CBRN Mobile Laboratories

The FP7-SECURITY MIRACLE project: major recommendations
Position paper

Abstract

The EU-funded MIRACLE project has dedicated its work to the description of needs and advantages of an EU capacity of CBRN Mobile Laboratories. To achieve this, the consortium has developed a set of scenarios for which a mobile laboratory should be of added value, including in support of the implementation of EU policies and international conventions. Subsequently the existing capacity in EU MS and gaps were identified with regards to these scenarios. Finally the consortium has delivered a set of aligned operational functions based on a generic mission cycle as well as a set of basic requirements including communication and forensic techniques. During the project, the major Ebola outbreak affecting three countries in West-Africa underlined the need for rapidly deployable laboratory capacities, and two members of the consortium deployed in West-Africa with their national capacity for assisting the WHO and local Authorities to contain the spread of Ebola disease. This field experience strengthened the overall findings of the MIRACLE project, the conclusions of which will be presented and discussed during its final conference on the 21st May 2015. The present position paper sets major recommendations regarding needs and opportunities for the EU to establish a Mobile Laboratory Capacity that can be deployed inside and outside the EU in case of a Chemical or Biological Incident; it highlights logical steps to be taken to build and organize such a capacity while making it fully and rapidly operational. Key recommendations include needs for (1) different concepts of mobile laboratory according to scenarios (locations, threat specificity, crisis intensity, driver-institution, etc.); (2) modular approach enabling timely relevant joint national and international intervention within or outside the EU with highly mobile light elements, followed by heavier and slower capacities according to duration and frequency of deployment; (3) preparing this capacity and train the operators before a real crisis, highlighting the crucial need for a network of training centers playing the role of technological incubator and innovation-drift; (4) EC coordination and support of a network of European national and international deployable modules in terms of harmonization and standardization process, user requirements interlaboratory exercises, operational deployment, and sustainability.

1. Policy background - Rationale for use of mobile laboratories

The generic role of CBRN mobile laboratories is to p*rovide rapid on scene evidential results to be generated routinely and to reduce the logistics and transportation burde*n. Consequently, this type of in-field capacity allows incident managers to develop timely relevant counter-measures while reducing associated risks and costs. This is especially true when a high number of samples from the field need to be processed in a short time. CBRN mobile laboratories are hence designed to be operated by a *rapidly deployable staff as an ideal complementary solution to the existing networks of reference laboratories*. The mobile laboratory provides therefore a *flexible and affordable working area for integrated or hybrid equipment and systems that combine the advantages of current and emerging technologies*. The challenge here is to take these instruments and methods out of the fixed-site laboratory facilities into the operational environment. To achieve this, tools, materials, and methods have to be adapted, compacted and tested against on-field conditions. The main points of concern are safety and security, with the main optimisation criterion based on rapidity of deployment and of samples assessment.

Needs for such mobile laboratories respond to a number of policy requirements implying rapid and in-situ measurements for a wide variety of CBRN substances and forensic/criminal investigations. At international level, several CBRN conventions are relevant in the defence

sector, namely the Treaty on the Non-Proliferation of Nuclear Weapons, the Chemical Weapons Convention, the Biological and Toxin Weapons Convention, and the UN Security Council Resolution 1540. NATO is also developing standards for rapidly deployable outbreak investigations for suspected use of Biological Warfare Agents, and stresses the need for analytical capacity with more appropriately-sized, more multifunctional, more mobile, more rapidly deployable and which are capable of mission tailoring. In the area Disaster Reduction and Humanitarian Aid, the Hyogo Framework for Action 2005-2015 has highlighted the need for innovative technologies and tools that can be easily deployed in case of a disaster; this framework is now prolonged by the Sendai Framework for Disaster Reduction for the period 2015-2025. The International Health Regulations 2005 also requires the availability of fast, mobile, laboratory facilities for the detection of health-related threats.

At the EU level, development and use of mobile CBRN laboratory with a forensics dimension[1] is tightly integrated into a set of EU policies and initiatives. Core policies in this respect are the *EU CBRN Action Plan*[2] and the *Explosive Action Plan*[3] which aim to reduce the threat of, and damage from, CBRN and explosive incidents of accidental, natural and intentional origin, including terrorist acts while complementing national measures that address existing gaps and promote exchanges of information and best practices. Among the various objectives dealing with prevention, detection, preparedness and response, several measures are potentially requiring mobile laboratories, e.g. for detecting CBRN materials in order to prevent CBRN incidents, to efficiently respond to incidents involving CBRN materials and to recover from them as quickly as possible, to analyze potential problems in the transport of CBRN contaminated evidence across borders within the context of criminal investigations and emergency situations, to ensure that collected forensic evidence in CRBRN crime-scenes is of high enough quality to be admissible in court proceedings in the EU Members Sates, etc.

CBRN risk mitigation at the international, regional and national levels is also an objective of the *CBRN Centers of Excellence* (CoE) sponsored by the European Union through the *EU instrument for Stability and Peace 2014-2020*[4]. They represent one of the key external assistance instruments that enable the EU to take a lead in helping to prevent and respond to actual or emerging crises around the world. The CBRN CoE is implemented jointly by the Joint Research Centre (JRC) of the European Commission and the United Nations Interregional Crime and Justice Research Institute (UNICRI). The MIRACLE Project will actively liaise with the CBRN CoE that will be a crucial point of contacts to promote the project, disseminate the results, and to understand CBRN needs of the interested countries. This will be in line with the objective pursued by the European Commission, together with its partners: to consolidate what has already been done, in terms of assistance to countries to enhance their capabilities to prevent, detect and respond to illicit trafficking of CBRN materials, into regions of concern such as: South East Asia, South-East Europe-Caucasus, the Mediterranean Basin and Africa.

Regarding the sector of Civil Protection, the policy is represented by the *EU Civil Protection Mechanism*[5] whilst the operational dimension is coordinated by the *Emergency Response Coordination Mechanism (ERCC)* and the *European Emergency Response Capacity (EERC)* in the form of *EU voluntary pool* of pre-committed capacities from the Member states, trained experts and *Common Emergency Communication and Information System*. This policy is tightly connected

[1] CBRN forensics is not only identifying and profiling CBRN agents but also investigating and examining contaminated forensic traces

[2] **EU CBRN Action Plan (COM 2009) 273 final and COM (2014) 247 final.**
http://europa.eu/legislation_summaries/justice_freedom_security/fight_against_terrorism/jl0030_en.htm

[3] **EU CBRN Action Plan (COM 2009) 273 final and COM (2014) 247 final.**
http://europa.eu/legislation_summaries/justice_freedom_security/fight_against_terrorism/jl0030_en.htm

[4] **Instrument contributing to Stability and Peace -** http://ec.europa.eu/dgs/fpi/what-we-do/instrument_contributing_to_stability_and_peace_en.htm

[5] **EU Protection Mechanism**

- http://ec.europa.eu/echo/files/civil_protection/C_2014_7489_EN_ACT.pdf
- http://ec.europa.eu/echo/files/aid/countries/factsheets/thematic/civil_protection_en.pdf

to "*Disaster Risk Management*" policies addressing the management of natural and man-made hazards through *EU's Internal Security Strategy* (DG HOME), *health* (DG SANCO), *external action* (EEAS) and *Research and Innovation* (DG R&I). Outside the union, disaster response is coordinated with the United Nation International Strategy for Disaster Reduction (UN-ISDR) in relation to the Sendai Framework for Action.

The use of existing mobile military CBRN capacities and logistics is nowadays considered as an acceptable solution for humanitarian aid according to the scale of the crisis situation and if placed under civilian lead. This may be seen as an extension of the current CIMIC (civil military – operation) when civilian and militaries are both active in the same area in crisis situation.

Response strategies have been developed in the EU to enable the smooth transition from initial response to recovery phase and are based on the use of intelligence and information from a range of sources (detection, identification and monitoring equipment, symptomology, human intelligence etc.). When responding to an incident, it is indeed critical to be able to deal with a real time CBRN incident appropriately which implies forensic awareness, but also to minimise disruption and mitigate reputational risk when an incident is a deliberate hoax. Many situations require immediate exchange of information among Commission rapid alert systems (RAS) such as *ECURIE system* for radiological emergencies, the *Early Warning and Response System* (EWRS) for communicable diseases, the *RAS-BICHAT* for biological and chemical health threat. The Health Security Committee plays an important role in responding to health threat while the European Centre for Disease Control (ECDC) provides risk assessment for communicable diseases.

2. MIRACLE: return on experience – feedback from the field

The "*Return on Experience*" and direct feedback (lessons learned) from C, B, or RN mobile laboratory operators back from mission inside and/or outside the EU are of direct benefits for policies. Practical examples of national contributors from which return on experience has been exploited in the MIRACLE project and highlighted throughout this "Position Paper" document are the deployment of the *Belgian light fieldable B-LiFE laboratory in Guinea* (December 2014 - March 2015), the *German Bundeswehr light fieldable laboratory* in Mali (December 2014), the *European Mobile Laboratory in West Africa* (March 2014 - ongoing), and the Canadian Mobile laboratory for Public Health Agency, Winnipeg, Canada, all contributing in the Ebola crisis. *Further, the Dutch Environmental Assessment Module (EAM) deployed by the Dutch National Institute for Public Health and the Environment (RIVM) as* Environmental Emergency Response Mission, in Zamfara State, Nigeria for assessing lead pollution in water associated with poisoning crisis (September 2010).

Two mobile B lab interventions, the Belgium B-LiFE / B-FAST project and the European Mobile Lab consortium, both related to the Ebola outbreak in West Africa, provided significant inputs to the findings and analysis of the MIRACLE project. The usability of such interventions is however also valid in case of C or RN-related crises, particularly through the use of aligned operational functions:

In both projects light biological laboratory were deployed directly adjoining Ebola Treatment Centres in West Africa. The main goal of these laboratory missions was to conduct a rapid DNA-based identification of Ebola virus in samples from suspected patients in the outbreak areas. Several scientific projects were carried out concomitantly (e.g. study of the clinical efficacy of antiviral drugs, validation of new rapid diagnostic tests and mapping of Ebola contamination in different clinical samples and the environment).

In March 2014, *WHO's Global Outbreak Alert and Response Network (GOARN)* asked for assistance from the *European Mobile Laboratory (EMLab)* project. The Project shipped one of its laboratories – packed in 10–15 boxes that weigh 30 kg each and can be transported by commercial airplane or two trucks – to West Africa. The EMLab project is funded by *EuropAid* –

DG Development and Cooperation (DEVCO) and almost all the European biosafety-level-four (BSL4) laboratories and other institutes specialized in the diagnosis of haemorrhagic fever diseases have provided the EMLab consortium with skilled scientists and technicians. Training for response and operation of the mobile laboratory units was performed at the *Bundeswehr Institute of Microbiology* which is also a member of the MIRACLE consortium. The training enabled the responders to run the laboratory units in the field, with logistical support for reagents and consumables from their home bases.

Since the beginning of the outbreak, two more EMLab units and *over 100 European scientists* have been deployed for an average of 4 weeks each. *Over 10.000 samples* (of blood, swabs and urine) have been tested so far, *over 3.500 of which tested positive for Ebola virus* in the EMLabs in Guinea, Sierra Leone, Nigeria, and Liberia.

The B-LiFE / B-FAST mission (Biological Light fieldable laboratory / Belgian First Aid and Support Team) was deployed to N'Zerekore, Forest Guinea from 20th of December 2014 until 22nd of March 2015. The team consisted of members from Civil Protection, Defence and Laboratory operators from CTMA (Centre for Applied Molecular Technologies / IREC / UCL). The project was financially supported by the B-*LiFE project funded by the European S*pace Agency and *the project FP7 MIRACLE* funded by the European DG HOME. The mission was an important European advance as it was the first time that the "voluntary pool" of the European Mechanism for Civil Protection was rapidly activated.

The B-LiFE project and the "Emergency.lu" service provided by the Luxembourg Government also enabled the laboratory to have an *outstanding satellite communication capability allowing secure communications* at very high speed to Belgian and international operational centres. This capacity benefited from a *close collaboration with the European Space Agency, the European Commission (DG ECHO and ERCC).* The *COPERNICUS Emergency Management Service* enabled the laboratory to integrate advanced technologies developed by *small and medium-sized Belgian enterprises* (Nazka MAPPS, Aurea IMAGING and EONIX) and satellite operator SES TechCom Luxembourg.

The return of experience from those two projects and other laboratory interventions, e.g. light fieldable laboratory deployed by the German Bundeswehr in Mali in December 2014, the Canadian Mobile laboratory for Public Health Agency in Winnipeg (Canada), the Dutch Environmental Assessment Module (EAM) deployed by the Dutch National Institute for Public Health and the Environment has been incorporated in the MIRACLE project's recommendations for CBRN mobile laboratories' structure and operational.

3. Recommendations about CBRN mobile laboratories' structure and operational features

The structure of CBRN mobile laboratories is determined by basic factors: type of CBRN threat, nature of the incident, activation mechanisms, location of deployment and accessibility, duration of mission, frequency of deployment, and considerations about ownership and laboratory-driver institutions. The following recommendations can be expressed in consideration of the need for a spectrum of mobile facilities with various sizes, configurations, levels of autonomy and management:

CBRN specificity: This is the *first and main factor determining the structure* of a CBRN mobile laboratory. There is a large consensus that single C, B, RN or forensic capacities should be preferred to mixed or comprehensive CBRN and forensic capacities due to major differences in sample collection and processing. While existing capacities (e.g. C-B laboratory) are often based on heavier laboratory (on wheel or container), single C, B, RN or forensic specificity is the most common model, usually developed as national (Defense or Health department) capacities. Accordingly, the nature of the incident and the driver institutions, the scale of the intervention

and the need for forensic resources will impact on the type of capacity. Whilst crisis situations inside the EU may justify combining C, B and RN technologies inside a single mobile laboratory, especially when the threat is not known, they are not easily nor rapidly deployable outside the EU. *The recommendation is therefore to use a single laboratory specific for C, B, RN or forensic capacity, especially if a rapid deployment is required outside the EU.* These, in turn, can act jointly in a multinational configuration *in return of a global coordination.*

- **Heavy structure vs. light module**: From the above, different concepts regarding the most suitable characteristics of a mobile capacity should be developed. It is noteworthy that the *location of deployment* (i.e. areas easily accessible versus poorly accessible by road, like in very remote areas with no passable road), *duration* (short-term versus long-term) and *frequency* of the mission should determine the most suitable features (weight / volume) of the laboratory.
  i. **In C or B crisis situation outside the EU** where *remoteness and accessibility to the site of deployment is often a main issue*, urgent interventions ideally require a *specific light fieldable version of existing B or C capacities*. *For a CB crisis outside the EU and cross border crisis anywhere in the world,* it is recommended to develop *international or multinational joint capacities*, as demonstrated by the successful joint co-intervention of light national and international laboratories deployed side by side from more than one year in West Africa during the Ebola crisis. . This would also pave the way *to ensure efficiently regular interventions* in countries at risk of repeated CB crises. The unusual and dramatic Ebola crisis in West Africa has indeed pinpointed the *need for laboratories which can rapidly move from one area to another while staying operational for a long period of time* (more than a year in the current crisis). In this situation, the recommendation is to develop light rapidly deployable laboratories.
  ii. **For CB incidents inside the EU**, heavy national CB laboratories (on wheel, large container on truck) as single of mixed capacities are suitable for rapid intervention and preservation of forensic evidence. Except for military capacities made for intervention abroad, such mobile CBRN laboratories are rather conceived for short term homeland intervention.
  iii. **Mixed solution combining light and heavier deployment** should be considered in a prolonged crisis situation. Until today, a prolonged intervention outside the EU has indeed been a rather infrequent situation which represents therefore the biggest challenge for light fieldable CB capacities. Frequent crises in remote countries should rather favor stable structural solutions such as creation of new fixed-site stationary labs or reinforcement of existing laboratories in the host country. A valuable alternative consists in planning a rapid intervention of light fieldable capacities at a very early phase of response, with a takeover by heavier structures (truck; container) at a later step. This will depend on mission duration (weeks, months or years), intensity of the crisis and accessibility of the location.
- **Sustainability of the mobile capacity:** Lessons learned demonstrate that (1) national capacities are suitable for short term homeland mission but can be rapidly confronted with limiting turnover of own technologically experienced staff in case of long-term international mission; moreover, when a national capacity is deployed in inaccessible remote area outside the EU, the military logistics is usually considered as mandatory especially if resources needed for self-proficiency require heavy air carrier landing in "operational conditions". However, humanitarian operations fall out of classical scope of military engagement and therefore face several "*military showstoppers*" (e.g. MEDEVAC and security issues) slowing or hampering a straightforward military contribution, if any; these issues should therefore be solved at the EU level; (2) the same recommendation applies to deployment of national private (mainly research) institutions as they face the same logistic issues when requiring a national military support; (3) whilst commercial capacities do not enter into consideration as autonomous capacity in the management of a CB crisis, acquisition of comprehensive or partial commercial solutions are often privileged by private, national or international entities so that needs for a standardization process and harmonization is recommended at the EU level for enabling joint multinational

interventions; commercial laboratories could however be part of EU deployment capabilities, for instance for supporting a new therapeutic trial, in return of a clear business model defining the service offered, the mechanism for sustainability, the targeted stakeholders and the conditions of use; (4) international capacities (e.g. the EU mobile laboratory capacity) proved to be suitable for long-term deployment. A clear advantage was an easy recruitment of lab operators throughout Europe for the whole length of the Ebola mission in West Africa.

- **Activation mechanisms**: Besides the essential international coordination by e.g. ERCC, WHO, UN, alternatives to international coordination imply direct bilateral contacts and arrangements between a host and a participating nation. However, the latter requires coordinating a swift integration into the global international response. *The recommendation would be to harmonize the mechanism of activation and to enable a common activation and reciprocal support of national and international (if any) capacities. There is a clear need for European strategies orchestrating the best use of a spectrum of CBRN mobile laboratory capacities in the EU*.
- **Efficient information exchange**: The above highlights the *need for secure and formatted communication channel* between the on-field laboratory and the external world, which implies to make an interactive link with all key actors involved (i.e. network of laboratories and various operators in the field) as well as national/international coordination centers and international institutions involved in the crisis management (WHO, UNHCR, ECDC, etc.). It is recommended to *harmonize and strengthen access to the information* regarding the objective of deployment and analytical procedures to be carried out (pre-awareness), as well as on the level of CB threats (type of threats, scale of the problem, safety procedures, communicable diseases, epidemiological data, etc.).
- **Harmonization of results delivery process while respecting ethical issues:** Regarding information exchange applied to the transmission of results*, it is recommended that formatted results be always provided to authorized key operators (local, regional, international) while addressing them with the most suitable and readable information (i.e., ensuring compatibility with all ICT systems; defining a list of regularly updated recipients,….).* The aim should be to increase interoperability, making data and results readable and usable by key operators according to their respective position in national and international response teams. *Besides, it is also recommended that privacy and anonymity of patients' personal medical data or confidentiality of data source be guaranteed and preserved (cryptographic techniques for securing storage of data, data encryption).*
- **Self-sufficiency of analytical modules**: As recommended by Civil Protection Mechanism, self-sufficiency should be guaranteed by the offering member state, i.e., any analytical capacity working in the field should be able to be *self-sufficient for at least three days* while *anticipating the need for a chain of supply in case of longer-term deployment*. However, not all light fieldable capacities are necessarily equipped to meet this type of operational requirement which indeed requires a specific and dedicated logistic support. Existing EU and other coordination mechanisms should therefore be used as much as possible to support and coordinate a rapid deployment when self-sufficiency cannot be achieved on a national basis. The contribution of NGO already active in the crisis area and of institutional organisms such as World Food Program should be solicited.
- **Efficient quality management system**: The quality control of measurements needs to be ensured, requiring specific QA/QC rules (e.g. SOP, reference materials etc.). For CBRN-forensic investigations the legal and quality assurance requirements of forensic work could go further than the requirements of other types of CBRN-related analyses. In many situations maintaining a strict chain of custody, accreditation of forensic laboratory work as well as qualified (or certified) forensic experts are required if evidence is to be considered admissible to court.
- **Mandatory compliance with safety national and international rules and/or legislation:** Regulatory and legislative aspects also need to be taken into consideration. Regarding the transportation of dangerous goods, IATA rules should be respected in order to comply with the

custom rules of all countries which are flown over during (re)deployment. Regarding occupational regulations, *European occupational health and safety regulations* apply for fixed laboratory structures. There are two main aspects that should be considered: the "*Environmental protection act*" and the "*Worker protection act*". Existing European regulations for stationary CBRN laboratories have to be reviewed for their applicability in a mobile lab setting in austere field conditions abroad. It is realistic to accept a higher level of risk regarding health and safety in a mobile laboratory, and a common agreement on risk assessment is needed. When dealing with bio-threats in deployable capacities, the biosafety BSL3/BSL4 rules, practices and legal aspects cannot always be respected and this is particularly true *when deploying outside the EU: in this case, the best practices should prevail.* If the EU would provide guidance for a "*European Mobile Laboratory Standard"* this would be complimentary to existing standards of stationary laboratories.

- **Normative aspects**: These aspects which are indeed essential do not necessarily involve standardization *sensu stricto* (adoption of e.g. ISO or CEN standards) but rather considering the added value of harmonization (good practices adopted as guidelines, not necessarily as rigid standards) of the use of equipment, procedures, SOPs, and logistics. The aim should be to maintain these aspects compatible with international guidelines, in particular those issued by NATO. While harmonization of equipment and procedures is achieved with RN laboratories (in accordance with IAEA guidelines) and is quite satisfactory for C laboratories, the diversity of biological threats significantly slows down attempts to harmonize the methods used in B laboratories. Harmonization of the B sector is therefore lagging behind compared to C and RN specific domains. The normative aspects of forensic mobile capacities depend also on the legal system of the country or the institution where the evidence will be presented: accreditation should be considered inside the EU but, if not impossible, remains highly challenging outside the EU. Consequently, a useful and practical *recommendation* for "improving disaster management using CBRN mobile laboratories" would be *to promote a harmonized mobile laboratory concept with definition of key operational functions (OFs) using agreed semantics*. The recommendation is to align the OFs to set up a reference system enabling the comparison of different types of capacity, irrespective of their C, B, RN or forensics specificity or complexity (weight, volume, and mobility). To facilitate the decision making at all levels *the recommendation is to apply knowledge and information management methods based on ontological approach as a new way of increasing the operational performance of deployable capacities*. *Ontology* here is a formal, explicit specification of a shared conceptualization describing the CB mobile laboratory as an operational domain.
- **Network of EU national and international CBRN modules**: According to different ownership and considering the respective advantages of national versus international capacities, it is *recommended that a mechanism of reciprocal inter-laboratory cooperation be therefore promoted at the EU level, including a service level agreement*. In that respect the EC should strengthen, coordinate and support a network of European national and international deployable modules in terms of harmonization and standardization process, user requirements, inter-laboratory exercises, operational deployment, and sustainability. Meanwhile*, it is recommended to set up a mechanism of inter-laboratory coordination and communication* in order to improve the work efficiency and exchange of precious information regarding the evolution of the crisis, best practices, successful innovations, difficulties, problems and need for mutual assistance.

4. Recommendations on other specific needs

Training CBRN mobile laboratory operators

It is *recommended to create and support a European network of training capacities addressing operational and safety issues in field conditions*. The role of training is twofold: it is crucial for improving the preparedness and for offering a maximum protection of responders; it is also

crucial for providing a sufficient number of adequately trained laboratory operators. It is recommended to train laboratory operators on the basis of existing experience, using if possible harmonized operational functions and best practice in the field. Moreover, new solutions to solve technological issues are best proposed, assessed and validated by immediate interaction between trainers, operators and developers using existing and newly elaborated scenarios (applied games/scenarios) through the channel of training centres and via iterative improvements. In that respect, *mobile laboratories are a perfect technological incubator acting as a cradle of technology push and innovative drift.* It is recommended that the mission of capacities deployed outside the EU *integrates also education and training of indigenous staff*. *Also appropriate training of first responders and mobile laboratory staff in forensic awareness is recommended. This should improve considerably the possibilities of forensic investigation in CBRN incidents.*

Ensuring uninterrupted, rapid and efficient chain of supply

Ensuring a continuous, rapid and efficient delivery of specific reagents, material, equipments and spare parts is vital but highly challenging outside the EU. It is therefore recommended to *strengthen and secure the supply chain*. Experience demonstrates that supply *cannot always be delivered on time in remote and poorly accessible areas outside the EU and that inherent difficulties as discussed above make support of military logistics mandatory*. One additional point to be considered is the *EU legislation which makes compulsory to have a call for tender with specifications and three offers* for commercial companies. *Exceptions to this rule exist at the EC level but, from lessons learned, are not always known by operating actors. To speed up urgent acquisition of material and equipment, it is recommended that all institutions or organisms dealing with urgent purchase of equipments, reagents or goods in case of crisis situation and emergency situation are made aware of this exception to the rule and to how proceed with it.*

Decontamination and waste management: legal, safety and harmonization requirements

It is recommended to establish a *state of the art in CB decontamination and waste management* and to *harmonize the procedures based on the best practices as well as current international and national legislations,* particularly when operating a laboratory outside the EU. Ad hoc legislations *are sometimes lacking outside the EU*. Alternatively, *international law, policies, treaties, and agreements identify certain rights and obligations that may affect the management of the operations*. These legal requirements may pose constraints and restraints. Whilst a *European Mobile Lab Safety Regulation Standard* appears as a necessity, it should be different from best practice on stationary labs, due to the specific conditions of operational field requirements. *In the repatriation and redeployment phase, there is need to have clear guidelines regarding the best decontamination practices for the equipment and material* in order to facilitate homeland repatriation and redeployment in accordance with the law.

Scope of the mission: pre-awareness and flexibility

Before the deployment, it is recommended that the lab-coordinator and operators receive reliable information regarding the scope of the mission, including all expectations regarding the objective of deployment and analytical procedures to be carried out (rapid diagnosis of the cause of the outbreak, need for differential diagnosis according to local epidemiology, monitoring of patients' vital parameters, complementary investigations related to clinical studies or R&D needs, post-crisis medical assessment) as well as on the level of CB threats (type of threats, scale of the problem, safety procedures, communicable diseases, epidemiological data, etc…). The scope of the mission, as firstly defined, should be carefully and interactively reviewed, (re)assessed and adapted if necessary during the mission, requiring from the team a maximum of flexibility for rapid implementation.

Communication tools and integration of space research-based tools

Reliable in-field communications between national and international actors and operators is vital. *It is therefore recommended to push the integration of European space capacities like*

COPERNICUS and GALILEO into the operational function of CBRN mobile capacities. It is also recommended *to define the optimal architecture of communication tools* that would be adaptive according to the field operational requirements and the potential added value of complementary technologies (e.g. geolocation and earth observation, possibly through *Unmanned Aerial System*).

Harmonization of the results delivery process while respecting ethical issues

It is recommended to harmonize the results delivery process while maintaining the privacy and anonymity of patients' personal medical data. Database results should be formatted to increase interoperability, making them readable and usable by key operators. *Special attention should therefore be paid to the harmonization of format of results, to the identification of data recipients and to the level of protection to be provided* (Data Encryption and storage of cryptographic techniques).

Proposal for R&D&I projects addressing gaps and technological challenges

a. *New analytical tests:* There is a need for new tests combining detection and identification, being more portable, reliable, rapid, and cost-effective.

b. *Need for widening the spectrum of analyses carried out in the field.* Analysis should enable a differential diagnosis according to the type of CBRN threats. It should also enable complementary analyses able to monitor the patient vital condition after exposure to a CBRN threat.

c. *Sampling and handling all kinds of samples:* It is recommended to develop universal methods and technologies enabling the decontamination, preparation and processing of different matrixes for environmental and human samples. In that respect, harmonization of laboratory procedures is also mandatory.

d. *Need for developing new tools and equipment* with (a) suitable features for in-field use (volume, weight, low energy consumption, wireless transmission of results); (b) easy transport and deployment such as temperature-insensitivity, low energy appliance, small volume, small weight, and automatic wireless (WiFi) transmission of results to the laboratory command station. These tools are expected to be useful for rapid investigations of the cause (natural, accidental, or criminal) of a C or B crisis and its consequence on humans and environment (food, water). It is also recommended to develop equipments enabling to combine detection and identification; (c) concomitantly the EU also needs tools to properly assess and investigate a potential criminal C or B release (forensics); (d) finally, development of user-friendly materials (e.g., Airco, electric power supply, Satcom, water sanitation, decontamination of equipment ….) is mandatory as these often request a technical expertise extending far beyond the pure medical or CB expertise available from laboratory operators in the field. This also requires adequate technological specifications.

e. *Need to fight fragmentation among suppliers with improved end-user oriented solutions.* It is recommended to integrate this process through the channel of training centres associating operators, trainers and developers). *There should also be a mechanism for comparing mature technologies or solutions when they look very much alike (test and evaluation tools).*

f. Ensuring the chain of custody: recommended procedures include tracking (geolocation) and securing samples, preventing tampering and tracking records of samples with potential link to geolocation in order to follow the evolution of environmental or patients contamination with CBRN agents.

g. Need for advanced forensics research: Importance of preserving forensic evidence in a CBRN event which also implies finding suitable solutions for discrepant constraints regarding decontamination and preservation of forensic evidence.

h. Need for further research in human factors: wide range of stressful conditions in the field (confinement, temperature, humidity, workload, life-threatening issues, etc...).

Annex – MIRACLE Snapshot

Project full title: Mobile Laboratory Capacity for the Rapid Assessment of CBRN Threats Located within and outside the EU. Website: http://www.cbrnlab.eu/miracle/
Coordination and Support Action
Grant Agreement N°: 312885
Start date: 01/12/2013 - End date: 31/05/2015

MIRACLE Partners:

- UCL, Centre for Applied Molecular Technologies & BE-Defence, BE (Coordinator)
- IMB, Bundeswehr Institute of Microbiology, Munich, DE
- EADS Astrium, (Airbus Defence & Space), FR
- FOI, Swedish Research Agency, Umea, SE
- FFI, Forsvarets forskuningsinstitutt, NO
- NFI, Netherlands Forensic Institute, Ministry of Security & Justice, NL
- PHAC, Public Health Agency of Canada, Winnipeg, CA
- PSNI, Police Service of Northern Ireland, UK
- RIVM, National Institute of Public Health and the Environment, NL

Background: In case of major international, accidental or natural CBRN incident, fast detection and identification of agents on scene are crucial deciders enabling to take timely proper counter measures for stopping the spread of the agent, and mitigating its impact on humans, animals and environment. Consequently, a determining factor is to bring a rapidly deployable CBRN diagnostic and forensic capacity as close as possible to the crisis area. However, there are many different ways to understand and define what a CBRN mobile capacity should ideally be, how to develop and best operate it in field conditions, and how to maintain it sustainable. In that respect, the possibility to develop scalable capacities for joint multinational intervention is crucial.

Objective: In order to present practical recommendations regarding optimal structure, composition and function of CBRN Mobile Laboratories, the MIRACLE consortium analysed various practical cases of laboratory deployment and credible scenarios of missions, identified existing capabilities, current capability shortcomings and explored potential end-user relevant solutions. In this document a solely CBRN military deployment is considered to be out of scope as there are other specific mechanisms already in place to deal with such issues and is therefore not described. A joint intervention of civilian and military resources was considered at the light of civilian natural, accidental or intentional CBRN crisis.

The objective of MIRACLE is to harmonize the definition of a mobile CBRN laboratory, to define the key generic operational functions, and subsequently to provide useful recommendations to European policy-makers and stakeholders in terms of optimal structure, composition and function of CBRN Mobile Laboratories to be developed for use in- and outside the EU in case of CBRN crisis. These recommendations are synthetically formulated by the consortium in this Position Paper.

MIRACLE project is co-funded by the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement No. 312885