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From:	European External Action Service (EEAS)
To:	European Union Military Committee (EUMC)
Subject:	Minimum Technical Requirements for Contracted in-theatre Role 1 services for EU Operations and Missions

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Delegations will find attached document EEAS(2017) 76 REV 4.

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# EUROPEAN EXTERNAL ACTION SERVICE



## Working document of the European External Action Service

of 5 April 2017

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This document contains 72 pages, including the cover page.

# EUROPEAN EXTERNAL ACTION SERVICE



## EUROPEAN UNION MILITARY STAFF

**Brussels, 5 April 2017**

**EEAS(2017) 76 REV 4**

**CSDP/PSDC  
EUMC**

### **NOTE**

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From:	European Union Military Staff (EUMS)
To:	European Union Military Committee (EUMC)
No. Prev. doc.:	-
Subject:	MINIMUM TECHNICAL REQUIREMENTS FOR CONTRACTED IN-THEATRE ROLE 1 SERVICES FOR EU OPERATIONS AND MISSIONS

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Delegations will find attached the revised draft "MINIMUM TECHNICAL REQUIREMENTS FOR CONTRACTED IN-THEATRE ROLE 1 SERVICES FOR EU OPERATIONS AND MISSIONS ", as agreed during EUMCWG on 30 March 2017.

**MINIMUM TECHNICAL REQUIREMENTS**  
**FOR**  
**CONTRACTED IN-THEATRE ROLE 1 SERVICES FOR EU OPERATIONS AND**  
**MISSIONS**

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## **1. Introduction and Aim**

- 1.1. The purpose of this document is to provide minimum Technical Requirements (TR) for contractor support to EU-led military Operations and Missions (Ops/M). It expands the guidelines within EU concepts and provides guidance on requirements for contracting in-theatre Role 1 to Troop 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. Normally the Role 1 MTF Health and Medical Support is integral or allocated to a unit and remains national responsibility. The civilian contracted Role 1 will comprise the provision of routine sick calls and the management of the minor sick and injured for immediate return to duty (RTD) as well as specialised first aid, triage and immediate life-saving and stabilisation measures. Besides basic occupational and preventive medical advice to the chain of command it is also responsible for the patient transport from any point on the base to the Role 1 and the preparation of casualties for evacuation to a higher level MTF, including patient tracking, evaluating and reporting. The latter depending on the SOP of the mission.
- 1.3. If a mission consists of many nationalities on one location and no nation can provide a Role 1 MTF a contracted Role 1 is the last resort.
- 1.4. For the purposes of these technical requirements Role 1 medical services are defined as being Primary Health Care (PHC) on general practitioner level (including basic occupational and preventive medicine advise and nursing) as well as Prehospital (Emergency) Care (including triage/MASCAL handling and stabilization medical services).
- 1.5. The table below states the framework for mandatory and additional capabilities. Specific details on the clinical capabilities associated with this definition are provided within Chapter 5.

Capability	Role 1 Core Capability Description
<b>Overall capabilities: Provision of primary healthcare and pre-hospital care (PHC)</b>	<p>The Role 1 must be able to ensure general medical practice including basic occupational and preventive medicine advice, pre-hospital (emergency) as well as nursing care.</p> <p>This includes <u>always</u></p> <ul style="list-style-type: none"> <li>- first emergency physician lifesaving and stabilizing treatment for sick, wounded or injured patients,</li> <li>- responding to MASCAL (Mass Casualties) situations,</li> <li>- performing patient tracking,</li> <li>- guaranteeing thorough medical documentation,</li> <li>- conducting administrative tasks,</li> <li>- managing stores for sterile equipment, medicines and consumables.</li> </ul> <p><u>If applicable</u>, it must be able to transfer patients in a qualified, medical accompanied way from place of sickness, wounding or injury to Role 1 and from Role 1 to the next suitable medical treatment facility.</p> <p><u>If applicable</u>, it must be able to manage CBRN contaminated patients and/or highly infectious patients of an epidemic plagues (outbreak).</p> <p><u>If applicable</u>, it must be able to perform field sterilization and control stock levels in transport assets.</p>
<b>Mandatory capabilities: Provision of general medical practice including basic occupational and preventive medicine advice</b>	<ul style="list-style-type: none"> <li>a. Assess and treat patients</li> <li>b. Refer patients to specialized care when required</li> <li>c. Record and update patient related observations and treatment</li> <li>d. Produce all technical and administrative documents for patient (minimum core data, epidemiologic table)</li> <li>e. Issue medical certificates</li> <li>f. Deliver preventive medical treatment</li> <li>g. Control and realize vaccinations</li> <li>h. Prepare and train the medical teams</li> <li>i. Ensure that personnel exposed to a blast potentially affected by a Mild Traumatic Brain Injury (mBTI) is identified and traced. This information is transmitted to the appropriate national defense health service</li> <li>j. Be able to manage a patient exposed to hazardous materials (HAZMAT)</li> <li>k. Understand procedures to be followed in case of death</li> <li>l. Record medical activities</li> <li>m. Know command procedures</li> </ul>

<b>Mandatory capabilities: Provision of pre-hospital (emergency) care including handling of MASCAL situations</b>	<ul style="list-style-type: none"> <li>a. Assess and categorize patients based on their general condition</li> <li>b. Perform basic and advanced (trauma) life support</li> <li>c. Apply general principles of emergency care at Primary Healthcare level (e.g. pre-hospital trauma life support)</li> <li>d. Perform analgesia (intravenous and/or local or regional anaesthesia)</li> <li>e. Perform immobilization</li> <li>f. Conduct triage. Know the rules of triage at individual and multiple patient level</li> <li>g. Establish MASCAL plans and procedures and act in accordance with</li> <li>h. Ensure patient tracking</li> </ul>
<b>Mandatory capabilities: Managing of nursing care</b>	<ul style="list-style-type: none"> <li>a. Assess patient and deliver nursing care</li> <li>b. Ensure or maintain hemorrhage control</li> <li>c. Prepare and administer medication (including pain relief)</li> <li>d. Dress and bandage wounds check proper application of plasters and splints</li> <li>e. Ensure cleanliness and comfort of patient</li> <li>f. Assist and inform physician and</li> <li>g. Manage clinical waste</li> </ul>
<b>Mandatory capabilities: Managing stores for sterile equipment, medicines and consumables</b>	<ul style="list-style-type: none"> <li>a. Maintain stock levels</li> <li>b. Control storage condition including climate and document it</li> <li>c. Control stock of drugs</li> <li>d. Control stock for sterile equipment</li> <li>e. Control medical oxygen stock and other medical material</li> <li>f. Control stock of consumables</li> <li>g. Manage stores</li> <li>h. Manage clinical waste</li> <li>i. Control stock levels in transport assets</li> </ul>
<b>Mandatory capabilities: Evacuation</b>	<ul style="list-style-type: none"> <li>a. Assess patient and deliver pre-hospital trauma life support</li> <li>b. Prepare patient for transport</li> <li>c. Transport patient to Role 1</li> <li>d. Hand over patient to Role 1</li> <li>e. Assist and inform physician</li> </ul>
<b>Additional capabilities: Managing of patient transfer</b>	<ul style="list-style-type: none"> <li>a. Inform higher MTF level and commanders (MEDEVAC procedure)</li> <li>b. Assist in preparation of equipment for the evacuation of a casualty.</li> <li>c. Prepare patient for transfer and explain transport procedures to the patient</li> <li>d. Complete medical records and transfer documentation to ensure proper handover</li> <li>e. Include necessary procedures for case of death</li> </ul>



<b>Additional capabilities: Managing of CBRN contaminated patients</b>	<ul style="list-style-type: none"> <li>a. Know the different CBRN triage principles, decontamination procedures and (air) medevac</li> <li>b. Recognize CBRN patient</li> <li>c. Perform CBRN patient assessment including 'Quick Look'</li> <li>d. Triage CBRN patient. Know the rules of triage at individual and multiple patient level within the different CBRN Environments</li> <li>e. Provide life-saving interventions in a CBRN environment including trauma</li> <li>f. Perform patient hazard management (contain, assist patient decontamination on the camp and/or isolation and use of CBRN casualty or isolation bags)</li> <li>f. Manage chemical patient</li> <li>g. Manage biological patient including sepsis</li> <li>h. Manage radiated patient</li> <li>i. Consider the special requirement of CBRN-patient(s) for MEDEVAC</li> </ul>
<b>Additional capabilities: Managing of highly infectious patients of an epidemic plagues (outbreak)</b>	<ul style="list-style-type: none"> <li>a. Know the different regional epidemic plagues, transmission path, diagnostic, threat for the patient and the medical and other personnel, containment, treatment and way of reporting</li> <li>b. Recognize highly infectious patients of an epidemic plagues</li> <li>c. Triage highly infectious patients.</li> <li>d. Provide life-saving interventions for highly infectious patients by respecting all containment measures</li> <li>e. Perform patient hazard management (contain, patient isolation)</li> <li>f. Perform waste management</li> <li>g. Prepare handling of deceased patients</li> <li>Consider the special requirement for highly infectious patients for MEDEVAC</li> </ul>
<b>Additional capabilities: Manage field sterilization services</b>	<ul style="list-style-type: none"> <li>a. Receive contaminated equipment</li> <li>b. Clean and disinfect equipment</li> <li>c. Inspect and service equipment</li> <li>d. Pack and sterilize equipment</li> </ul>

- 1.6. These standards are to assist the Commanders of Operations and Missions (Cdr) and their staff in ensuring Role 1 support for their Operations or Missions where no participating Member State or Third State has offered this capability as part of the force generation process. This document can be used in whole or in part to prepare the necessary tendering documents for a contracted solution. It can also provide the reference standards for a structured solution such as a framework contract or other pre-mission arrangements. When applying these to a specific Ops/M, the relevant elements can be extracted respecting the requirements of a given Ops/M.
- 1.7. The Medical capabilities at Role 1 level will vary considerably, depending on the type of mission and national policies and resources but as always have to be mission tailored. Therefore the end composition has to respond to the medical risk assessment for the mission or operation, considering its needs and all environmental aspects (e.g.

including a physician with specialisation in medical challenges in a tropical or arctic environment or high-altitude conditions).

- 1.8. This document shall provide capabilities, minimum standards of specifications, guidance to responsibilities, capabilities and the limits of outsourcing and versatility of contracted in-theatre Role 1. These TRs will be limited to a static Role 1 on a base. Extra modules as mobile Role 1, medical teams for support activities outside the base location and dental modules are beyond the scope of these TRs. The size of Role 1 facilities and the resources required, need to be mission-tailored. If needed by the mission or operation extra modules can be added to the Role 1 medical treatment facility or to the Role 1 itself can be attached to another or higher Role.
- 1.9. These TRs will be applicable to all contracted services required to support Role 1 in EU-led Ops/M.
- 1.10. As required by the Contracting Authority the Contractor will provide and sustain the specific services as described within this schedule of requirements to an acceptable standard for provision to all entitled and covered forces.

## **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.
- 2.2. The Contractor shall ensure that all medical acts, tasks, liabilities or functions comply with the legal pre-requisites of the EU and that these are utilised as evidence-proven best practice.
- 2.3. For the duration of the contract period, the Contractor is to provide and maintain a publications library that details guidance and direction for delivery of related contract services within 30 days of contract award and for duration of the contract period.

## **3. Command and Control**

- 3.1. Command and control authority is held by the Commander of the EU Operation or Mission (Cdr).
- 3.2. The Contracting Authority will be determined in accordance with ATHENA regulations.
- 3.3. The Cdr will be supported by his/her staff, ATHENA and EUMS.
- 3.4. This support concerns the technical management of the contract, coordination with the customer and contractor, evaluation, facilitation and mediation of recommended changes in scope or deliverables and appropriate contractual modification as required.

- 3.5. Medical Authority resides with the Cdr's designated MEDAD.
- 3.6. In times of emergency response, Role 1 is expected to provide medical support and the operational authority resides with the Cdr who may delegate authority to the Incident Commander on scene.
- 3.7. The Medical Plan and advising to Force commander is a role for Mission Medical Advisor. It is mandatory for the physicians of the Role 1 to attend tactical briefings and give advice on medical support as needed. The Role 1 physician is expected to advise the local Cdr on Force Health Protection (FHP) on tactical level. The Role 1 physician will provide feedback to the local Cdr or his/her designated representative as required. The Role 1 physician(s) will at all times report to the Mission Medical Advisor about the tactical advices, if applicable.

<b>4. Guidelines, Constraints, Risks</b>
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- 4.1. All contracted support shall be in line with the EU Concept for Contrator Support to EU-led military operations.
- 4.2. Annex II provides specific requirements for Role 1 infrastructure; this reflects the needs for minimum requirements of the Role 1 medical treatment facility. This will be adapted to mission needs but has to include:
  - Reception area. (6 m2)
  - Waiting area. Outpatients capacity for 40 patients per day. (12 m2)
  - Treatment/Emergency room with ultrasound and Electro Cardio Graph (ECG) (24 m2)
  - 2 x consulting and examination room. (18 m2)
  - Observation Room and inpatient ward, with isolation capabilities, with 2 beds for 24 hours. (18 m2)
  - Kitchen for ward (9 m2)
  - Storage area (consumables) at room temperature (15°-25° Celsius). (5 m2)
  - Administration, secretarial room and medical records. (12 m2)
  - Laboratory (6 m2; if sterilisation room is added: 12 m2)
  - Pharmacy and medication store room. (12 m2)
  - Separate restrooms (3,5 m2 each) for patients and separate restrooms for medical personnel. Separate male and female restrooms are required.
  - Staff common and duty room. (12 m2)
  - Nearby the treatment/emergency room a MASCAL area (minimum 40 m2) has to be foreseen. Has not to be own area but can be in multiplexing.
  - Access Ramp
  - Adjacent parking for 2 x ambulances and parking space for the (armoured) ambulances of the Cdr.
- 4.3. 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 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 may constitute a change in contracted requirements. All infrastructure and base activities shall be coordinated with the Base manager. Medical support for patrols

outside the base should be national support of the patrol, or part of a separate or enlarged contract.

- 4.4. Contractors will be self-sustainable. Any services for real life support will be negotiated on case by case basis when this framework contract (FWC) is activated, depending on the capability of the Ops / mission. Self-sustainability shall include but shall not be restricted to:
- Building area for a Role 1 facility to be constructed with direct access for ambulances (200 m<sup>2</sup>, if built single floored)
  - Power source and reserve
  - Fresh water and sewage treatment
  - Clinical waste capability
  - Removal of waste matter
  - Heating and cooling of the building(s), depending on the climate, including HEPA (High Efficiency Particulate Air filter) system for treatment and laboratory area.
  - The ward, if additionally requested, needs to be able to have an isolation pressure system, for highly contagious patients as reverse isolation for patients with severely disturbed immune system.
  - IT, radio and phone connection
  - Food and laundry services
  - Domestic accommodation.
  - Vehicle fuel (if applicable)
- 4.5. The Contractor shall establish emergency support serviced to provide a callable capability to extend/expand medical support in response to MASCAL and medical peaks, also using Ops/M's facilities, if possible and appropriate.
- 4.6. The Contractor shall define standard day-to-day capabilities in number of events supportable, of operational assets, teams dispatched including ability, conditions and terms for expanding services in response to catastrophic events.
- 4.7. These minimum requirements are defining a requested Role 1 capability, for which the contractor's personnel leaving the base compound as defined by fences, gates, and lines of demarcation is not required during normal daily operations. If there is a requirement for Role 1 support to military operations or civilian patrols outside the camp, this capability will normally be provided by force or mission elements.
- 4.8. Some of multinational force elements on the Base may have some organic medical treatment capability for use in expeditionary missions. However, within the scope of this contract, this additional support should not be considered as part of the Base

medical capability unless specifically stated by the Base authorities. The best possible co-operational support must be trained and co-ordinated, especially with mass casualty incidents.

- 4.9. Supply chain difficulties within the AOO and surrounding countries can occur and cause significant delays in the processing of goods to destination. These factors can be cultural, political, administrative, geographical and/or directly or indirectly related to the security situation. Problems with paperwork processing, customs clearance and physical transport due to poor maintained roads and vehicles are common occurrences. Contractors operating within the theatre of operations must be aware of these issues and develop procedures to overcome and compensate for these difficulties.
- 4.10. Seasonal variations such as flooding and snowfall may occur where the supply routes are located. Contractors must plan for this and take appropriate actions to prevent loss or damage of equipment and infrastructure to mitigate risk, and to compensate at their own cost for the associated delays and potential losses.
- 4.11. The Contractor is to be aware of specific conditions within and around the Base and to be ready to respond to emergencies, including but not limited to: structural alarms, fires, in support of the Fire Rescue Services, that may threaten life or property, automotive, aircraft or vehicle accidents, medical emergencies, rocket or base intrusion attacks, hostiles, insurgencies, hazardous material incidents and natural disasters.
- 4.12. 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.
- 4.13. The Contractor has to ensure medical support to its employees supporting this contract, either through the Contracting Authority itself or by arrangements with third parties. Medical support to non-entitled personnel in theatre is restricted to emergencies for life, limb, or eyesight when the Role 1 is directly confronted or requested by the Cdr.
- 4.14. Intellectual and industrial property rights.
  - 4.14.1. The Contractor and contracted personnel shall treat all documents and information received in connection with the contract as private and confidential, and shall not, save in so far as may be necessary for the purposes of the performance thereof, 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.
  - 4.14.2. 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 Agency unless otherwise specified. The Contractor shall, upon completion of the contract, deliver all such documents and data to the Contracting Agency. 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.

4.14.3. 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 4.14.1.

4.14.4. 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.

4.15. Patient Rights are to be consistent with overarching EU and international medical standards and regulations for patient care.

The Role 1 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/her medical health status and planned therapy in the defined language of the operation or mission and in English, or in a language he/she 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.

4.16. Patient Complaints Management

4.16.1. The Role 1 shall be required to have in place patient complaints management system. The Role 1 patient complaints management system shall ensure:

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

4.16.2. The Role 1 shall design and operate a patient complaints management system that:

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

4.16.3. The Role 1 shall ensure all complaints are:

- Recorded within 24 hours of receipt
  - Notified to the Contracting Agency within 24 hours after registration
  - Acknowledged by the Role 1 to the patient making the complaint, upon recording;
  - Patient given full cooperation as required by the Contracting Agency
- 4.16.4. The Role 1 and the Contracting Agency shall conduct monthly reviews of patients 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.

<b>5. Description of the Services Required</b>
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5.1. The Contractor has to provide a physician-led Role 1 primary medical care and emergency medical response service throughout the base to entitled personnel. Role 1 emergency capabilities (including MASCAL situation and, if applicable, ground MEDEVAC) has to be available 24/7, but routine sick calls or vaccination procedures are limited to daily duty hours only. The Contractor will make every effort to accommodate the Cdr's requirements for Role 1 care. The continuum of care must be ensured at all time. In no account downgrading of medical support standards is allowed.

- 5.1.1. All patients requiring Role 2 and higher medical levels of care will be coordinated according to the mission's/operation's SOPs.
- 5.1.2. Any X-ray, CT- Scan or dental issues will be outside the scope of this requirement and will be provided by referring to an adequate specialist or in Role 2 or higher level.
- 5.1.3. The manning for this contract should be maintained at the lowest effective but sustainable level to undertake the requirement (minimum military requirement or minimum mission requirement). The minimum expected number of personnel is 5, two of these general practitioner and emergency physician to ensure permanent emergency service. If ambulance service is included with an additional ambulance driver.
- 5.1.4. The maximum population for one physician should be approximately 750 persons at risk.
- 5.1.5. The contractor is to provide a liaison officer to the HQ as agreed with the Cdr. This task may be filled double hatted.

5.2. The Contractor is, including but not limited, to:

- 5.2.1. Provide a daily sick call clinic service at prescribed times, at least 6 hours a day, supplemented by processes for ad hoc sick calls. Moreover the general practitioner care has to cover basic diagnostic (electrocardiography, ultrasound) and laboratory tests including quick tests for common and local infectious or contagious diseases according to current standards, drug tests as well as small surgery (e. g. closure of minor wounds)

- 5.2.2. Provide pharmaceuticals as they are 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 a 2-month stock of essential consumables and pharmaceutical provisions to cover all common medical conditions, sufficient to maintain effective medical treatment delivery.
- 5.2.3. Monitor re-order levels and track expiry dates of all drugs and ensure that expired drugs are not given to patients.
- 5.2.4. Provide of proposal submittal a list for
- medical instruments and diagnostic devices required to fulfil the primary care service,
  - basic ultrasound capability,
  - electrocardiography,
  - laboratory equipment including quick tests,
  - basic surgery instruments (single-use instruments possible) and
  - sterilization equipment, if applicable,
- to become part of the contract.

5.3. In case of emergencies, including but not limited to

- 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 Member States (MS).
- structural alarms; fires, in support of the Fire Rescue Services, that may threaten life or property; automotive, aircraft or vehicle accidents; rocket or base intrusion attacks; hazardous material incidents.
- accidents and incidents involving persons on the base.

The Contractor is to provide to these emergencies, including but not limited, to:

Provide emergency medical care and trauma resuscitation according to current standards of advanced medical and trauma oriented life support (A(C)LS / (B)ATLS).

Serve as the medical first responder for any accident including MASCAL/major incident situations.

Execute triage of casualties in the event of any incident and/or medical problems.

Prepare the patient for aeromedical evacuation to a higher treatment facility according to the current standards.

If applicable, provide necessary medical patient transport from any point on the base to the Role 1. Aeromedical Evacuation of patients is coordinated through the HQ Patient



Evacuation Coordination Centre (PECC).

Provide on-scene medical standby support as directed by the Command Authority during any base community events.

- 5.4. 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.
- 5.5. Entitled personnel will consist of all mission/operation military personnel, dedicated EU and International Civilians and international contractors. Local national contracted staff will have access to regional facilities and should only be treated in emergency cases of risk to life, limb or eyesight. The Cdr can decide to provide extra medical Role 1 service to the local national contracted staff in support of the Force Health Protection of the mission members. Personnel will be identified by their military ID, National ID or Base ID.
- 5.6. The Contractor is to provide Integral Medical Primary Care including Preventive Medicine during the mission and Occupational Health activities and advice. Food Hygiene and Pest Control activities are subject to the request of the Cdr.
- 5.7. Principally the Role 1 minimum requirements have not to involve ambulance services. Nevertheless ambulance services are assigned to the Role 1. If needed, ambulance services will be entailed in the contract and the Contractor is to provide then medical services in support of all operations and activities within residential and industrial areas of the base through an agreed response request system. The Contractor will:

Receive and respond to emergency services calls.

Establish and maintain emergency reporting logs recording key details of calls received.

Provide logs as required to support accident investigations and reporting.

- 5.8. The Contractor is to provide technical guidance and expert knowledge to support the base emergency services.

Develop and maintain relevant emergency response plans for contract services provided, coordinated and developed in cooperation with the Fire Services.

Support the Command Authority in developing contingency, crisis response and emergency action plans and checklist.

Describe the capabilities, response actions, procedures, responsibilities and interaction with military, police or Ops/M personnel in details.

Planning includes but is not limited to Base Emergency Response Plan, Mass Casualty Response Plan, Outside Perimeter Response Planning and Emergency Route Plan.

Participate in training, table -top and local exercises. Participate in accident reporting, investigation and mitigation planning. Attend and participate in Command

incident/accident debriefs.

5.9. Supply, Equipment and Vehicle Maintenance (all conditions for vehicles only, if they are part of the contract):

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.

The Contractor shall take all actions required to coordinate and track maintenance of vehicles to ensure serviceability supports performance of contracted emergency services.

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.

The Contractor shall establish a medical supply account to provision all supplies required to meet the contract, including pharmaceutical supplies. A 2-month supply of clinician-led pharmaceutical stocks is recommended. Additionally, all clinical waste containers are the Contractor's responsibility. Medical waste management shall be arranged in line and coordinated with the missions SOPs as well as the Ops/M's situation.

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 Command Authority and the Contracting Agency to prevent service degradation.

The Contractor shall maintain effective accounting for and storage of all drugs and pharmaceuticals. This will include adherence to EU regulation of controlled drugs and effective maintenance of the cold chain for supply, respecting SOFA/SOMA or national / host nation's regulations.

5.10. Preventive/Corrective Maintenance Program:

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.

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 Agency review upon request.

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.

The PMP shall include the Contractor's Operating Procedures, Maintenance / Inspection Schedules and Checklists.

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 Agency if warranty terms and conditions cannot be maintained due to operating location, lack of local service provider, etc.

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.

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 Initial Operational Capability (IOC) at the beginning of the Ops/M, but not later than 30 days after contract approval. Full Operational Capability (FOC) of its services, 24/7, continuously throughout the contract latest within 2 months after contract approval. There will be no reduction in capability for the duration of the contract for any reason.

6.2 The Mobilisation section (para 15) shall provide further details.

## **7. Contractor Human Resources Required and Qualifications**

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

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

All Role 1 personnel list of qualifications, copies of original documents and Curriculum Vitae/Resumes shall be available to the HQ to be reviewed and validated prior to personnel deployment to theatre. This includes the right to reject personnel if qualifications are not verifiable or are not in conformity with the EU standards or in case of security concerns.

As a minimum, the Health Care Practitioner shall hold a medical degree recognised in an EU Member State or in case of a non-EU medical degree individually accepted by one EU Member State, and nurses shall have recognised pre-hospital trauma and resuscitation training (PHTLS/ITLS, etc). Both must hold a State Registration recognised within the EU or in case of a non-EU licence individually accepted in one EU Member State and ideally have prior experience of Primary Care practice. Details of this are further expanded in Annex I.

Ambulance driver(s) shall hold a State Registration as Paramedic or as ambulance driver recognised within the EU or in case of a non-EU licence individually accepted in one EU Member State and shall be familiar with applicable radio and driving procedures for medical ambulances and competent to achieve any operating qualification specific to the base.

All personnel must be mentally and physically fit to be able to fulfil the demanding physical aspects of emergency response. Paragraph 13.8 elaborates the further medical requirements.

All Emergency Response personnel shall be fully familiar with the base layout.

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

At least one physician of the Role 1 on the base shall hold a valid security clearance to permit participation in base briefings and contingency planning as required. This requirement has to be fulfilled regardless of personnel rotations and other absences.

All personnel shall be cleared and security screened prior to arrival and in accordance with the base procedures.

All medical personnel shall have medical malpractice insurance individually or effected by the Contractor to cover liabilities.

Excellent language skills in the preferred language of the Ops/M as well as spoken and written English and technical English, are essential for all key personnel and requested on an acceptable level for all other personnel.

The Contractor shall not make changes to the agreed personnel without the prior written approval of the Contracting Agency. 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 1 infrastructure. Nevertheless it is not excluded that Ops/M 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 list 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. In principle 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 contractual obligations for services and maintaining all infrastructure and equipment required to support this contract.
- 8.6. The Contractor will have to coordinate with HQ a planning for mission infrastructure and facilities. These might be provided by Ops/M or the Contractor.
- 8.7. 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. Any facility/infrastructure construction, whether temporary or permanent, shall be coordinated through the Contracting Agency prior to execution in order to obtain proper authorisation from the Base Authorities.
- 8.8. Contractor provided infrastructure and facilities shall be constructed to an approved standard regarding safety, security and hygiene and shall remain the property of the Contractor.
- 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. Follow on planning after termination of the contract has to be implemented in the contract. Depending on the respective situation they shall be removed by the Contractor at their expense upon termination of the contract or an alternative concept has to be presented to the Contracting Authority (e.g. handing over to the host nation).
- 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 1 is equipped to meet requirements established in standards listed in Paragraph 2 and based on base operations, AOO operations, size, population, facilities and nature of operations / missions to meet standards for continuum of care and appropriate treatment of the patients. This includes but is not limited to:

If applicable, ambulances fully equipped to meet standards for continuum of care and appropriate treatment of patients during evacuation to the Role 1, AIR MEDEVAC landing site or Role 2, depending on the situation.

Proof of appropriate vehicle insurance shall be provided for the ambulance.

All required personal protective equipment including medical gowns and eye protection.

All other associated tools, equipment, supplies, medical supplies, items required for administrative support, and items required for user maintenance of facilities.

## **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 as double hatted function 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 Agency, the 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 for the patient rights.
- 9.5. The Contractor shall establish a Site Manager, depending on the Contractors strength as double hatted function, 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.
- 9.6. 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.
- 9.7. The maintenance of infrastructure and life conditions encompasses the prevention of vermin, poisonous or dangerous animals, vectors, germs (e.g. in the water) and also hygiene inspections on a regular base.
- 9.8. The Contractor shall be responsible for the repair or replacement for any losses or damage caused by misuse, neglect, bad practice, wilful harm etc. by contractor

personnel on any infrastructure, equipment or supplies for which the Contractor has control and accountability.

- 9.9. The Contractor shall provide a management / inventory report of all equipment and infrastructure supporting the contract to the Contracting agency regularly, on a quarterly basis as a minimum.
- 9.10. The Contractor shall work with the HQ to establish a list designating Mission Essential Equipment and Infrastructure establishing critical levels for this Mission Essential Equipment and Infrastructure. This list shall consider all equipment required to meet contract service requirements.
- 9.11. 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.
- 9.12. The Contractor shall brief the Contracting Agency on status and progress of corrective actions for any equipment remaining down for maintenance for more than two days. For essential equipment without redundancy (e.g. ambulance, ultrasound, ECG) the Cdr and Contracting Agency has to be informed within 24 hours.
- 9.13. 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.
- 9.14. The Contractor shall operate all systems inclusive of equipment, instruments and interfaces in accordance with Original Equipment Manufacturers (OEM) specifications and recommendations.
- 9.15. 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 Agency QMS shall review this program for compliance with applicable technical standards.
- 9.16. 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.
- 9.17. The Contractor shall maintain asset registers and records detailing any testing, statutory inspections or obligations, monitoring, diagnostics and analysis. These records shall be used to identify any recurring defects or adverse trends. The recording and maintaining of records, stock levels/inventories etc. are a key function and shall be managed accordingly.
- 9.18. 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.

- 9.19. Any cross utilisation or sharing of equipment amongst contractors or service areas shall be approved by the Contracting Agency prior to transfer/loan.
- 9.20. 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 customer.
- 9.21. The Contracting Agency shall audit/inspect all infrastructure, equipment and supply management, maintenance and associated documentation. The contractor will make equipment available for inspection by the Contracting Agency personnel on request without prior notice.
- 9.22. 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. As a minimum, the Contractor shall equip and maintain:
- 10.1.1. 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.
  - 10.1.2. 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.
  - 10.1.3. 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.
  - 10.1.4. If the security situation allows it, internet access can be installed by the contractor for Role 1 personnel.

### Communication equipment for medical personnel

Type	No
Fixed mobile radio transceiver and/or portable transceiver (one for each member)	5
Portable alerting system. This could be included in the portable radio receiver (number per member)	1
Access to the public telephone network e.g. via the normal radio transmitter or by mobile telephone. Also for the ambulance. (number per member and	1



per ambulance)	
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## 10.2. Medical Records

- 10.2.1. All treatment provided, including medications, are to be fully documented in the patient's medical records.
- 10.2.2. The Role 1 shall have an established system for maintaining medical records, including the administration, custody, safekeeping of medical records.
- 10.2.3. Original medical records are the property of the Role 1 and shall not be removed from the control of the Role 1 except by court order or subpoena.
- 10.2.4. The Contractor is to make available the electronic or hard copies of all medical records on request from specific medical staff of the customer military medical service. For military operations or missions the medical records will be handed over to the MOD of the native country of the military patient. For civilian missions the medical records will be handed over to the EEAS at the end of the contract.
- 10.2.5. All medical records are to be treated as "Medical-in-confidence" and shall not be released to any unauthorized persons.
- 10.2.6. 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.
- 10.2.7. All medical record entries shall be legible, complete and dated by the person responsible for ordering the service, providing or evaluating the service.
- 10.2.8. Each medical record shall contain documentation of any complications, acquired infections, and adverse reactions to medical treatment and care.
- 10.2.9. 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.
- 10.2.10. Disclosure of Medical Records. If a mission member requests, he/she will be furnished with a copy of his/her individual medical records. This may be rejected if the record might harm someone else's privacy.
- 10.2.11. New Contractor. If there is a change of the Medical Contractor, the predecessor shall hand over the medical records to the successor on signature.

## 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.

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 Agency and local command Security guidance pertaining to installation access.

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.

The Contractor shall include a Safety Management Plan 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 Agency with an updated safety program upon start of services. Continue to review and provide updates to this document throughout the contract performance period.

All elements of safety shall be implemented upon start of mobilisation and continue until the last person leaves the installation upon end of services.

This safety plan shall be tailored to local operations.

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.

The Contractor shall train and guide personnel in the safest way to conduct the work.

The Contractor shall provide appropriate protective, safety, and warning equipment for HAZMAT situations to all personnel. He shall ensure that personal protective equipment such as, but not limited to head, hand, foot, eye and face including protective/NBC mask), and hearing protection is used where it is not possible to eliminate or control a hazard by other means.

All persons needing to wear personal protective equipment shall be instructed in its proper use, and where appropriate, in its service and maintenance.

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 Agency of any accidents/incidents occurring to contractor personnel on station. This includes non-work related events as well as work related events. Timeliness 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 Agency.
- 11.6. Regarding military security and safety issues the HQ is the ultimate authority. Security issues concerning obligatory care of POW's 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.
- 12.2. The Contractor has to ensure that POL products contaminating the soil by its motor vehicles (e.g. ambulances) and shall use a catch basin.
- 12.3. All land and facilities shall be returned to the Base on demobilisation, free from any requirement for environmental clean-up and, if requested by the Contracting Authority or the host nation, in the same condition as received.
- 12.4. The Contractor shall develop a program for environmental management as defined within ISO 14001.

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

- 13.1. The Contractor shall provide Base Senior Medical, Base Fire Officer, Base Commander, HQ and the Contracting Agency 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.
- 13.2. 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.
- 13.3. As creator of the documents, the Contractor has to guarantee the archiving of patient's records for a time period of 30 years in an appropriate way. Following the above mentioned procedures (10.2.4.) the Contractor ensures that all military medical records will be handed over to the respective national military medical service. For all civilian participants in Ops/M, the Contractor safeguards either the delivery of the medical records to EEAS or, as special arrangement of the contract, stores the records for 30 years under Contractor's supervision and responsibility.

- 13.4. The Contractor had to provide Commanders staff/Base Senior Medical and Ground Safety with immediate feedback on detected health and safety issues and accident response.
- 13.5. The required items and format of the reports specified above will be alterable at the discretion of Base Commander.
- 13.6. Project Management Plan (PMP):
- 13.6.1. The Contractor shall develop and provide to the Contracting Agency, 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.
  - 13.6.2. Provide this plan within the Technical Proposal. Update the plan upon contract award and provide the updated plan to the Contracting Agency not later than 30 days after contract award.
  - 13.6.3. 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.
  - 13.6.4. This plan shall include, as a minimum, an organisational chart, position descriptions, qualification requirements for key positions as well as for positions requiring specific technical skills or professional certification.
  - 13.6.5. Clearly define skill requirements by specific duty position. This may be accomplished by using some internationally or nationally recognized occupational code system. Define this system within the Technical Proposal and ensure the Contracting Agency has access to the codes.
  - 13.6.6. Clearly identify operational skills sets and/or positions that shall be staffed at all times.
  - 13.6.7. Identify means of providing back-up/redundant personnel to cover all required skills and/or duty positions during personnel leave or during absence.
  - 13.6.8. Provide nomination of the key personnel and submission of CVs to the Contracting Agency for review within the Technical Proposal and prior to personnel deployment for the duty positions.
  - 13.6.9. As an integral part of the Project Management Plan, organisation structure shall be formalised and approved by the Contracting Agency 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.

- 13.6.10. 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.
- 13.6.11. Any organization structure changes resulting in personnel transfer or personnel level adjustments after this point require written justification and approval by the Contracting Agency.
- 13.6.12. Projected personnel levels and skills requirements associated with position shall remain stable throughout the contract.
- 13.6.13. 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 R&R schedules, providing redundancy of skills to ensure adequate capability exist. The contractor will immediately notify the Contracting Agency's Technical Officer in the case unforeseen personnel shortfalls occur. These shortfalls shall be documented in a coordinated get-well plan with established timelines for correction and mitigation actions.
- 13.6.14. The Contractor shall clearly describe the personnel sourcing and hiring process within the Technical Proposal.
- 13.6.15. Describe necessary steps taken to ensure recruitment and hiring practices employed conform to the requirements by the Contracting Agency.
- 13.6.16. Describe use of hiring agencies (if any) to include third party agencies contacted or used by the primary hiring agency.
- 13.6.17. Define corporate level support offered or required to sustain project activities.
- 13.6.18. Provide outline of support capability in terms of skills and personnel available for this support.
- 13.6.19. Define how support will be obtained and expected amount of hours support can be provided.
- 13.6.20. The Contractor shall develop and implement a cost control and cost tracking program to assist the Contracting Agency. 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.
- 13.7. 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.
- 13.8. Medical Plan:

- 13.8.1. The Contractor shall develop a Medical Plan that describes how the contractor will comply with the requirements established within this document for their own employees. The plan must be available for the HQ prior mobilisation. The Contractor's employees might be treated by the Contractor itself, MTFs of the Ops/M or through agreements with third parties.
- 13.8.2. As a minimum the Medical Plan shall address the following areas of pre-deployment and continuous medical/dental screening and vaccinations/prophylaxis, Role 1 medical and dental care support, continuous contract health screening, special health arrangements for specialist employees (i.e. food handlers), access to Role 2/3 medical capability, arrangements for MEDEVAC/TACEVAC/STRATEVAC, repatriation of dead, support to MASCAL Response plans and arrangements for medical health recording and maintenance.
- 13.8.3. Pre-Deployment Health Checks. The Contractor shall explain the extent of health screening undertaken for employees and will be able to offer evidence in support of any declarations. This will include pre-deployment vaccination regimes applied to Contractor staff.
- 13.8.4. Screening for Specialist Personnel. Some contracted employees may represent high risks to themselves or others by the nature of their artisan activity (i.e. food handlers, medical personnel). The Medical Plan shall indicate what additional screening measures have been taken for these specialist groups, the frequency of the measures and how this screening is recorded. Besides the operational force protection measures occupational specific vaccinations are applicable for the medical staff.
- 13.8.5. Role 1 Medical & Dental Care shall be available to all employees as part of a duty-of-care. This care may be delivered by organic capability provided by the contractor or it may be sourced through agreements with third parties. The details described will form part of a regular audit to demonstrate compliance with clinical governance.
- 13.8.6. Role 2/3 medical capability is not expected to be within the resources of the Contractor. However, the Medical Plan shall identify and describe how contracted employees are provided access to such capability in case of medical emergency.
- 13.8.7. The Contractor shall be ready to obtain medical insurance for the persons employed or contracted by it under the contract including medical repatriation to the respective home country if needed. Ops/M shall be under no liability in respect of the medical expenses of the Contractor.
- 13.8.8. MASCAL and Emergency Incident Planning. Contractors are expected to provide support within their capabilities for the collective Base MASCAL or Major Incident Response Plan. The Medical Plan should identify what support the contractor is able to offer and whether this support forms part of the Base MASCAL Plan.

13.8.9. 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.

13.8.10. Provide a final update to the Contracting Agency 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. Incident reports:

13.9.1. 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.

13.10. Operational Reports:

13.10.1. 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.

13.11. All reports concerning operations shall be submitted in the determined language of the Ops/M and, if English is not the Ops/M language, also in English language on request.

<b>14. Quality Assurance and Performance Measurement</b>
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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. The Contracting Agency will provide a regular and independent Subject Matter Expert schedule of visits to the Role 1 to maintain the required levels of confidence in medical governance for the customers. The Contracting Agency will develop from these visits, a Contracting Agency Progress and Performance Report for the customers and the Contractor. Assistance should be provided to representatives of Troop Contributing Nations when carrying out their own health care governance visits as required.

14.3. If vehicles are part of the contract, vehicle serviceability shall support the capability, 100% of the time.

14.4. Meet established levels of supplies/consumables in accordance with mission requirements at all times.

14.5. Corrective measures will be identified with the consultant and shall be put into practice within an agreed timeline.

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

- 14.6.1. The Contractor shall clearly define QMP 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.
- 14.6.2. 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 Agency Quality Manager (QM) for review and approval.
- 14.6.3. 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.
- 14.6.4. Develop Operating Procedures (OPs), Policies, Checklist, 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 Agency QM not later than 20 days prior to start of service. Provide copies of these documents to the Contracting Agency QM for review and approval.
- 14.6.5. 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.
- 14.6.6. This program shall include Occupational Health and Safety as defined within OHSAS 18000 series of standards.
- 14.6.7. This program shall include environmental management as defined within ISO 14001 series of standards.
- 14.6.8. 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.
- 14.7. 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. In this respect Monitoring criteria and Evaluation criteria.
- 14.8. Monitoring criteria:
  - 14.8.1. 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.



14.8.2. 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.

14.8.3. 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.

14.9. Evaluation criteria. Role 1 medical facility services can be evaluated through the following indicative list of Performance Indicators per expected result:

14.9.1. Design of the Role 1 medical facility:

- Quality and applicability of the final design; measured by means of a one-off evaluation report to be carried out by the Cdr; indicators may include the completeness and functionality of the designs, as well as the time and effort it took to reach consensus.

14.9.2. Structure and fittings of the Role 1 medical facility, including their maintenance

- Quality of assembly of the Role 1 units; measured by means of a one-off audit report to be carried out by the Cdr; indicators may include the completeness and integrity of works, smooth integration with Role 2 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 mission staff members working on other Camp A/B areas regarding the Role-1 infrastructure.

14.9.3. 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 1 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-1 level of hygiene in the surrounding / open-space areas.

14.9.4. Equipment to be used in the Role 1 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.

#### 14.9.5. Disposable items to be used in the Role 1 medical facility

- Functionality and hygiene; measured by internal audit report to be carried out by the 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 external consultant (annually); main indicator is number of failures or negative incidents.

#### 14.9.6. Specialised medical personnel to staff the Role 1 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.).
- Attendance; Contractor is expected to implement a system to monitor attendance records. The “Senior Physician” shall submit relevant report to the Project Manager on a weekly basis.

Note: due to the sensitive nature of such surveys and reports, they should be conducted with utmost respect for confidentiality, and under the auspices of a panel of medical professionals that can ensure objectivity.

## **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 Operating Capability (IOC). Personnel in place providing medical services capability for one ambulance on first day of arrival on base. This will commence at the beginning of the Ops/M, but not later than 30 days after contract approval.

15.1.4. Full Operation Capability (FOC): The commissioning of facilities, equipment and, if applicable, vehicles for readiness as well as validation of manning for the contract must be completed not later than 60 days after signing the contract. Within this timeframe it is expected the Contractor's declaration that all services are fully deployed and operational 24/7, continuously throughout the contract, 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 Facilities and Services are outlined below. The statements below provide general guidance for planning considerations.

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 local Commander or the Contracting Agency.

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 standard to be used within the Technical Proposal.

15.2.3. The Contractor must identify power requirements. The Contracting Agency 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 Real Life Support (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 Agency 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 mobilization 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 CBRN threat to be able to issue personnel CBRN gear and antidotes.
  - 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 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. Detail facility development and/or construction requirements, equipment, supply and facility inspection requirements and proposed timeline.
    - 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 mobilization success.

#### 15.6. Mobilization Reports:

- 15.6.1. The Contractor shall provide Weekly Mobilisation Reports to ATHENA/HQ describing mobilisation status for all key areas mentioned in the Mobilisation Plan. The Contractor shall identify significant problems that may cause a slippage in key mobilisation milestone activities. The report shall include a summary of 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 100% of 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 Agency Site Office no later than seven (7) working days prior to start of service.

#### 15.7. Demobilisation:

- 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/M, 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 Agency and reviewed annually at contract anniversary.
- 15.7.3. Demobilisation requirements include all activities required to dispose of equipment and infrastructure, repatriate employees and render the site suitable for return to local authorities. Therefore a Demobilisation Plan shall be sent and agreed with the HQ 3 months before contract closure, defining all inherent issues.
- 15.7.4. 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 infrastructure.

- 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 to include provision of supplies 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 person leave theatre.

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. Demobilizing 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 demobilization 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.

<b>16. Templates and Forms</b>
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16.1. To be developed in cooperation with the Base Commander and the Contracting Agency:

- 16.1.1. Manning Report – Listing people by qualification.
- 16.1.2. Asset Register – Identifying all assets, with condition and ownership.
- 16.1.3. Activity Log – Record of incidents, training, repairs and deficiencies.
- 16.1.4. Medical Report – Status of vaccinations, sickness and MEDEVACs.
- 16.1.5. Shift Report – List of personnel manning and stations.
- 16.1.6. Drug/Consumables List – Itemising usage and retained stocks.
- 16.1.7. Vehicle Maintenance Logs – Checks, inspections, maintenance.
- 16.1.8. Facility Custodian Log – Record all accommodation/station infra issues.
- 16.1.9. Health & Safety Accident Log – Record all accidents/incidents.

## 17. 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. 5.7.2	Emergency Log	Mobilization	Update as required
Para. 5.7.3	Accident Investigation Log	Mobilization	
Para. 5.8.1	Emergency Response Plan	8 weeks after NTP	
Para 13.8.8	MASCAL Plan		
Para 5.8.4	External Response Plan		
Para 5.8.4	Emergency Route Plan	Mobilization	
Para 5.9.2	Vehicle Tracking/Maintenance Plan	Mobilization	
Para 5.9.3	Calibration Recording	Mobilization	Monthly thereafter
Para 5.9.4	Medical Supply Account	Mobilization	Monthly thereafter
Para 5.9.6	Cold Chain Records	Mobilization	Monthly thereafter
Para 5.10.1	Preventive Maintenance Plan	30 days after NTP	
Para 7.2.1	Staff CV's and Resumes	Mobilisation	As required thereafter
Para 7.2.6	Security Clearances	Mobilisation	As required thereafter
Para 2.1.2	EU Language Checks	Mobilisation	As required thereafter
Para 8.10	Facilities Custodian	Mobilisation	As required thereafter
Para 13.1	Fire Wardens and Commodity Manager	Mobilisation	As required thereafter
Para 8.7	Property Accounts	Quarterly	
Para 4.10	Equipment Replacement Plan	12 weeks after NTP	Quarterly thereafter
Para 5.9.1	Inventory of Assets	Mobilisation	6-monthly 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 13.1	Daily Shift Roster Vehicle Readiness Activity Report	Weekly/Monthly	Annual Report also
Para. 13.6	Project Management Plan	Technical Proposal	Final 30 days after contract award
Para. 13.6.3	Staffing / Manning Plan (Integral part of Project Management Plan)	Technical Proposal	Final 30 days after contract reward. Formal review 45



Reference	Description	First Delivery	Remarks (and subsequent deliveries)
			days after start of services.
Para 13.8	Medical Plan	Technical Proposal	Reviewed at 6 months
Para 14.2	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. 15.6.1.	Mobilization Plan	Technical Proposal	Final upon contract award
Para. 15.7	Demobilisation Plan	Technical Proposal	Update 6 months prior to end of service

## ANNEX I - REQUIREMENTS FOR PERSONNEL

### 1. General Requirements

- 1.1. All requirements mentioned below shall be considered as minimum.
- 1.2. The Contractor has to provide personnel to fulfil all tasks as described in para 5 main document.
- 1.3. The Contractor is responsible for the safe accommodation of all contracted personnel in the AOO. The HQ will denominate the location of the accommodation and Role 1.
- 1.4. The Contractor is responsible for transfer flights and/or shipping in and out of the AOO of the Contractor's personnel.
- 1.5. The Contractor must provide liability insurance. 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/M from responsibility where the Contractor will be operating on Ops/M facilities.
- 1.6. The Role 1 will be permanently on standby and ready for all casualties.
- 1.7. In case of temporary and sudden unavailability of any member, especially key personnel, due to unforeseen reasons (sickness or other), an equivalent replacement must be available on the site within 24 hours. Such unavailability has to be reported without delay to the HQ.
- 1.8. All staff members appointed by the Contractor must be holders of the necessary licences and / or medical clearances, which must be presented to the Contracting Agency Project Manager, and must be valid while the staff members are deployed in the Mission.

- 1.9. All staff members must be healthy, physically, dental and mentally fit for the area of operation. This includes preparatory measures (including necessary vaccinations) and a medical check before deployment to the AOO.
- 1.10. It should be planned to have the same staff on duty rosters not less than 2 month and not more than 6 months before rotating them.
- 1.11. Personnel have to wear suitable clothes for the designated tasks.
- 1.12. Working hours and shift schedules have to be in accordance with European law and regulations.
- 1.13. 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 to guarantee unhampered communication with patients as well as Ops/M Cdr. In addition physicians shall be capable of level C1 and all medical staff of level B1 in case of another Ops/M 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 or the Ops/M specific language.
- 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 is a preference, including military training or experience in EU or international operations and missions.
- 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.
- 2.1.5. Medical personnel must be fit to perform as described in the SKILL SET ANNEX V.

### 2.2. Role 1 Medical Staff Configuration (minimum):

- 2 GP Doctor
- 3 A(T)LS trained Nurses with at least one nurse with qualifications on handling pharmaceutical products, and all should be able to handle simple blood lab techniques
- 1 Paramedic ambulance driver, if applicable

2.3. If the population that needs to be treated by far exceeds 750 persons then the staff should be added with 2 Nurses. For more than 1500 persons 1 GP and appropriate nurses have to be added.

2.4. Physician:

- 2.4.1. Physician with a current EU Member States medical licence in primary health care, or in case of a non-EU licence individually accepted by an EU Member State, usually a General Practitioner;
- 2.4.2. University degree in Medicine in accordance with EU Commission directive 2005/36/EC or with an Non-EU University degree in Medicine individually accepted by an EU member State;
- 2.4.3. Minimum 5 years of relevant professional experience after being certified as physician; experience in emergency medicine or intensive care; basic skills in gynaecology and obstetrics; “medical currency” and proven record of working as a physician in primary health care for minimum twelve (12) months within the last two years prior of a deployment to the Mission, demonstrating involvement of at least 3 consultancy days, on average, during this working period.
- 2.4.4. General professional experience: at least 1 year of work in the context of a military role 1, UN level 1, humanitarian aid, natural disaster sites, post conflict areas, or equivalent is an advantage.
- 2.4.5. Current and experienced in A(C)LS or equivalent, ATLS/BATLS or equivalent, MIMMMS or equivalent. Depending on the geographical area of the Area of Operation knowledge of the local diseases including diagnosis and treatment, also knowledge of acclimatisation including prevention and treatment of heat and cold induced casualties.

2.5. Nurse:

- 2.5.1. In an EU Member State Registered Nurse in accordance with EU Commission directive 2005/36/EC or in case of a non-EU licence individually accepted by an EU Member state;
- 2.5.2. Knowledge and working experience in primary health and or clinical nursing, including emergency medicine services and pre-hospital care;
- 2.5.3. Minimum 2 years of relevant professional experience after certification as registered nurse; “medical currency”, i.e. proven record of working as a nurse in a primary health care setting for minimum twelve (12) months within the last two years prior of a deployment to the Mission, demonstrating involvement in at least 3 working days a week, on average, during this working period.
- 2.5.4. General professional experience: at least 1 year as nurse in the context of of a military role 1, UN level 1, humanitarian aid, natural disaster sites, post conflict areas, or equivalent is an advantage.
- 2.5.5. Current and experienced in emergency practice such as Immediate/Advanced Life Support; Trauma Nursing Core Course / Advanced Trauma Care for Nurses, etc.

2.6. Paramedic ambulance driver:

- 2.6.1. State approved licence as paramedic ambulance driver by an EU Member State, or in case of a non-EU licence individually accepted by an EU Member state;
- 2.6.2. Minimum 2 years of relevant professional experience after being certified as registered paramedic ambulance driver;
- 2.6.3. Knowledge and working experience as an ambulance driver in emergency medicine services, pre-hospital care and transportation medicine;
- 2.6.4. General professional experience: at least 1 year as paramedic ambulance driver in the context of military ambulance, UN level 1, humanitarian aid, natural disaster sites, post conflict areas, or equivalent is an advantage;
- 2.6.5. Specific professional experience: at least 2 years of serving paramedic ambulance driver; “medical currency”, i.e. proven record of working as a paramedic ambulance driver for minimum twelve (12) months within the last two years prior of a deployment to the Mission, demonstrating involvement in at least 3 working days a week as an paramedic ambulance driver , on average, during this working period.

## **ANNEX II - REQUIREMENTS ROLE 1 INFRA**

<h3><b>1. General Requirements</b></h3>
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- 1.1. All requirements mentioned below shall be considered as minimum.
- 1.2. 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.
- 1.3. Construction and materials conform 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 are 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.
- 1.4. The flooring of the Role 1 should be:
  - Nonslip/hardwearing,
  - Vinyl/resin/polyurethane type flooring,
  - Seamless and edged up the wall by at least 200mm,
  - Resistance to solvents,
  - Resistance to detergents.
- 1.5. If additional capabilities in accordance with the Table in para.1.5 of the main body which is managing CBRN contaminated patients and/or managing highly infectious

patients applies, then the most essential rooms should be made to give collective CBRN protection. The Role 1 shall have a patient ward with reversible pressure regulation. Higher room pressure for severe immunocompromised patient and a lower room pressure for severe contagious patient.

- 1.6. All infrastructure units allow for internal power distribution module, air-conditioning, lockable hard doors, raised floors. Passage ways are included in the infrastructure architecture delivering a closed path system for patients and medical staffs.
- 1.7. Role 1 climate control:
  - Heating,
  - Cooling,
  - HEPA filtered climate control in the treatment area.
- 1.8. Interior lighting shall be provided at a minimum of 300 lux. The examination and treatment area will be a minimum of 500 lux.
- 1.9. The mains should be provided to prevent earth leak currents.
- 1.10. The Role I deployment includes the following Infrastructure and utility services:
  - Communications (radio and internet connectivity)
  - Air conditioning in all rooms
  - Power and electric system in all rooms
  - Potable water system, purification and reticulation
  - Water distribution and collection system
  - Waste management system
  - Incinerator
  - Fire extinguishers
  - Emergency lighting

<b>2. Specific Requirements – floor space to be seen as minimum requirement</b>
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- 2.1. Reception area and waiting room,
  - Reception 6 m2
  - Plumbing: one washroom with toilets for patients.
  - Waiting room 12 m2
  - Doors for bed passage, preferably automatic or double door construction
- 2.2. Treatment/Emergency room with ultrasound and Electro Cardio Graph (ECG):
  - Plumbing: washbasin with warm/cold water and elbow handle
  - Doors for bed passage, preferably automatic or double door construction

- 24 m2
- 2.3. Two consulting and examination rooms:
- Plumbing: washbasin with warm/cold water and elbow handle
  - 18 m2 each
- 2.4. Observation Room and in patient ward with 2 beds for 24 hours:
- Plumbing: washbasin with warm/cold water and elbow handle
  - Doors for bed passage, preferably automatic or double door construction
  - If applicable, the ward needs to be able to have a isolation pressure system, for highly contagious patients as reverse isolation for patients with severely disturbed immuumsystem
  - 18 m2
- 2.5. Kitchen for ward:
- Plumbing: washbasin with warm/cold water
  - 9 m2
- 2.6. Storage area (consumables) at room temperature (15°-25° Celsius):
- 5 m2
- 2.7. Admin, Secretarial room and medical records:
- 12 m2
- 2.8. Laboratory, sterilisation room, if applicable:
- Plumbing: washbasin with warm/cold water and elbow handle
  - 6 m2; if sterilisation room is added: 12 m2
- 2.9. Pharmacy and medication store room:
- 12 m2
- 2.10. Separate restrooms for patients and separate restrooms for medical personnel.
- Separate male and female restrooms are required
  - Plumbing: washbasin with warm/cold water and elbow handle
  - 3,5 m2 each
- 2.11. Staff common and duty room.
- 12 m2
- 2.12. MASCAL Area:
- Nearby the treatment/emergency room a MASCAL area has to be foreseen.
  - Area has not to be own area, but can be in multiplexing
- 2.13. Access Ramp.
- 2.14. As appropriate, adjacent parking for the Operation/Mission's ambulances and an additional parking space for an emergency vehicle.

## ANNEX III - REQUIREMENTS FOR ROLE 1 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 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 1 needs to have a CBRN patient transport bag for CBRN Patients after decontamination or for the severe contagious patients for transport in an ambulance.

### 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.

### 3. Gas supply

- 3.1. Pressure regulators and pressure regulators with flow metering devices shall conform to EN ISO 10524-1 or EN ISO 10524-3. The pressure regulators shall be directly connected to the source of supply. Flow metering devices for connection to terminal units shall conform to EN 13220.
- 3.2. The range of the nominal distribution pressure for medical gases shall be 400 kPa; the pressure measured at the terminal units (if fitted) shall be within  $\pm 10\%$  of the nominal distribution pressure at a test flow of 40 l/min. 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.

### 4. Medical devices, products and equipment

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

#### A.1 Patient transfer devices (No's for Role 1 and Ambulance separately)

Generic device group	Examples of European Standards	No	Comments
Main stretcher	EN 1865	1	
Undercarriage / Trolley transport/transfer	EN 1865	1	
Vacuum mattress	EN 1865	1	Straps must be attached permanently to the mattress. Flame resistant
Carrying sheet or Transfer mattress	EN 1865	1	
Long spinal board with head immobilizer and securing straps.	EN 1865	1	Backboard with pins and with the Speed-Clip Restraints system. Flame resistant
Break-away stretcher	EN 1865	1	With pins and with the Speed-Clip Restraints system.
Scoop stretcher		1	



Wheelchair		1 in Role 1	
Crutches		2 pairs in Role 1	

**A.2 Isolated extremity and upper spinal immobilization devices (No's for Role 1 and Ambulance separately)**

Generic device group	Examples of European Standards	No	Comments
Traction device		1	
Immobilisation set for fractures		1	
Cervical upper spinal immobilization devices/Cervical collar-set		1	
Extraction upper spinal immobilization device or Extension devices/Short spinal board		1	
Extraction Harness		1	Only in Ambulance
Pelvic Sling		1	

**A.3 Ventilation and respiration devices (No's for Role 1 and Ambulance separately)**

Generic device group	Examples of European Standards	No	Comments
Stationary oxygen, with a quick-connection Appropriate amounts for refill	EN ISO 15002 EN ISO 9170-1:2008 EN ISO 10524-1	1 in ambulance 2 for Role1	Oxygen system with 2 flow controlled patient-outlet (2-15 L/min) and quick-connection to the portable ventilator Min. 2000 L.
Portable oxygen, min. 400 l, with a quick-connection and a carrying system	EN ISO 9170-1:2008 EN ISO 10524-1	2	Oxygen cylinder/each set with flow controlled patient outlet (2-15 L/min)
Oxygen tubing		4	
Oxygen Mask Adult		4	
Nebulisation device		1	Oxygen driven
Transport ventilator for controlled and assisted ventilation with adjustable PEEP-valve <sup>a</sup> / CPAP-function <sup>b</sup> .	EN 794-3:1998 +A2:2009	1	
Stationary suction device <sup>c</sup>	EN ISO 10079-1	1	

	EN ISO 10079-3		
Portable suction device	EN ISO 10079-2	1	
Intubation devices set including laryngoscope handle (-s) with suitable blades	EN ISO 5356-1:2004 EN ISO 5367:2014	1	
Endotracheal tubes set with connectors	EN 1282-2:2005+A1:2009 EN ISO 5361:2012	1	All sizes and 4 extra in size 7.5, 8, 8.5 and 9
Oropharyngeal airways set	EN ISO 5364:2011	4	
Intubation cuff manometer		1	
Nasopharyngeal tubes		4	
Catherization sets		1	
HME-filter <sup>d</sup>		4	
Tube fixing materials		1	
"AMBU" balloon		1	
Tracheostomy kit <sup>e</sup>		2	See A 6
Thorocentesis kit		2	See A 6
Chest tube-catheter set		1	
a) Positive End Expiratory Pressure. b) Continuous Positive Airway Pressure. c) Stationary non-manual suction device with a minimum negative pressure of 40 kPa, with a collection container with a minimum capacity of 1 l, can be portable. d) Heat and Moisture Exchange e) Insertion stylets, inflation tube clamp, inflation syringe, Magill forceps etc.			

#### **A.4 Medical devices for diagnosis and monitoring (No's for Role 1 and Ambulance separately)**

Generic device group	Examples of European Standards	No	Comments
Patient examination couch/table		2 in Role 1	
Footsteps for examination couch		2 in Role 1	
Monitor/Defibrillator with non-invasive pacing providing us with all vital parameters (minimum): HR, NIBP, ECG, etc		1	
ECG, 12 lead		1 in Role 1	
Non-invasive BP Monitor	EN ISO 81060-1:2012	2 in ambulance 3 in Role 1	
Pulse oximeter	ISO 80601-2-55:2011	1 in ambulance	

		3 in Role 1	
Capnometer	EN ISO 21647:2004	1	
Stethoscope		1 in ambulance 3 in Role 1	
Otoscope		1	
Ophthalmoscope		1	
Gynaecological speculum		1 in Role 1	
Eye Loupe		1 in Role 1	
Snellen Eye Chart		1 in Role 1	
Height measurement		1 in Role 1	
Ear thermometer (15-42 °C)		1 in ambulance 2 in Role 1	
Weighing machine		1 in Role 1	
Reflex hammer		1	
Diagnostic light		1 in ambulance 3 in Role 1	
Glucometer		1	
Spirometre (PEF)		1 in Role 1	
Power pack, spare batteries for medical equipment			

#### A.5 Laboratory and Pharmacy room Role 1 Including consumables

Generic device group	Examples of European Standards	No	Comments
Basic Hematology Analyzer		1	
Basic Biochemistry Analyzer		1	
Microscope		1	
Laboratory Slide holder		1	
Laboratory Slide maker		1	
Laboratory Test Tube Rack		1	
Centrifuge		1	
Shaker		1	
Pipettes set 8 sizes with tips, burette		1	
Rapid Test Kits: Malaria (only in Malaria area)		4	
Dengue (only in Dengue		4	

area) Ebola (only in Ebola area) HIV Urinalysis Fluorescence Anthrax		1 box 1 box 1	
Refrigerator for drugs and lab consumables		1	
Cold chain – Data logger		1	
Cold chain – Transport Box		1	
Lab stool		1	
Swivel stool		2	
Urine measuring bottle		1	
Water distiller			

#### **A.6 Devices for injection and infusion (No's for Role 1 and Ambulance separately)**

<b>Generic device group</b>	<b>Examples of European Standards</b>	<b>No</b>	<b>Comments</b>
Devices for injections and infusions	EN 1707 EN 20594-1 EN ISO 7886-1,-2 EN ISO 7864 EN ISO 10555-1,-5 ISO 6009	4	Isolation cover for infusion bag and line.
Infusion container temperature regulator $38 \pm 2$ °C		2	Not required to be portable.
Volumetric infusion device	EN 60601-2-24	1	Syringe driver
Automatic infusion device with volumetric properties		1	For secondary transport
IV Stand / Perfusion stand		2 in Role 1	
Pressure Infuser Cuff		1	

#### **A.7 Devices for managing life-threatening problems (No's for Role 1 and Ambulance separately)**

<b>Generic device group</b>	<b>Examples of European Standards</b>	<b>No</b>	<b>Comments</b>
Defibrillator with rhythm display, recording, and documentation of patient data	EN 60601-2-4	1	See monitor above A 4
External pacing facility		1	See monitor above A 4
Portable Advanced Resuscitation System (PARS): Manual resuscitators		1	

Airways, Aspirator, and Suction catheters			
Haemostatic control		4	e.g. Combat Application Tourniquet (CAT)
Tracheostomy kit		2	
Pleurocentesis kit		2	
Surgical cut-down kit		2	For vascular access and hemostasis
Injector for intraosseous infusion		4	e.g. Vitaid Ltd. EZ-IO G3 + accessories
Emergency bag fit for physician, nurse, ambulance driver.		1 per person	
CPR Back board		1	
Scissors- Rescue		1	

#### **A.8 Bandaging and nursing devices (No's for Role 1 and Ambulance separately)**

<b>Generic device group</b>	<b>Examples of European Standards</b>	<b>No</b>	<b>Comments</b>
Wound treatment materials/haemostatic dressing		10	Different sizes
Treatment materials for wounds caused by burns and corrosives		10	Different sizes
Examination Halogen Lamp		2 in Role 1	
Steriliser / autoclave		1 in Role 1	Not needed with single use equipment.
Ring cutter		1 in Role 1	
Adhesive fixing materials		10	
Kidney bowl set		1 in ambulance 2 in Role 1	
Gastric tube with accessories	EN 1618	10	
Sterile surgical glove, set of pairs.	EN 2 -1, -2, -3 and -4	2	All sizes
Minor Surgery set and surgical instruments		4 only Role 1	
Skin cleaning and disinfection material set	Standards from CEN/TC 216 <i>Chemical disinfectants and antiseptics</i>	10	
Bowl		2	
Screen on wheels		2 in Role 1	

Refrigerator with temperature monitoring (can also be separate temperature monitoring)		1 in Role 1	
Clock		2	
<sup>a</sup> E.g. scalpels, suture holder, stitch cutter, forceps, scissors, clamps etc.			

#### **A.9 Rescue and protection equipment etc. (No's for Role 1 and Ambulance separately)**

<b>Type</b>	<b>No</b>	<b>Comments</b>
Light rescue tools, set	2	Only for ambulance
Seat belt cutter (number per ambulance member)	1	Only for ambulance. Pre-hospital pocket-tool including belt cutter, window punch and a knife
Warning lights	2	Only for ambulance
Fire extinguisher	1 in ambulance 4 in Role 1	
Spotlight (number per ambulance member)	1	Headlight
Basic protective clothing including safety helmets and safety gloves, per person	1	
CBRN protective clothing including cbrn industrial and chemical filters (Number per person)	1	
CBRN Patient protection and isolation bag	5 in Role 1 1 in ambulance	
Vomiting bag set	10	
Sharps container	1 in ambulance 3 Role 1	
Crash Cart / Resuscitation trolley	1 in Role 1	
Sheets, Blankets and pillows	2 in ambulance 4 in Role 1	
Waste box/bag /garbage can	10	
Urinal	1	
Gel bags	10	
Jug	1 in Role 1	
Body bag	1	
Gloves boxes, nitril and latex	1 in each size	
Hand towel Dispenser	At all washbasins	
Hand wash bottle dispensers	At all washbasins	
Hot water bottle	1 in Role 1	
Hot water bottle cover	2 in Role 2	

Insect killer		
Laundry – Iron	I in Role 1	

#### **A.10 Reception area and waiting room Role 1**

<b>Type</b>	<b>No</b>	<b>Comments</b>
Reception desk	1	
Chairs office	2	
Filling cabinets with security lock	2	
Computer/printer	1	
telephone	1	
Chairs patients	5	
Tables	1	

#### **5. Role 1 treatment and emergency room**

- 5.1. The treatment and emergency room, 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.
- 5.2. 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.
- 5.3. There shall be a fixed lockable container available for the storage of controlled drugs. Means shall be provided for keeping temperature sensitive drugs cool ( $6 \pm 2$  °C) and to warm up infusion bags ( $38 \pm 2$  °C).
- 5.4. It is desirable to have windows in the patient compartment being positioned or screened to ensure the privacy of patients when required. To prevent hypothermia the regulation of the room temperature to 18 - 28 °C should be in place at all times.

#### **6. Information to be supplied by the manufacturer**

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

## **7. Medical devices, products and equipment for Emergency's Role 1 and ambulance**

- 7.1. Ambulance is defined as a special vehicle equipped for emergency care for qualified patient transport to a medical treatment facility.
- 7.2. The ambulance has to be equipped to provide resuscitative care, administer basic drugs and begin administration of intravenous fluids in addition to providing basic first aid.
- 7.3. The ambulance has to be capable to transport one littered patient, but preferable more with a MASCAL.
- 7.4. Advanced communication capability for coordination with PECC and accompanying units

## **ANNEX IV – PHARMACEUTICAL STOCK HOLDINGS**

### **1. General**

- 1.1. Cold chain integrity for medical items that are temperature sensitive is ensured 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 1 and ambulance responsibilities. The contracting Agency 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 40 outpatients and 5 inpatients for 60 days.
- 1.4. All drugs should be approved by the European Medicines Agency (EMA)

<b>Groups of Medicinal products (Drugs)</b>
Analgesics, general and local
Antipyretics
Antibiotics, antiparasitic, antiviral, including malaria prophylaxis
Common respiratory drugs
Common cardiovascular drugs
Common gastro-intestinal drugs
Common musculo-skeletal drugs
Anti-anxiety drugs
Ophthalmology drops and ointment
ENT drugs
Condoms
Topical drugs
Resuscitation drugs



Anaesthesia drugs
Intravenous infusion fluids
Vaccines, including Rabies
Antidotes: against local venoms, including human rabies immunoglobulin (HRIG), CBRN antidotes according to lead nation
CBRN decontamination products for patients
Refrigerator, Pharmaceutical Storage

## ANNEX V – SKILL SET

Module	Capability	Skill Set
<b>Primary Healthcare</b>	Provision of general medical practice including basic occupational medical advice	<ul style="list-style-type: none"> <li>- Assess and treat a patient</li> <li>- Refer patient to specialised care when required</li> <li>- Deliver preventive medical treatment</li> <li>- Control and realise vaccinations</li> <li>- Preparation and training of the medical team</li> <li>- Be able to manage CBRN patient (Hazard Management Capability, i.e decontamination or casualty bags)</li> <li>- Ensure that personnel exposed to a blast potentially responsible of a Minimal Traumatic Brain Injury is identified and traced. This information is transmitted to the appropriate national defence health service or civilian connecting medicating treatment facility</li> </ul>
	Perform pre hospital care and life support	<ul style="list-style-type: none"> <li>- Apply basic life support techniques</li> <li>- Apply decontamination procedures (contaminated and infectious)</li> <li>- Effect patient tracking</li> <li>- Perform advance (trauma) life support</li> </ul>
	Manage severe casualties (trauma and wound injuries)	<ul style="list-style-type: none"> <li>- Conduct triage</li> <li>- Assess patients</li> <li>- Apply pre-hospital trauma life support principles</li> <li>- Knowledge of: triage, radiation, decontamination procedures (radio contamination and infectious) and (aero) medevac</li> <li>- Record and update patient related observations and treatment</li> <li>- Conduct Damage Control Resuscitation</li> <li>- Perform analgesia (intravenous and/or local or regional anaesthesia)</li> <li>- Perform immobilisation</li> </ul>

	Manage patient transfer	<ul style="list-style-type: none"> <li>- Inform higher MTF level and commanders (MEDEVAC procedure)</li> <li>- Assist in preparation of equipment for casualty evacuation.</li> <li>- Prepare patient for transfer and explain transport procedures to the patient</li> <li>- Complete medical records and transfer documentation to ensure proper handover</li> <li>- Include procedures to follow in case of death</li> </ul>
	Manage nursing care	<ul style="list-style-type: none"> <li>- Assist and inform physician</li> <li>- Assess patient and deliver nursing care</li> <li>- Dress and bandage wounds</li> <li>- Ensure or maintain haemorrhage control</li> <li>- Prepare and administer medication (including pain relief)</li> <li>- Check proper application of plasters and splints</li> <li>- Ensure cleanliness and comfort of patient</li> <li>- Manage clinical waste</li> </ul>
	Manage infectious and CBRN contaminated patients (if applicable)	<ul style="list-style-type: none"> <li>- Recognise CBRN patient</li> <li>- Triage CBRN patient</li> <li>- Perform CBRN patient assessment including 'Quick Look'</li> <li>- Provide life-saving interventions in a CBRN environment including trauma</li> <li>- Perform patient hazard management (contain, decontamination and/or isolation)</li> <li>- Manage chemical patient</li> <li>- Manage biological patient including sepsis</li> </ul>
	Manage field sterilisation services (if applicable) and manage storage of sterile equipment	<ul style="list-style-type: none"> <li>- Receive contaminated equipment</li> <li>- Clean and disinfect equipment</li> <li>- Inspect and service equipment</li> <li>- Pack and sterilise equipment</li> <li>- Maintain stock levels</li> <li>- Manage store</li> </ul>
	Conduct administrative tasks	<ul style="list-style-type: none"> <li>- Produce all technical and administrative documents for patient (minimum core data, epidemiologic table)</li> <li>- Record medical activities</li> <li>- Issue medical certificates</li> <li>- Follow procedures in case of death</li> <li>- Knowledge of command procedures</li> </ul>

	Control stock levels in transport assets (if applicable) and manage stores	<ul style="list-style-type: none"> <li>- Control stock of drugs</li> <li>- Control medical oxygen stock and other medical material</li> <li>- Manage stores</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>
Module	Capability	Skill set
<b>Patient Holding</b>	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 dressings 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>
	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	- Be able to act IAW the established MASCAL plans and procedures
Module	Capability	Skill Set
<b>Isolation Ward (If applicable – use table if this capability is added to the contract)</b>	Handle an infectious and/or CBRN contaminated patient	<ul style="list-style-type: none"> <li>- Be able to provide personnel and patient protection to safely treat contaminated or infectious patients</li> <li>- Be able to use protective equipment according to the applicable procedures</li> <li>- Be able to use the applicable procedures relevant to functioning in an isolation ward</li> </ul>
	Treat an infectious and/or CBRN contaminated patient	- Be able to provide the same level of care as described for the ward module in the environment of the isolation ward with regard to the risks of contamination
	Transfer of an infectious and/or CBRN contaminated patient	<ul style="list-style-type: none"> <li>- Have knowledge and be able to transfer a contaminated patient without posing a risk for others.</li> <li>- Be able to recognise the level of infectiousness of the contaminated patient.</li> <li>- Be able to apply measures in regard to the level of infectiousness.</li> <li>- Know procedures to follow in case of death</li> </ul>
	Handling of contaminated waste	<ul style="list-style-type: none"> <li>- Have knowledge of and be able to use the described procedures for handling contaminated waste in the isolation ward.</li> <li>- Have knowledge of and be able to use the described procedures for safely moving contaminated waste from the isolation ward IAW the effective waste handling procedures</li> </ul>
	Handling isolation ward specific and other materials	<ul style="list-style-type: none"> <li>- Ensure the appropriate level medical materials and equipment for use in the isolation ward and for transport of contaminated patients</li> <li>- Have knowledge of and be able to use the procedures for moving medical materials and equipment from the isolation ward</li> <li>- Have knowledge of resupply resources and procedures</li> </ul>
	Respond to MASCAL	- Be able to act IAW the established MASCAL plans and procedure
Module	Capability	Skill Set

<b>Chemical, Biological, Radiation and Nuclear Decontamination</b> <b>(If applicable – use table if this capability is added to the contract)</b>	Manage trauma and contaminated under Individual Protective Equipment.	<ul style="list-style-type: none"> <li>- Triage CBRN patients</li> <li>- Perform CBRN patients assessment including ‘Quick Look’</li> <li>- Provide life-saving interventions in a CBRN environment including trauma</li> <li>- Perform patient hazard management (contain, decontamination and/or isolation)</li> <li>- Manage combined chemical patients</li> <li>- Manage combined biological patients including sepsis</li> <li>- Manage combined radiological patients including nuclear</li> </ul>
	Manage contamination or contagious risks	<ul style="list-style-type: none"> <li>- Perform patient hazard management (contain, decontamination and/or isolation)</li> <li>- Establish a patient decontamination area / centre</li> <li>- Establish patient isolation area</li> </ul>
	Manage the medical aspects of a CBRN incident	<ul style="list-style-type: none"> <li>- Identify on scene CBRN hazards</li> <li>- Mitigate any on scene CBRN hazards</li> <li>- Establish incident zones and cordons</li> <li>- Establish command and control</li> <li>- Establish communications and a reporting chain <ul style="list-style-type: none"> <li>· Produce a CBRN medical incident report</li> <li>· Complete a CBRN verbal handover</li> <li>· Complete a CBRN casualty report form</li> </ul> </li> <li>- Complete a medical assessment of the scene</li> <li>- Carry out CBRN and conventional triage</li> <li>- Establish on scene medical infrastructure</li> <li>- Advise on the use of post-exposure Medical Countermeasures</li> <li>- Conduct operational epidemiology</li> </ul>
	Manage chemical contaminated patient	<ul style="list-style-type: none"> <li>- Assess a patient for life-threatening chemical intoxication</li> <li>- Treat a patient for life-threatening chemical intoxication</li> </ul>
	Manage biological contaminated patient	<ul style="list-style-type: none"> <li>- Assess a patient for signs of infection and sepsis</li> <li>- Assess a patient for signs of biological toxin exposure</li> <li>- Assess a patient for risk of a contagious disease</li> <li>- Treat a patient with sepsis</li> <li>- Treat a patient with a significant infection</li> <li>- Treat a patient with a biological toxin exposure</li> </ul>

	Manage irradiated contaminated patient	<ul style="list-style-type: none"> <li>- Assess a patient for signs of significant irradiation</li> <li>- Treat a patient for prodromal symptoms of acute radiation syndrome</li> <li>- Manage a combined radiological casualty</li> <li>- Manage the early stages of acute radiation injury</li> </ul>
	Supervise stocks level	<ul style="list-style-type: none"> <li>- Control oxygen stock</li> <li>- Control antidotes, antibiotic and vaccine stock levels</li> <li>- Be able to access medical stockpiles when available</li> </ul>
	Manage specific equipment and personnel	<ul style="list-style-type: none"> <li>- Store and manage operational equipment</li> <li>- Ensure control procedures, and CBRN defence equipment reliability</li> <li>- Manage human resources</li> </ul>
	Logistic and administrative functions	<ul style="list-style-type: none"> <li>- Supply consumables (water, soap, etc.)</li> <li>- Provide activity reports</li> <li>- Order CBRN medical resupply</li> <li>- Record the use of medical countermeasures</li> <li>- Record any possible or confirmed CBRN exposure</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>Laboratory</b>	Provide laboratory service	<ul style="list-style-type: none"> <li>- Provide laboratory support</li> <li>- Collect clinical samples</li> <li>- Be able to arrange shipping of biological samples (including those presenting specific CBR hazards)</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 equipment</li> <li>- Manage the disposal of biological waste</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>Medical Supply</b>	Provide drugs and medical (disposable) supply.	<ul style="list-style-type: none"> <li>- Be able to deploy the capacity to provide sufficient medical supply tailored to the type of the Role 1 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 the re-supply of medical gases.</li> <li>- Be able to advice on the handling of medical waste.</li> <li>- Be able to respond to MASCAL</li> </ul>
<b>Module</b>	<b>Capability</b>	<b>Skill set</b>
<b>Oxygen</b>	Provide medical oxygen	<ul style="list-style-type: none"> <li>- Be able to provide medical oxygen IAW agreed standards</li> <li>- Be able to validate the required quality of medical oxygen</li> <li>- Be able to provide the quantity of medical oxygen required by the medical system to be supported</li> </ul>
	Manage storage and supply	<ul style="list-style-type: none"> <li>- Be able to store medical oxygen IAW the applicable safety and storage regulations</li> <li>- Be able to provide medical oxygen in cylinders as required by the system to be supported Be able to provide a guaranteed and continuous flow of medical oxygen for fixed hospital supply systems (if applicable)</li> </ul>



	Manage communication and administration	- Be able to register, track and trace produce and distributed medical oxygen.
	Respond to MASCAL	- Be able to act IAW the established MASCAL plans and procedures
<b>Module</b>	<b>Capability</b>	<b>Skill set</b>
	Provide pharmacy services	<ul style="list-style-type: none"> <li>- Be able to deploy a sufficient medical supply capacity to support the Role 1</li> <li>- Be able to advise the commander of the Role 1 in the domains of pharmacy and medical supply.</li> <li>- Be able to provide the pharmacy support to the Role 1.</li> <li>- Be able to manage the stock and the distribution of medical materiel.</li> <li>- Be able to advice on the handling of medical waste.</li> </ul>
	Respond to MASCAL	- Be able to act IAW the established MASCAL plans and procedures
<b>Module</b>	<b>Capability</b>	<b>Skill Set</b>
<b>Preventive Medicine</b>	Provide sampling services	<ul style="list-style-type: none"> <li>- Collect samples</li> <li>- Develop sampling protocols</li> <li>- Process samples (shipment, storage) according to international regulations</li> <li>- Develop sample processing procedures</li> </ul>
	Perform analysis	<ul style="list-style-type: none"> <li>- Develop requirements for analysis</li> <li>- Analyse samples</li> <li>- Provide technical validation of methods and results</li> <li>- Provide record of reported results</li> </ul>
	Provide preventive medicine advise	<ul style="list-style-type: none"> <li>- Provide advice for infectious diseases management to commanders at all levels</li> <li>- Provide advice for defence against health risks to commanders at all levels</li> <li>- Provide preventive medicine information in theatre</li> <li>- Maintain communication with reference laboratories</li> </ul>
	Manage rodent control	- Provide rodent control

	Manage administrative and logistical functions	<ul style="list-style-type: none"> <li>- Supervision of laboratory team</li> <li>- Manage and maintain PrevMed equipment</li> <li>- Supervision of consumable re-supply</li> <li>- Redaction of procedures and protocols</li> <li>- Provide activity reports</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>
Module	Capability	Skill set
<b>Response and or In-transit Ambulance (If applicable – use table if this capability is added to the contract)</b>	Manage pre hospital care and life support	<ul style="list-style-type: none"> <li>- Pre-hospital trauma life support principles</li> <li>- Knowledge of: triage, CBRN insults and hazards, decontamination procedures (CBR contamination) and management of infectious patients, and (aero) medevac</li> <li>- Record and update patient related observations and treatments</li> </ul>
	Manage severe casualties (trauma and wound injuries)	<ul style="list-style-type: none"> <li>- Manage a patient according to ATLS or Battle ATLS procedures</li> <li>- Conduct triage</li> </ul>
	Manage patient tracking and transfer	<ul style="list-style-type: none"> <li>- Inform higher MTF level and commanders (IAW medical evacuation procedures)</li> <li>- Prepare equipment for casualty evacuation</li> <li>- Know and be able to apply techniques for immobilisation, mobilisation and transport of patients</li> <li>- Prepare patient for transfer and explain transport procedure to the patient</li> <li>- Complete medical records and transfer documentation to ensure a proper handover</li> <li>- Be familiar with procedures to be followed in case of death</li> </ul>
	Manage CBRN patients	<ul style="list-style-type: none"> <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 patient 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> </ul>

	Manage nursing care	<ul style="list-style-type: none"> <li>- Assess patient and deliver nursing care</li> <li>- Dress and bandage wounds</li> <li>- Ensure or maintain haemorrhage control</li> <li>- Prepare and administer medication (including pain relief)</li> <li>- Check proper application of plasters and splints</li> <li>- Ensure cleanliness and comfort of patient</li> </ul>
	Ensure transport	<ul style="list-style-type: none"> <li>- Hold appropriate driving licences</li> <li>- Check and maintain the proper state of the vehicle (minimum mechanic vehicle control)</li> <li>- Knowledge of the (aero) medevac organisation and structure</li> <li>- Record medical activities</li> <li>- Know command procedures according the appropriate SOP's</li> <li>- Be able to use maps, GPS and communication system</li> </ul>
	Supervise stock levels in transport assets and manage stores	<ul style="list-style-type: none"> <li>- Control stock of drugs</li> <li>- Control oxygen stock and other medical material</li> <li>- Manage stores</li> <li>- Manage clinical waste</li> </ul>
	Respond to MASCAL	<ul style="list-style-type: none"> <li>- Be able to act IAW the established MASCAL plans and procedure</li> </ul>

Module	Capability	Skill set
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<b>Medical Plans</b>	Plan medical support to operations	<ul style="list-style-type: none"> <li>- Be aware of the medical footprint, the medical capabilities, capacities and limitations of all medical systems in the mission area including air, sea and ground transportation means</li> <li>- Be aware of the planned military operations</li> <li>- Be able to advise the Medical Advisor and Operational Commander(s) on the medical support for future operations</li> <li>- Be able to prepare and plan for MASCAL situations.</li> <li>- Be able to anticipate and act on changing requirements for medical support depending on the actual situation that have effect on future operations</li> <li>- Be able to disseminate all necessary information to the parties involved</li> <li>- Ensure the regular update of all planned operational medical support information</li> <li>- Be able to prepare and plan for CBRN incidents (CBRN contingency plan)</li> </ul>
	Information handling	<ul style="list-style-type: none"> <li>- Have knowledge of the available communication and information systems</li> <li>- Have knowledge of who to contact and how to contact all stakeholders for the planned medical support to operations</li> <li>- Be able to log and report on planned medical support activities</li> <li>- Be able to evaluate executed operational medical support plans</li> <li>- Be able to identify lessons learned and apply these to future operational medical support plans</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>

Module	Capability	Skill set
<b>Medical Operations</b>	Control medical support to operations	<ul style="list-style-type: none"> <li>- At all times be aware of the medical footprint, the medical capabilities, capacities and limitations of all medical systems in the mission area including air, sea and ground transportation means</li> <li>- Be aware of the planned medical support for ongoing and near future planned operations</li> <li>- Be able to inform the Medical Advisor and Operational Commander(s) immediately on the medical operational situation</li> <li>- Be able to anticipate and act on changing requirements for medical support depending on the actual situation for on-going and near future operations</li> <li>- Be able to disseminate all necessary information to the parties involved</li> <li>- Ensure the continuous update of all operational medical information</li> <li>- Be able to advise on adaptation of medical planning</li> </ul>
	Communication	<ul style="list-style-type: none"> <li>- Have knowledge of the available communication and information systems</li> <li>- Have knowledge of who to contact and how to contact all stakeholders in the ongoing and near future planned medical support to operations</li> <li>- Ensure the use of the communication to effectively coordinate and advise on medical support</li> <li>- Be able to log and report on operational medical support activities IAW MedOps procedures</li> <li>- Be able and report all MEDOPS daily activities IAW MEDOPS 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>

## ANNEX VI – References

1. Comprehensive Health and Medical Concept for EU-led Crisis Management Missions and Operations ST 10530/14 - EEAS 00559/6/14
2. EU concept for Contractor Support to EU-led military operations, ST 8628/14 - EEAS 00754/14
3. European Union Military Concept on Environmental Protection and Energy Efficiency for EU-led military operations ST 13758/12 - EEAS 01574/12
4. EUMC Glossary of Acronyms and Definitions, ST 6330/17 - EEAS (2017) 121, 14. February 2017
5. EU Commission - Medical Device Directive 93/42/EEC
6. Directive 2005/36/EC of the European Parliament and of the Council, 7 September 2005 on the recognition of professional qualifications
7. EU Commission Regulation no. 965/2012
8. Council of Europe (2011). Common European Framework of Reference for Languages: Learning, Teaching, Assessment. Council of Europe.
9. Council Directive of 14 June 1993 covering medical devices (93/42/EEC)
10. Council Directive of 12 May 1986 on the protection of workers from the risks related to exposure to noise at work (86/188/EEC)
11. Council Directive of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (89/391/EEC)
12. ISO 9703-3 Anesthetic and respiratory care alarm signals - Part 3: Guidance on application of alarms ventilators
13. ISO 14644-4 Cleanrooms and associated controlled environments – part 4: Design, construction and start-up
14. ISO 14698-1, Cleanrooms and associated controlled environments—Biocontamination control, Part 1: General principles and methods
15. ISO 14698-2, Cleanrooms and associated controlled environments—Biocontamination control, Part 2: Evaluation and interpretation of biocontamination data
16. EN 3-3 Portable fire extinguishers - Construction, resistance to pressure, mechanical tests
17. EN 3-6 Portable fire extinguishers - Part 6: Provisions for the attestation of conformity of portable fire extinguishers in accordance with EN 3 part 1 to part 5
18. EN 3-7 Portable fire extinguishers - Part 7: Characteristics, performance requirements and test methods to pressure and mechanical tests for extinguishers with a maximum allowable pressure equal to or lower than 30 bar
19. EN 3-9 Portable fire extinguishers - Part 9: Additional requirements to EN 3-7 for pressure resistance of CO2 extinguishers
20. EN 340 Protective clothing – General requirements
21. EN ISO 9170-1:2008 Terminal units for medical gas pipeline systems -- Part 1: Terminal units for use with compressed medical gases and vacuum
22. EN 738-4 Pressure regulators for use with medical gases - Part 4: Low-pressure regulators intended for incorporation into medical equipment
23. EN 794-3:1998+A2:2009 Lung ventilators. Particular requirements for emergency and transport ventilators
24. EN ISO 21647:2004 Medical electrical equipment. Particular requirements for the basic safety and essential performance of respiratory gas monitors
25. EN 980 Graphical symbols for use in the labeling of medical devices
26. EN 1041:2008 Revision to the Medical Devices Directive: Information supplied by the manufacturer with medical devices

27. EN ISO 5356-1:2004 Anaesthetic and respiratory equipment. Conical connectors. Cones and sockets
28. EN 1282-2:2005+A1:2009 Tracheostomy tubes. Paediatric tubes
29. EN 1707 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Lock fittings
30. EN 20594-1 Conical fittings with a 6 % (Luer) taper for syringes, needles and other certain medical equipment - Part 1: general requirements (ISO 594-1:1986)
31. EN 455-1:2000 Medical gloves for single use. Requirements and testing for freedom from holes
32. EN 455-2:2015 Medical gloves for single use. Requirements and testing for physical properties
33. EN 455-3:2015 Medical gloves for single use. Requirements and testing for biological evaluation
34. EN 455-4:2009 Medical gloves for single use. Requirements and testing for shelf life determination
35. EN 1618:1997 Catheters other than intravascular catheters. Test methods for common properties
36. EN ISO 5361:2012 Anaesthetic and respiratory equipment. Tracheal tubes and connectors
37. EN 1789 Medical vehicles and their equipment – Road ambulances
38. EN 1865 Specifications for stretchers and other patient handling equipment used in road ambulances
39. EN ISO 5364:2011 Anaesthetic and respiratory equipment. Oropharyngeal airways
40. EN ISO 5367:2014 Anaesthetic and respiratory equipment. Breathing sets and connectors
41. EN 13220 Flow-metering devices for connection to terminal units of medical gas pipeline systems
42. EN 14605 Protective clothing against liquid chemicals - Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])
43. EN 60068-2-6 Environmental testing - Part 2: Tests - Tests Fc: Vibration (sinusoidal) (IEC 60068-2-6:1995 + Corrigendum 1995)
44. EN 60068-2-29 Basic environmental testing procedures - Part 2: Tests - Test Eb and guidance: Bump (IEC 60068-2-29:1987)
45. EN 60068-2-32 Basic environmental testing procedures - Part 2: Tests - Test Ed: Free fall
46. EN 60068-2-64, Environmental testing - Part 2: Test methods - Test Fh: Vibration, broad-band random (digital control) and guidance (IEC 60068-2-64:1993 + Corrigendum 1993)
47. EN 60529 Degrees of protection provided by enclosures (IP code) (IEC 60529:1989)
48. EN 60601-1 Medical electrical equipment - Part 1: General requirements for safety
49. EN 60601-2-4 Ed. 2: Medical electrical equipment – Part 2-4: Particular requirements for safety of cardiac defibrillators (2011)
50. EN 60601-2-24 Medical electrical equipment – Part 2: Particular requirements for the safety of infusion pumps and controllers (IEC 60601-2-24:2015)
51. EN 60601-2-27 Medical electrical equipment – Part 2: Particular requirements for the safety of electrocardiography monitoring equipment (IEC 60601-2-27:1994)
52. EN 60601-2-30 Medical electrical equipment – Part 2-30: Particular requirements for the safety, including essential performance of automatic cycling non-invasive blood pressure monitoring equipment (IEC 60601-2-30:1999)

53. EN 60601-2-31 Medical electrical equipment – Part 2: Particular requirements for the safety of external cardiac pacemakers with internal power source (IEC 60601-2-31:1994)
54. EN 60601-2-34 Medical electrical equipment – Part 2: Particular requirements for the safety of blood pressure monitoring equipment (IEC 60601-2-34:2000)
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58. EN 61000-4-6 Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 6: Immunity to conducted disturbances, induced by radio-frequency fields (IEC 61000-4-6:1996)
59. EN ISO 10297:2014 Transportable gas cylinders - Cylinder valves - Specification and type testing
60. EN ISO 407:2004 Small medical gas cylinders - Pin-index yoke-type valve connections
61. ISO 6009:2016 Hypodermic needles for single use -- Colour coding for identification
62. EN ISO 7864:2016 Sterile hypodermic needles for single use. Requirements and test methods
63. EN ISO 7886-1:1997 Sterile hypodermic syringes for single use. Syringes for manual use
64. EN ISO 7886-2:1997 Sterile hypodermic syringes for single use. Syringes for use with power-driven syringe pumps
65. ISO 9001:2015 Quality management systems -- Requirements
66. EN ISO 10524-1:2006 Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices
67. EN ISO 10524-3:2005 Pressure regulators for use with medical gases -- Part 3: Pressure regulators integrated with cylinder valves
68. EN ISO 10555-1:2013 Intravascular catheters. Sterile and single-use catheters. General requirements
69. EN ISO 10555-5:2013 Intravascular catheters. Sterile and single-use catheters. Over-needle peripheral catheters
70. EN ISO 14971 Medical devices - Application of risk management to medical devices
71. EN ISO 18777 Transportable liquid oxygen systems for medical use – Particular requirements
72. EN ISO 11197 Medical supply units (ISO 11197:2004)
73. EN ISO 19054 Rail systems for supporting medical equipment
74. ISO 7137:1995
75. ISO 80601-2-55:2011 Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
76. EN ISO 81060-1:2012 Non-invasive sphygmomanometers. Requirements and test methods for non-automated measurement type
77. EN ISO 10079-1 Medical suction equipment – Part 1: Electrically powered suction equipment – Safety requirements (ISO 10079-1:1999)



78. EN ISO 10079-2 Medical suction equipment – Part 2: Manually powered suction equipment (ISO 10079-2:1999)
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