaminated patients (if applicable).
	Assess and manage critically ill or trauma patients	<ul style="list-style-type: none"> <li>- Manage a patient according ATLS or BATLS procedures (i.e. conduct DCR, perform general anaesthesia, analgesia, immobilisation, triage, etc.)</li> <li>- Assess patient and deliver high care</li> <li>- Understand and manage monitoring equipment and respiratory support (including ventilators) and other technical equipment as required</li> <li>- Prepare and administer medical treatment</li> <li>- Provide adequate pain relief and adjust treatment as necessary</li> <li>- Perform blood transfusion</li> <li>- Dress and bandage wounds</li> <li>- Check comfort and fit of plasters and splints</li> <li>- Ensure cleanliness and comfort of patient</li> <li>- provide general ward clinical support on request</li> </ul>
	Manage infectious and CBRN contaminated patients	<ul style="list-style-type: none"> <li>- Recognize CBRN patients</li> <li>- Triage CBRN patients</li> <li>- Perform CBRN patient assessment including ‘Quick Look’</li> <li>- Provide life-saving interventions in a CBRN environment including trauma</li> <li>- Perform patients hazard management (contain, decontamination and/or isolation)</li> <li>- Manage chemical patients</li> <li>- Manage biological patients including sepsis</li> <li>- Manage radiological patients including nuclear</li> <li>- Manage the medical aspects of a CBRN incident (hospital phase)</li> </ul>

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	Supervise stock levels	<ul style="list-style-type: none"> <li>- Control stocks of drugs and other materiel stock</li> <li>- Control oxygen stocks</li> <li>- Manage clinical waste</li> </ul>
	Prepare patient for transfer	<ul style="list-style-type: none"> <li>- Knowledge of the use and limitations medical transport (ground, air and sea)</li> <li>- Explain transport procedures to patient</li> <li>- Prepare the patient for transfer (in-hospital and/or inter-hospital)</li> <li>- Preparation of equipment for casualty evacuation</li> <li>- Inform higher MTF level and commanders (MEDEVAC procedure)</li> <li>- Complete medical records and transfer documentation to ensure proper handover</li> <li>- Include procedures to be followed in case of death</li> </ul>
	Conduct administrative tasks	<ul style="list-style-type: none"> <li>- Manage medical data recording before evacuation</li> <li>- Know command procedures according the appropriate SOP's</li> </ul>
	Respond to MASCAL	<ul style="list-style-type: none"> <li>- Be able to act IAW the established MASCAL plans and procedures</li> </ul>

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Module	Capability	Skill set
<b>Command, Control, Communication, Computers and Information (C4I)</b>	Provides all C4I	The module must be able to provide command and control using the available communication, computers and information systems to ensure the functioning of applicable modules, systems and processes. It is able to arrange contingencies for MASCAL.
	Provide command	<ul style="list-style-type: none"> <li>- Be able to perform, direct and guide IAW the applicable (MMU/ MSS) command processes in order to fulfil the assigned tasks efficiently and effectively at all times</li> <li>- Be aware of the assigned task, responsibilities and restrictions within the functional area</li> <li>- Be aware and be able to apply the Medical Rules of Eligibility</li> <li>- Be aware to handle according to the applicable national regulations and legal constraints for each participating or contributing nation</li> <li>- Arrange contingencies for MASCAL, establish MASCAL plans and procedures</li> </ul>
	Provide control	<ul style="list-style-type: none"> <li>- Control the manning of the medical and supporting elements to ensure medical support IAW the assigned tasks</li> <li>- Ensure interoperability between each medical and supporting elements</li> <li>- Control the effective functioning of applicable modules, systems and processes</li> <li>- Have knowledge of the available means to control the medical, logistical and personnel related processes</li> <li>- Be able to respond and control a MASCAL situation.</li> </ul>
	Provide communication	<ul style="list-style-type: none"> <li>- Have knowledge of the available communication means</li> <li>- Ensure the effective use of the available communication means</li> <li>- Be aware of and be able to make the proper use of the applicable communications procedures</li> </ul>

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Module	Capability	Skill set
	Provide computers	<ul style="list-style-type: none"> <li>- Ensure the availability of the required systems at all times in order to operate the system including telemedicine</li> <li>- Ensure logging of all available digital information</li> <li>- Ensure the use of a data backup system</li> <li>- Ensure the availability of backup procedures or system in order to continue operations</li> <li>- Ensure the safety of privileged data IAW the regulations in effect.</li> </ul>
	Provide information	<ul style="list-style-type: none"> <li>- Be able to validate/verify information</li> <li>- Be able to assess, analyse and apply received information required to function effectively</li> <li>- Be able to disseminate information effectively</li> <li>- Have knowledge of and make use of the appropriate logging and reporting requirements</li> <li>- Confidential data dissemination</li> </ul>



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Module	Capability	Skill set
<b>Post-Operative (PostOp) / High Dependency Unit (HDU)</b>	Manage Post-operative patient care and transfer	Post-Op must be able to manage post-operative patients, including the provision of sedative care and pain control. It must be able to prepare the patient for transfer. It controls stock levels.
	Manage PostOp patient	<ul style="list-style-type: none"> <li>- Be able to assess PostOp patient</li> <li>- Be able to perform Damage Control Resuscitation</li> <li>- Be able to treat a critically ill patient or injured patient</li> <li>- Perform blood transfusion</li> <li>- Provide general ward clinical support</li> <li>- Maintain communications</li> </ul>
	Provide sedative care	<ul style="list-style-type: none"> <li>- Perform patient assessment</li> <li>- Prescribe sedative regime</li> <li>- Monitor level of sedation and adjust regime, if necessary</li> <li>- Be able to provide pain control</li> </ul>
	Manage patient transfer	<ul style="list-style-type: none"> <li>- Prepare patient for transfer</li> <li>- Manage an in-hospital transfer</li> <li>- Manage an inter-hospital transfer</li> <li>- Produce all technical and administrative documents (general ward clinical support, operative report)</li> <li>- Include procedure to be followed in case of death</li> </ul>

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	MEDEVAC procedures	<ul style="list-style-type: none"><li>- Knowledge of the use and limitations medical transport (ground, air and sea).</li><li>- Explain transport procedures to patients.</li><li>- Capability to undertake transfer of critically ill patients</li> <li>- Produce all technical and administrative documents (general ward clinical support,</li></ul>
	Supervise stock levels.	<ul style="list-style-type: none"><li>- Ensure adequate stock levels of:</li><li>- Blood and blood products</li><li>- Oxygen</li><li>- Drugs</li> <li>- Include the resupply sources and procedures</li></ul>
	Respond to MASCAL	<ul style="list-style-type: none"><li>- Be able to act IAW the established MASCAL plans and procedures</li></ul>

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Module	Capability	Skill set
<b>Patient Holding</b>	Provide nursing care and management of patients	The module must be able to temporarily manage critically ill patients or critically wounded casualties, provide high care nursing and, if applicable, post-operative nursing care. It is able to prepare patient for transfer.
	Manage critically ill patients or critically wounded casualties	<ul style="list-style-type: none"> <li>- Basic knowledge of triage procedures</li> <li>- Be able to perform Basic Life Support (BLS) procedures</li> <li>- Assist medical personnel in Advance Life Support (Trauma) Survey dressings (i.e. abdominal vacuum pack, bandages, limb dressing etc.)</li> <li>- Survey plastered and splinted limbs</li> <li>- Ensure cleanliness and comfort of patient</li> <li>- Provide general ward clinical support on request</li>   <li>- Basic knowledge of decontamination procedures (contaminated and infectious).</li> </ul>
	Manage high nursing care including postoperative nursing care	<ul style="list-style-type: none"> <li>- Assist and inform physician</li> <li>- Assess patient and deliver nursing care</li> <li>- Understand and manage monitoring equipment and respiratory support and other technical equipment as required</li> <li>- Prepare and administer medical treatment</li> <li>- Provide adequate pain relief</li> <li>- Ensure cleanliness and comfort of patient</li> </ul>
	Supervise stock levels	<ul style="list-style-type: none"> <li>- Control stocks of drugs and other materiel stock</li> <li>- Control oxygen stocks</li> <li>- Manage clinical waste</li> </ul>

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	Prepare patient for transfer	<ul style="list-style-type: none"> <li>- Knowledge of the use and limitations medical transport (ground, air and sea)</li> <li>- Explain transport procedures to patient</li> <li>- Prepare the patient for transfer (in-hospital and/or inter-hospital)</li> <li>- Preparation of equipment for casualty evacuation</li> <li>- Inform higher MTF level and commanders (MEDEVAC procedure)</li> <li>- Complete medical records and transfer documentation to ensure proper handover</li> <li>- Know procedures to be followed in case of death</li> </ul>
	Respond to MASCAL	<ul style="list-style-type: none"> <li>- Be able to act IAW the established MASCAL plans and procedures</li> </ul>
<b>Module</b>	<b>Capability</b>	<b>Skill set</b>
<b>Specified Diagnostic</b>	Provide field laboratory testing and basic imaging	The module must be able to provide digital field radiography, ultra sound (sonography) and basic laboratory services. It is able to respond to MASCAL.
	Provide field radiography and ultra sound (sonography) and basic laboratory services	<ul style="list-style-type: none"> <li>- Perform radiography, imaging and ensure radio protection</li> <li>- Provide standard x-ray views</li> <li>- Develop x-ray films (optional)</li> <li>- Perform eFAST</li> <li>- Control and dispose of contaminated waste and equipment</li> <li>- Provide minimum field laboratory support required for surgery and resuscitation</li> <li>- Collect clinical samples</li> <li>- Analyse clinical samples</li> <li>- Ensure supply of consumables</li> <li>- Ensure registration of laboratory results and samples</li> <li>- Perform basic maintenance of laboratory and radiography equipment</li> </ul>

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Module	Capability	Skill set
	Respond to MASCAL	- Be able to act IAW the established MASCAL plans and procedures
Module	Capability	Module Core Capability Description
<b>Medical Supply Unit</b>	Provide drugs and medical (disposable) supply and supply coordination under supervision of a pharmacist in accordance with Good Distribution Practice.	<ul style="list-style-type: none"> <li>- Be able to deploy the capacity to provide sufficient medical supply tailored to the number and type of MTF's to be supported.</li> <li>- Be able to advise the commanders of the supported units and medical modules in the domains of pharmacy and medical (re)supply.</li> <li>- Be able to manage the stock and the distribution of medical materiel. Be able to verify calibration and repair or replace malfunctioning equipment.</li> <li>- Be able to assure safe storage and handling of all pharmaceuticals</li> <li>- Be able to assure the quantitative and qualitative reception and distribution of blood and blood products. (if applicable)</li> <li>- Be able to assure the (re-)supply of medical gases.</li> <li>- Be able to advice on the handling of medical waste.</li> <li>- Be able to assure Quality management in regard to GDP</li> <li>- Be able to respond to MASCAL</li> </ul>
	Respond to MASCAL	- Be able to act IAW the established MASCAL plans and procedures

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### ANNEX VI - References

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2. Minimum Technical Requirements for Contracted in-theatre Role 1 services for EU Operations and Missions EEAS(2017) 76 REV 4
3. EU concept for Contractor Support to EU-led military operations
4. Minimum Technical Requirements for Contracted In-Theatre Aeromedical Evacuation Services for EU Operations and Missions EEAS(2016) 933 REV 3
5. European Union Concept for EU-led Military Operations and Missions EEAS 00990/6/14 REV 6
6. EU Concept for Logistic Support for EU-led Military Operations and Missions EEAS 01580/5/14 REV5
7. European Union Military Concept on Environmental Protection and Energy Efficiency for EU-led military operations EEAS 01574/12
8. EUMC Glossary of Acronyms and Definitions, EEAS (2015) 216, 13. February 2015
9. EU Commission - Medical Device Directive 93/42/EEC
10. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC
11. Directive 2005/36/EC of the European Parliament and of the Council, 7 September 2005 on the recognition of professional qualifications
12. Directive 2003/88/EC of the European Parliament and of the Council of 4 November 2003 concerning certain aspects of the organisation of working time
13. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 on setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC
14. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use
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22. Council Directive of 14 June 1993 covering medical devices (93/42/EEC)

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