FP7-SEC-2012-4.4-1

(CSA-Coordination action):

MIRACLE

MobIle Laboratory Capacity for the Rapid Assessment of CBRN Threats Located within and outside the EU

The overall objective of this feasibility study is to provide a global deliverable "CBRN mobile laboratory architecture(s)" that relies (a) on a better understanding and definition of the need and optimal solutions for mobile lab, and (b) on a clear and straightforward interface with existing EU capabilities / structures.

This report is one of the deliverables (D6.3) of the larger MIRACLE project.

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Project title: Mobile Laboratory for the Rapid Assessment of CBRN Threats Located within and outside the EU

Proposal acronym: MIRACLE

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Topics addressed: Topic SEC-2012.4.4-1 *Development of mobile laboratories, structures and functions to support rapid assessment of CBRN events with a cross-border or international impact*

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3	Bundeswehr Institute of Microbiology	IMB	DE	Government
4	Forsvarets forskningsinstitutt	FFI	NO	RTO
5	Totalforsvarets forskningsinstitut	FOI	SE	RTO
6	Nederlands Forensisch Instituut	NFI	NL	RTO
7	Public Health Agency	PHAC	CA	Government
8	Police Service of Northern Ireland	PSNI	UK	Government
9	National Institute of Public Health & the Environment	RIVM	NL	RTO

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1. Executive Summary

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.

2. MIRACLE: snapshot

- ✓ **Project full title**: Mobile Laboratory Capacity for the Rapid Assessment of CBRN Threats Located within and outside the EU: 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 Molecular Technologies & BE-Defense, 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: the generic role of CBRN mobile laboratories is therefore to *provide rapid on scene evidential results to be generated routinely and to reduce the logistics and transportation burden*. Results from this type of in-field capacity enables 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 designed to be operated by *a rapidly deployable staff as an ideal complementary solution to the existing networks of reference laboratories*. The time needed for transporting and deploying the mobile laboratory should be short since the different components can be easily packaged and moved together with a limited staff of trained experts. Accordingly, the "projection" of a CBRN mobile laboratory to the source of a threat where people are exposed to the risk helps control so-called "secondary dissemination or contamination" associated with the transportation of patients and samples.

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, including stationary, reference and reach back capacities, into the operational environment. To achieve this, tools, materials, and methods have to be adapted, compacted and tested against field conditions. The main points of concern are safety and security, with the main optimisation criterion based on mobility.

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 of this position paper as final MIRACLE deliverable:

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 main goal *of MIRACLE is to harmonize the definition of a mobile CBRN laboratory irrespective of existing differences, 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 which are synthetically formulated by the consortium in this position paper are also linked to the international and European policy background.

3. Policy Background - Rationale for use of mobile laboratories

3.1 International CBRN conventions and policies

Needs for 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. As detailed hereafter, l, several CBRN conventions are relevant at international level 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.

- **N: Treaty on the Non-Proliferation of Nuclear Weapons**, **commonly known as the Non-Proliferation Treaty (NPT)**, is an international treaty whose objective is to prevent the spread of nuclear weapons and weapons technology, to promote cooperation in the peaceful uses of nuclear energy, and to further the goal of achieving nuclear disarmament and general and complete disarmament. Opened for signature in 1968, the Treaty entered into force in 1970. On 11 May 1995, the Treaty was extended indefinitely.
  The Treaty establishes a safeguards system under the responsibility of the IAEA, which also plays a central role under the Treaty in areas of technology transfer for peaceful purposes.
- **C: The Chemical Weapons Convention (CWC**) is an arms control treaty which outlaws the production, stockpiling, and use of chemical weapons and their precursors. The full name of the treaty is the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction and it is administered by the Organisation for the Prohibition of Chemical Weapons (OPCW/OIAC), an intergovernmental organization based in The Hague, Netherlands. The treaty entered into force in 1997. The parties' main obligation under the convention is to prohibit the use and production of chemical weapons, as well as the destruction of all current chemical weapons. The destruction activities are verified by the OPCW.
- **B: The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (usually referred to as the Biological and Toxin Weapons Convention** (BTWC)) was the first multilateral disarmament treaty banning the production of an entire

category of weapons. The Convention was the result of prolonged efforts by the international community to establish a new instrument that would supplement the 1925 Geneva Protocol. The Geneva Protocol prohibits use but not possession or development of chemical and biological weapons.

- **United Nations Security Council resolution 1540:** This resolution was adopted unanimously on 28 April 2004 regarding the non-proliferation of weapons of mass destruction. The resolution establishes the obligations under Chapter VII of the United Nations Charter for all Member States to develop and enforce appropriate legal and regulatory measures against the proliferation of chemical, biological, radiological, and nuclear (CBRN) weapons and their means of delivery, in particular, to prevent the spread of weapons of mass destruction to non-state actors.
- **Council Regulations N° 1257/96:** This regulation governs the implementation of all Union operations providing humanitarian assistance to victims whose own authorities are unable to provide effective relief. This is an important aspect of external relations and, by focusing on supplies and services, the policy aims to prevent and alleviate suffering. To ensure that policy is both effective and comprehensive, coordination between the Member States and the Commission is reinforced by cooperation with NGOs and international organisations.
- **Hyogo Framework for Action 2005-2015 (HFA):** it is the first plan to explain, describe and detail the work that is required from all different sectors and actors to reduce disaster losses. It was developed and agreed on with the many partners needed to reduce disaster risk - governments, international agencies, disaster experts and many others - bringing them into a common system of coordination. The HFA outlines five priorities for action, and offers guiding principles and practical means for achieving disaster resilience. This means reducing loss of lives and social, economic, and environmental assets when hazards strike.
- **Sendai Framework for Disaster Reduction 2015-2035**: this extends HFA and set up . a far reaching new framework for disaster risk reduction with seven targets and four priorities for action. The framework outlines seven global targets to be achieved over the next 15 years: a substantial reduction in global disaster mortality; a substantial reduction in numbers of affected people; a reduction in economic losses in relation to global GDP; substantial reduction in disaster damage to critical infrastructure and disruption of basic services, including health and education facilities; an increase in the number of countries with national and local disaster risk reduction strategies by 2020; enhanced international cooperation; and increased access to multi-hazard early warning systems and disaster risk information and assessments.
- **International Health Regulations 2005**: This binding instrument of international law entered into force on 15 June 2007 in response to the exponential increase in international travel and trade, and emergence and reemergence of international disease threats and other health risks, to implement the International Health Regulations (2005) (IHR). The stated purpose and scope of the IHR are "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade." Because the IHR are not limited to specific diseases, but are applicable to health risks, irrespective of their origin or source, they will follow the evolution of diseases and the factors affecting their emergence and transmission.

- **NATO policy:**
  - *Comprehensive, Strategic-Level Policy for Preventing the Proliferation of Weapons of Mass Destruction (WMD) and Defending against Chemical, Biological, Radiological and Nuclear (CBRN) Threats* http://www.nato.int/cps/en/natolive/official_texts_57218.htm
  - NATO Standard, AMedP-74, Rapidly Deployable Outbreak Investigation Team (RDOIT) for suspected use of Biological Warfare Agents: draft version based on initial draft January 2011 and edition 2, Version SD1, November 2013. The need for analytical capacity with more appropriately-sized, more multifunctional, more mobile, more rapidly deployable and which are capable of mission tailoring is expressed.
  - *NATO STANAG 4632 JAS (Edition1) – Deployable NBC analytical laboratory*: The aim of this agreement is to establish capability standards for the NATO Deployable NBC Analytical Laboratories (referred to as "NBC-AL"). The aim of the NBC-AL is to enhance situational awareness by providing expert sampling and identification of chemical, biological, radiological and nuclear agents within a NATO Area of Operations (AOR). This assists the NATO commanders in achieving timely decisions on the appropriate course of action.

3.2 European bodies, policies and initiatives

The development and use of mobile CBRN laboratory with a forensics dimension[1] is tightly integrated into a set of EU mechanisms, policies and institutions' initiatives (e.g., initiatives and policies from DG-HOME, DG-ECHO, DG-DEVCO, DG-ENV, DG-SANCO, DG-Research, EDA and ESA) and EU mechanisms of activation linked with a series of EU bodies.

a. DG-HOME and the *CBRN action plan:*

The development of mobile CBRN facilities with a forensics dimension meets several objectives described in the CBRN action plan.

The risks posed by terrorist groups acquiring chemical, biological, radiological or nuclear (CBRN) materials require coordinated action. In recent years, such measures have been taken at both national and European Union (EU) level. In January 2009, the CBRN Task Force produced a final report which constitutes the basis for the *EU CBRN Action Plan*[2]. This plan aims to reduce the threat of, and damage from, CBRN 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. The main objective of the EU CBRN Action Plan is to develop a more comprehensive strategy to CBRN-E policies at EU level creating synergies from the two Action Plans on CBRN and Explosives, and connecting policy and actions better to related fields, such as detection, developing common scenarios in the CBRN detection field, good practices in security training, awareness building, better using research, improving emergency response plans and support to exercises at EU and international level.
The Action Plan focuses on prevention, detection, preparedness and response:

- Detection: having the capacity to detect CBRN materials in order to prevent or respond to CBRN incidents (Goal 4, action H28, initiate the development of mobile

[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

detection, identification and sampling capabilities, supported by the Commission at the EU level.)

- Preparedness and Response: being able to efficiently respond to incidents involving CBRN materials and to recover from them as quickly as possible (Goal 2, Action H34: the location of the available capabilities to assess the response capacity made available by the Member States through the Community Civil Protection Mechanism. Goal 5, action H42: training on forensic awareness in a CBRN crime-scene; action H43: analyze potential problems in the transport of CBRN contaminated evidence across borders within the context of criminal investigations and emergency situations; action H44: ensuring that collected forensics evidence in a CRBRN crime-scene is of high enough quality to be admissible in court proceedings in the EU Members Sates…..).

In order to assist the Commission in its tasks, a *CBRN Advisory Group*[3] was established in 2010, with a composition similar to that of the CBRN Task Force. In addition, the Commission has developed an *EU CBRN Resilience Programme to improve CBRN work* within the framework of the Civil Protection Mechanism (2). Its objective is to ensure better links between different civil protection activities in the field of CBRN and to tackle identified gaps in a coherent way.

b. DG DEVCO and CBRN-E Centers of Excellence

The creation of the *CBRN Centers of Excellence* (CoE) aims at implementing a coordinated strategy for CBRN risk mitigation at the international, regional and national levels. The CBRN CoE was sponsored by the European Union through the *EU Instrument for Stability (IfS - Regulation (EC) No 1717/2006; 2007-2013)* succeeded since March 2014 by *the Instrument contributing to Stability and Peace (IcSP) and EU instrument for Stability and Peace 2014-2020*[4] . IcSP is 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 services for Foreign Policy Instrument (FPI), working in close collaboration with other services of the European Commission and the European External Action Service (EEAS), mobilises the IcSP to provide for urgent short-term actions in response to situations of crisis or emerging crisis, often complementing EU humanitarian assistance, and longer-term capacity building of organisations engaged in crisis response and peace-building.

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

[3] **EU CBRN Advisory Group and EU CBRN Resilience Programme.**

- http://ec.europa.eu/dgs/home-affairs/what-we-do/policies/crisis-and-terrorism/securing-dangerous-material/index_en.htm
- http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%2015505%202009%20REV%201
- material/docs/eu_cbrn_action_plan_progress_report_en.pdf
- http://ec.europa.eu/echo/files/aid/countries/factsheets/thematic/civil_protection_en.pdf

[4] **Instrument contributing to Stability and Peace**

- http://ec.europa.eu/dgs/fpi/what-we-do/instrument_contributing_to_stability_and_peace_en.htm

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.

c. DG ECHO policy and ERCC

Regarding the sector of Civil Protection (DG ECHO), the policy is represented by the revised legislation on *Union 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 (i.e., modules, technical assistance and support teams, other response capacities and experts), and *Common Emergency Communication and Information System*.

Moreover, the group of experts of Civil Protection modules, acknowledging lessons learnt in past civil protection operations, identified and stressed the need to develop EU guidelines for the provision of host nation support (HNS) to States participating in the EU Civil Protection Mechanism, delivering assistance during a major emergency[6].

It is of note that DG ECHO policy is also tightly connected 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 and other relevant international actors with reference to *Council Regulations N° 1257/96 regarding Humanitarian aid*[7] (see supra synergies and link of MIRACLE deliverables with international CBRN conventions*).*

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.

d. Recommendations issued by the ESRIF Working Group 6 CBRNe

In addition to the CBRNe Action Plan, an EU initiative called ESRIF European Security Innovation Forum was established. One of the Working Groups within the ESRIF was entirely dedicated to CBRNe. In this setting, the ESRIF Working group on CBRNe made several

[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

[6] **Commission Staff Working document : EU Host Nation Support guidelines**
- http://ec.europa.eu/echo/files/about/COMM_PDF_SWD%2020120169_F_EN_.pdf

[7] **Council Regulations N° 1257/96 regarding Humanitarian aid**
- http:// http:// eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32013D1313http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:347:0924:0947:EN:PDF

recommendations under which the need to further develop "Transportable Laboratory", a concept that is in line with the MIRACLE project focusing on the global architecture of "Fieldable mobile laboratories, structures and functions"[8]. One of these recommendations from the working group was: "Response to CBRN crisis; identification and investigation: Standardized tests and equipment for testing CBRN threats with the goal of quickly ruling out at least 90% of hoaxes".

Additional to this recommendation the working group states that it is crucial for the crisis management system to identify the real nature of the incident as reliably and as quickly as possible through:

- Development of methods and procedures for forensic sampling, analysis for unknowns.
- Extended strain collections of B agents (bacteria and viruses) to represent world-wide geographic origin.
- Genome sequencing of B-agents with immediate comparison with extensive sequence databases.
- Micro-systems technology for miniaturization CBRN laboratory capability, transportable/movable/portable in order to be able to bring 'the lab to the traces' instead of bringing 'the traces to the lab'

e. EU bodies and agencies dealing with CBRN risks and disasters

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.

Serious cross-borders threats to health pinpoint the need for efficient international coordination and exchange of information. *While Decision No2119/98/EU covered epidemiological surveillance and control of communicable diseases in the Community, other threats (i.e., other biological or chemical agents or environmental events) also need to be considered*. The legal framework set up under Decision 2119/98/EC was therefore extended to cover these other threats and to provide for a coordinated wider approach to health security at Union level (*Decision 1082/2013/EU on serious cross-border threats to health;* http://ec.europa.eu/health/preparedness_response/docs/decision_serious_crossborder_threats_22102013_en.pdf).

[8] **European Security Innovation Forum (ERSIF) report 2009.**

- http://ec.europa.eu/enterprise/policies/security/files/esrif_final_report_en.pdf

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

EU should markedly benefit from "*Return on Experience*" and direct feedback (lessons learned) from C, B, or RN mobile lab operators back from mission inside and/or outside the EU. The return of experience from those two projects (*Belgian light fieldable B-LiFE laboratory in Guinea,* Dec 2014-Mar 2015; the European Mobile Laboratory (EMLab) intervention), 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 have been incorporated in the MIRACLE project's recommendations for CBRN mobile laboratories' structure and operational.
Starting from this return on experience, it is of note that the chronology of quick deployment is not comparable for B- and C-lab. Whereas an immediate B-intervention is always preferable, the intervention often takes place after clinical symptoms have occurred in a significant number of patients, which implies a delay of several weeks or months at best. Regarding a C-intervention, the collection of samples needs to be carried out within two hours after the incident. This is simply unconceivable when it needs to be implemented outside the EU except if organizing an immediate and adequate local sampling in return of appropriate training.

4.1 Biological threats

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 Space 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), has been incorporated in the MIRACLE project's recommendations for CBRN mobile laboratories' structure and operational.

4.2 Chemical threats

The Dutch Environmental Assessment Module (EAM) was deployed by the Dutch National Institute for Public Health and the Environment (RIVM) in the context of an Environmental Emergency Response Mission, in Zamfara State, Nigeria for assessing lead pollution in water associated with poisoning crisis (Sept 2010).
Reference: https://docs.unocha.org/sites/dms/Documents/Lead Pollution and Poisoning Crisis Environmental Emergency Response Mission Zamfara State Nigeria 2010.pdf

5. Main recommendations

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:
Preliminary consideration: As there are international and worldwide recognized mechanisms in place for the rapid response to Radiological or Nuclear incidents (IAEA), this position paper will now preferentially consider chemical and biological incidents rather the comprehensive CBRN spectrum.

- **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. Single C, B, RN or forensic specificity is by the way the most common model due to substantial differences in sample collection, processing, equipment, reagents, expertise and training.

Regarding the CB specificity, a valuable alternative is a *mixed C-B capacity,* especially when dealing with crises inside the EU. While situations exist where combining C, B and RN technologies inside a single mobile laboratory is justified, especially when the threat is not known, and should therefore not be ruled out, this type of capacities are usually heavier laboratory on wheel (truck) or in container, often developed for national purposes and owned by national/ federal institutions (such as Health Department or Defense) for homeland intervention. The advantage is that they are perfectly adapted to include forensic analyses.. However, their genuine restricted deployability consecutive to their weight, volume and requirement for a well developped road network, make them be less suitable for rapid intervention outside the EU, unlike rapidly deployable single C- or B-module. Moreover, it should be pointed out that crises outside the EU are usually related to either B- or C- rather than CB-crisis. Consequently, the type of incident (i.e., natural, accidental, or intentional) and the type of crisis (i.e., civilian or military), the scale of the intervention and the need for forensic resources will substantially impact on the type of capacity, the driver-institution and the need for forensics analytical resources.

Considering the variety and number of features determining the optimal structure, composition and function of CBRN and forensic mobile laboratories, there is clearly a need for a spectrum of facilities with various sizes, configurations, levels of autonomy and management. *The recommendation is 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.*

- **Location, duration and frequency of deployment**

Whereas location and length are main factors determining the structure of the CBRN mobile laboratory, all three parameters are tightly integrated and should therefore be considered

together when looking at their impact of the laboratory structure. It is assumed that mobile CBRN laboratories are above all designed for *short term intervention* whereas current existing CBRN capacities, except for military CB mobile facility, are often built for national crisis situation where the frequency of intervention is not an issue.
Until today, a long-term intervention outside the EU has been a rather infrequent situation which represents therefore the biggest challenge for mobile CB laboratories. Although this should logically favor alternative stable structural solutions such as the creation of new fixed-site stationary labs or the reinforcement of existing laboratories in the host country, the unusual and dramatic Ebola crisis in West Africa has pinpointed the need for extremely mobile laboratories which can be rapidly transported from one location to another (see hereafter). *In this situation as well as for regular interventions in remote areas outside the EU, having light rapidly deployable laboratories has obvious advantages. These light fieldable capacities deployed at a very early phase of the crisis could, in turn, be replaced by heavier structure at a later stage* (see also details hereafter in the paragraph "heavy versus light module").

- **Heavy structure versus light module?**

As from the above, *different concepts regarding the most suitable characteristics of a mobile capacity should be developed*. The return on experience for C and B scenarios confirms that urgent interventions like those related to public health issues (*major environmental or humanitarian crisis situation*) are better served when using light fieldable capacities for rapid C and B interventions (normal tent, inflatable tent, existing or easily built structures). 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. ***For a 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 co-intervention of light national and international deployed side by side from more than one year in West Africa during the Ebola crisis (the *International European Mobile Laboratory* was an initiative of DG DEVCO, developed by an international research consortium piloted by the Robert Koch Institute and operated in the field by successive lab teams from all across the EU). 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 have light rapidly deployable laboratories for rapid intervention at the very early phase, followed by heavier capacities if needed, according to the duration of the crisis (see paragraph above).
ii. **For C or B incidents inside the EU**, heavy national single C/B or mixed CB laboratories (on wheel, large container on truck, most of these being heavy structures owned by civilian, military or mixed civ-mil national/federal institutions) are suitable for

a very rapid intervention, fulfilling the mission while offering the best guarantee for preservation of forensic evidence and rapid processing of the sample. As a spectrum of such capacities exists within the EU, based on commercial solutions and/or own developments according to national CB needs and regulations, these should integrated in a network of rapidly deployable capacities used according to the type of crisis (inside or outside the EU). Except for military capacities made for abroad intervention, such mobile CBRN laboratories are indeed usually conceived for short term intervention on the homeland.

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**

Activation needs to take into consideration laboratory ownership and laboratory-driver institution: at first sight, a national ownership seems more suitable for coordinating the development phase and for maintaining the sustainability of the deployable capacity though national resources. Lessons learned from return on experience however demonstrates that: (1) if national capacities are suitable for short term mission, they can rapidly be confronted with limiting turnover of own technologically experienced staff in case of long-term mission; (2) when deployment occurs in a poorly accessible area, the national military logistics is often mandatory especially if the volume of material and logistic resources for self-proficiency require heavy air carrier in landing in “operational conditions”. As humanitarian operations fall out of classical scope of military engagement, and require avoiding “military showstoppers” such as MEDEVAC and security issues, this may however hamper a quick deployment, thereby substantially complicating the organization of the mission or even making it impossible; (3) deployment of private (mainly research institutions) faces the same issues as national capacities and often requires a national support; alternatively, analytical capacities could also independently be operated by NGO’s which are active in disaster management but examples of this type of mechanism of disaster management are still lacking; (4) whilst commercial capacities do not classically come 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 standardization, harmonization and complementarity in joint multinational interventions may be an issue and should therefore be carefully examined at the EU level when EC funding is used for developing the mobile capacity as a commercial product; 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) the return on experience confirms the suitability of international capacities (e.g., the EU mobile laboratory capacity) for long-term deployment. In the latter example, a clear advantage was

an easy recruitment of lab operators throughout Europe for the whole duration of the Ebola mission in West Africa.

Considering the respective advantages of national versus international capacities, it is recommended to create and implement a mechanism of reciprocal cooperation between laboratory-driver institutions at the EU level.

- **Activation mechanisms**

In disaster management, activation mechanisms appear to be very diverse. The EC plays a crucial role, via DG ECHO and ERCC, to offer and coordinate EU assistance, and is in charge of activating the European response. This occurs in cooperation with major international institutions like WHO and UN. Besides the essential international coordination by e.g. ERCC, WHO, UN, alternatives to international coordination imply direct bilateral contacts and arrangements between host and participating nations. 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 among which NGOs, international organisations like, ECDC, US-CDC, WHO, UN, UNICEF, etc...) as well as regular authorities from offering and affected participating states) while addressing them with the most suitable and readable information (i.e., ensuring compatibility with all ICT systems; defining and making available as early as possible 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 harmonization in the delivery process of analytical results, *it is also recommended that privacy and anonymity of patients' personal medical data or confidentiality of data source be guaranteed and preserved.* Indeed, humanitarian actions often imply a multiplicity of intervening actors(i.e., at the medical, epidemiological, logistical, organizational and political level)… all willing to dispose as quickly as possible of patients (dead and alive) database or master file with relevant medical information in order to adapt their counter-measure or

threat mitigation strategy. In that respect, to maintain the privacy and anonymity of patients personal medical data is extremely difficult, if not impossible. However, it should be pointed out the clinical results with private patient medical information is not necessarily of equal interest to all recipients, and therefore, does not need to be completely and indistinctly provided to all of them. Special attention should therefore be paid for providing the appropriate level of protection (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**

This implies an efficient quality management with a special focus on quality control of measurements 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.

Accordingly, using SOP, **protocols** and methods which ensure the quality of results should be established and validated to looking for the equipment maintenance...; it also implies an *efficient coordinating and interfacing laboratory work* where a dynamic and efficient link is made with:

i. *Other actors in the field* (other laboratories in the field, NGO's, first health responders, incident commanders and national/international crisis centers.

ii. *International institutions* involved in the management of the crisis like WHO, UNHCR, ECDC, DG ECHO, DG SANCO (not exhaustive list!). At the light of the return on experience in the Ebola crisis in West Africa, it appears indeed that *regional coordination between actors in the field* should markedly be improved, *implying a wider and quicker accessibility to laboratory results and better coordination between actors in the field, while protecting adequately private medical or other confidential data (see hereafter ethical issues).*

- **Need for harmonized mobile laboratory concept with transversal operational functions**

Harmonization is essential but does 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.

In order to harmonize the concept of mobile laboratory, developing a *concept with key operational functions (OFs) is profitable in terms of international cooperation and global coordination*. OFs indeed enable definition, comparison, development and analysis from different perspectives, a complex reality of CBRN mobile laboratories operational domain using the same semantics. *Consequently, a useful and practical recommendation for "improving disaster management using CBRN mobile laboratories" is 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).* T*ransversal OFs are intended to be applicable to any type of capacity irrespective of their C, B, RN or forensic specificity, or complexity (weight, volume, and mobility).* It therefore contributes to selection of the optimal organization and structure, selection of the best tools and their optimization, definition of corresponding SOPs while controlling the costs, proposition of backup or joint support capacities, and selection of the optimal activation procedure, best chain of supply and most appropriate MEDEVAC.

In a crisis response, collaborative decisions, information collection, sharing, collective sensemaking and coordination requires *a framework integrating all the versatile components and actors of the crisis situation*. 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. The ontological approach serves a multifold purpose:

i. To *harmonize a concept that combines many different elements* from existing CBRN analytical capacities, addressing therefore a wide diversity of CBRN and forensic disciplines across so many EU countries and a range of CBNR deployable laboratories; This concept should also consider the mission cycle at the light of very specific missions. This mission cycle should be testd and validated in realm or training conditions
ii. To *formalize and structure the domain of CB mobile laboratories*, describing concepts, their properties, relationships and constraints on relationships between them, providing consistent harmonized modelling of the procedures, functions, and / or delimiting others which are incompatible with the given mission or scenario;
iii. To *align the terminology, definitions, a shared vocabulary of concepts* to comply with the commonly recognized standards, best practices and procedures to facilitate common ground establishment between mobile laboratory operators and stakeholders;
iv. To *ensure technical and conceptual compatibility of sharable information* between the heterogeneous laboratory components;

v. To *provide easy access to all the information for users, and stakeholders*, and make the information reusable.

Reference: http://ec.europa.eu/echo/files/civil_protection/C_2014_7489_EN_ACT.pdf ; Article_12

- **Mandatory compliance with safety national and international rules and/or legislation**

Regulatory and legislative aspects need also to be taken into consideration: (a) Regarding transportation of goods and repatriation, there is a need:

i. To repack all the material and equipment necessary for the mission in order to ease transportation of all the material from the fixed-site / reach-back lab to the airport and to load the plane (or truck) according to the directives of the loadmaster, therefore complying with security rules for air or road transportation. These constraints are clearly more critical for air than for road transportation;
ii. To have a MATPACK (*Volume in m³ and weight in Kg*) list which needs to be produced at the customs of the different countries where the plane carrier has to land (refueling) and to the custom of the affected participating country where unloading will be controlled by the local custom.
iii. Regarding the transportation of dangerous goods, IATA rules should be respected (irrespective of a mil or civ air transport) in order to comply with the custom rules of all countries which are flown over during the deployment and redeployment (especially if landing for refueling is mandatory). Reference: IATA rules: http://www.iata.org/publications/dgr/Pages/index.aspx

(b) Regarding occupational regulations, there are European occupational health and safety regulations that apply for fixed laboratory structures. Two main aspects 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 (either for deployment during *cross-border crisis in Europe* as well as for *deployment outside the EU*. For individual risk analysis, themes such as containment of the laboratory, physical protection equipment, training of the staff, medical check-up and security (especially outside Europe) should be considered. 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. Taking example of biological threats, national or host nation BSL3/BLS4 legislation has to be applied for stationary laboratory in the EU. However the biosafety BSL3/BSL4 rules, practices and legal aspects cannot always be respected in laboratories deployed and this is particularly true when deploying outside the EU. For instance , there is a need for reliable and safe sample inactivation before analytical processing and for efficient decontamination (see paragraph decontamination and waste) and defining the best practice requires to consider to existing evidence from the literature, from past experience (lessons learned) and from practical experience developed inside a network of deployable laboratories and CBRN training centers. In this case, the best practices should prevail. If Europe would provide guidance for a "*European Mobile Laboratory Standard",* this would be complimentary to existing standards of stationary laboratories.

- **Normative aspects**

While harmonization of equipment and procedures is achieved with RN laboratories (in accordance with IAEA guidelines) and is quite satisfactory for chemical laboratories (http://echemnet.eu/, NIOSH-OSHA Manual of Analytical Methods; SIBCRA Handbook, AEP-66), the diversity of biological threats significantly slows down attempts to harmonize the methods used in biological 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 when outside the EU. While early standardization may be highly relevant for companies in terms of competitiveness and access to the market, it should be pointed out that this may not have added value for end-users. Consequently and as discussed hereafter in the following paragraph, a *useful and practical recommendation for "improving disaster management using CBRN mobile laboratories" would therefore be to promote improved harmonization* through the definition of *common transversal operational functions*. This needs however to be compatible with international guidelines [NATO (NATO handbook for sampling and Identification of CBRN Agents (SIBCRA) (AEP-66)/ Health Service Support (http://www.dtic.mil/doctrine/new_pubs/jp4_02.pdf)]; STANAG 4632- Deployable NBC analytical laboratory. NSA/0762-JAS/4632, NATO Multinational CBRN Defence Battalion). http://www.nato.int/docu/Review/2005/Combating-Terrorism/NATO-CBRN-Capabilities/EN/index.htm

NB*: Normative aspect for NATO deployable capacity*: the essential mission of the Multinational CBRN Defence Battalion is to provide NATO joint forces and commands, wherever deployed, with a rapidly deployable and credible defence against nuclear, biological and chemical attacks. This includes a CBRN deployable laboratory. As a secondary assignment, the unit may also be committed to assisting civilian authorities of Allied nations as during the 2004 Olympic and Paralympic Games, where elements of the Battalion were deployed to Halkida, Greece, as part of NATO's efforts to provide CBRN assistance to the Greek government.

References:

- 'Standardization of laboratory analytical methods' - SLAM http://www.cbrnecenter.eu/project/slam/, worked to validate sampling and analysis procedures. SLAM also reviewed existing standards, identifying similarities, necessary requirements and best practices for sampling, transport and analysis
- http://echemnet.eu/ https://docs.unocha.org/sites/dms/Documents/FEAT_Version_1.1.pdf
- P. Vanninen, Recommended Operating Procedures for Analysis in the Verification of Chemical Disarmament. VERIFIN, Department of Chemistry, University of Helsinki, Finland, 2011
- SIBCRA Handbook, AEP-66.
- NIOSH, OSHA Manual of Analytical Methods http://www.cdc.gov/niosh/docs/2003-154/

- **Laboratory ownership**

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.

- **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.

6. Recommendations on other specific needs

- **Training CBRN mobile laboratory operators**

Operating a laboratory in the field is not comparable to conditions of work. Safety limitations inherent to operational conditions inside a light deployable structure are indeed different from those endorsed in stationary CB lab as they imply a range of specific and complementary activities (i.e., rapid deployment, detection of exposure to CB substances using deployed equipment, assessment of contamination level and spread of contamination, safe waste management, and respect of the current, sometimes complex, legislations)! It is

recommended to create and support a European network of training capacities addressing specifically operational and safety issues in field conditions *enabling lab operators to* work in a safe CB environment whilst understanding the risks and mastering the counter-measures. There is therefore a major need for "*training capacities addressing operational and safety issues in field conditions*", *on the basis of existing experience, using if possible harmonized OFs and best practice in the field*.Training should ideally be performed in several European countries, according to harmonized training plans in order to achieve the appropriate coverage of diverse contexts and cultures. *Training has to be performed regularly to sustain and expand acquired capabilities, to cover response to new threats, to master new methods and technologies, and to comply with new regulations.*. Regarding nucleic acid-based testing in stringent P3 (biosafety level 3) or P4 (biosafety level 4) conditions, return on experience highlights the limiting number of well trained volunteers in case of long-term deployment. The role of training is therefore 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 lab operators*.

Moreover, *new solutions to solve technological issues are best proposed, assessed and validated by immediate feedback of users (trainers, operators and developers) through the channel of training centres*. In that respect, *mobile laboratories are a perfect technological incubator acting as a cradle of technology push and innovative drift.* It is very clear that innovative solution can only add value to CB crisis management and response if it meets the needs of responders and technology operators in terms of performance, design, applicability in the field and operational capabilities. Tools should therefore respect the context and organizational culture in which technologies, processes and decisions are embedded*. Tools properly assessed by trained operators on existing and newly elaborated scenarios (applied games/scenarios) tested in a network of training centres with participation of tools developers, and training professionals will have a better chance to comply with user's requirements*; they will indeed *benefit from improvements based on iterative procedure of testing and learning and lead to a two-fold knowledge transfer.* .

As also illustrated from the return on experience, *it is recommended that the mission of capacities deployed outside the EU integrates also a mission of education and training of indigenous staff combined to the* operational purposes. This is of importance when deployment occurs outside the EU, in countries where experienced local staff is lacking. *According to the subsidiarity principle*, it is a fact that an autonomous management of a CB crisis by the host nation should be privileged if possible. *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.*

- Reference: CBRN action plan ; one of the key functions is training

- **Ensuring uninterrupted, rapid and efficient chain of supply**

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. To speed up urgent acquisition of material and equipment, it is recommended to define exceptions to this rule in case of crisis situation and emergency duly recognized at the EU level.

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. The whole supply chain is indeed necessary for laboratory deployment for extended mission*, especially at the end of period of self-proficiency. Irrespective of the choice of capacity (light versus heavy), the need for a *timely supply of reagents, equipments or spare parts* should not be overlooked, especially when fragile equipment (e.g., Plexiglas glovebox with latex, nitrile or vinyl gloves; aspiration pumps….), engines or vehicles are essential for the success and safety of the mission, and therefore potentially overused in the field. Whereas this logistic support can *easily be provided inside the EU*, return on experience shows this can be very *complicated and not always be delivered on time in remote* and poorly accessible *areas outside the EU*. In that respect, evidence exists to consider that humanitarian missions can markedly benefit from *military logistic support*: to face logistic difficulties as discussed above, military logistic support with dedicated aircraft carrier and genuine military hierarchical organization are recognized as a clear added value to keep the facility in good working order. However, return on experience also pinpoints the difficulty (and in some cases, impossibility) to ensure the contribution and support of Defense departments for humanitarian mission except when the national political pressure is high due to insistent international request. It is indeed a fact that humanitarian actions are not part of the genuine military scope and out of classical military rules of engagement. The civ-mil collaboration should therefore be increased in case of humanitarian intervention and the work of the armed forces be differently prioritized in the future.

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. This may considerably slow down the process of material renewal and be detrimental when urgent actions need to be taken to replace downgraded equipment. Exception to this rule exists at the EC level but, from lessons learned, is not always known by operating actors. The recommendation is to ensure that this mechanism is well known by all institutions or organisms dealing with urgent purchase of equipments, reagents or goods. .

- **Decontamination and waste management: legal, safety and harmonization requirements**

Whereas commercial solutions exist for CB decontamination-detoxification systems, there is a very *specific need for dealing with decontamination, how to safely and legally handle C and B wastes and how to harmonize procedures for decontamination of the laboratory, equipment and waste*. CB decontamination and waste management are essential points to be considered in order to *protect the lab operators from dangerous waste, and to protect the local environment and indigenous populations from dangerous pollution*. Appropriate decontamination and waste management procedures contribute therefore to increase safety and security of the lab staff. Management should ideally *take into account the best practice according to international and national legislations of the offering and host countries) particularly when operating a laboratory outside the EU* . These ad hoc legislations *are sometimes lacking or inapplicable outside the EU*. Alternatively, *international law, policies, treaties, and agreements to which the offering country is a signatory 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, fast deployment of staff and compact equipment in terms of volume and weight. *In the repatriation and redeployment phase, there is need to have clear guidelines regarding the best decontamination practices for the equipment and material redeployed in order to facilitate homeland repatriation and redeployment in accordance with the law.*

- References:
  - Vinod Kumar, et al. Chemical, biological, radiological, and nuclear decontamination: Recent trends and future perspective J Pharm Bioallied Sci. 2010 Jul-Sep; 2(3): 220–238. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3148627/ F:
  - Waste Management for deployed forces, Technical manual, TM 3-34.5, MCIP 4-11.0, July 2013. United States government, US Army.

- **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 to be part of a mobile capacity**

When the CBRN mobile lab is deployed in remote areas outside the EU, it is especially important to have reliable in-field communications between national and international actors and lab operators. *It is therefore recommended to push the integration of European space capacities like COPERNICUS (for accurate mapping, emergency management service provision) and GALILEO (operational in 2016) into the operational function of CBRN mobile capacities*. Whereas there is *range of mature technological tools already available on the market to provide communication facilities (communication through voice, video, data, and image transmission; Radio Frequency Identifying Devices for CBRN, temperature and meteorological data sensors inside and/or outside the laboratory)*, *it is also recommended to define the optimal architecture of communication tools that would be adaptive according to the field operational requirements (mission purposes, location, and laboratory configuration, need for sensors networking and secure communication) and the potential added value of complementary technologies (e.g. geolocation and earth observation, possibly through Unmanned Aerial System), especially for* epidemiological mapping, or contamination mapping.

- **Proposal for R&D1I projects addressing gaps and technological challenges**

As evidenced by the consortium through roundtables and workshops and pinpointed by the return on experience, the following research and technological challenges need to be addressed.

a. *New analytical tests: There is a need for new tests combining detection and identification, being more portable, reliable, rapid, and cost-effective. This is further elaborated in annexe-1 section of this paper.*

b. *Need for widening the spectrum of analyses carried out in the field:* The new trend implies to widen current analytical capacity defined according to new strategic priorities which include detection of circulating RNA in patients sera, on-site sequencing, on-site electronic microscopy, tests enabling a quick differential diagnosis and the monitoring of patient vital condition (i.e., blood tests such as such as serum electrolytes liver and kidney function tests, AChe [Acetyl choline esterase] in case of poisoning with chemical warfare agents and pesticides, etc…). Up to now, this was out of scope for laboratories deployed in the field for CB investigation. This would however contribute to better patients care and therapeutic monitoring during the critical phase of the disease. *Consequently, it is recommended that these complementary tests (some carried out on fresh non-inactivated biological samples) are now included in mobile analytical capacities in parallel with increased and appropriate biosafety measures.*

c. *Sampling and handling all kinds of samples:* CBRN samples are usually collected by professional CB sampling team (Field Investigation Team or FIT) protected in full Protective Personal Equipment as well as by vaccination and/or chemoprophylaxis in case of B-threats. These samples represent a spectrum of different matrixes (blood, tissues, urine, soil, sand, water, air…) collected on a variety of support tubes (envelopes, plastic bags or special devices) which all require a thorough decontamination before being introduced into the lab. Moreover, and irrespective of the matrix, each sample processing requires pathogen inactivation before initiating the identification of potentially life-threating B-agents. *It is therefore 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 suitable features for in-field use: (i) It is recommended to develop tool specifications matching easy transport and deployment such as temperature-insensitivity, low energy consumption, 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). (ii) *It is also recommended to develop equipments enabling to combine detection and identification*. (iii) Concomitantly the EU also needs *tools to properly assess and investigate a potential criminal C or B* release (forensics). (iv) Finally, d*evelopment 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 *adapted technological specifications.*

b. *Need to fight fragmentation among suppliers*: when looking at development of new tools, approaches are sometimes identical leading to very similar solutions and technological duplication. Moreover, as discussed above, there is often a lack of orientation of R&D to the real end-user need so that operational factors (samples matrix, final applications, environment constraints, mission context…) are rarely taken into consideration in the early phase of novel technological developments. *There is a need for end-user oriented solutions. It is therefore recommended to integrate this process through* the channel of *training centres associating* operators, trainers and developers*. These actors are indeed best placed to provide immediate feedback and correct the ongoing technology development in its early phase* (as discussed and detailed above in the section "need for training"). There should also be a mechanism for *comparing mature technologies or solutions when they look very much alike (test and evaluation tools)*. Considering that end-users have difficulty to prefer one technology to another when differences are not obvious, priority should be given to validation and comparison of these technologies in operational (in-field) conditions and/or in dedicated and certified training centres. *Whether data integration into toolboxes (FP7-PRACTICE, FP7-EDEN, FP-7 DRIVER) are favoured by DG HOME, it is still currently unclear if major EU integrated projects may or will contribute to implementation of this solution*. Whether deliverables of international independent research should be integrated in joint international capacities is also not obvious. As aforementioned, R&D is indeed rarely end-user-oriented, thereby does not immediately takes into account the multiple requirements of the users.

    - Reference: CBRN action plan; the need for a Community of users (DG HOME initiative)

c. *Ensuring the chain of custody*: This aspect is crucial both for environmental and clinical samples. Chain of custody requirements aim to secure samples and to prevent tampering It *is recommended to track records of the samples potentially using geolocation* if necessary, in order to follow the evolution of the environmental or patients contamination with CBRN agents. *A chain of custody for samples should immediately been established* once they are brought to the decontamination area.. Failure to properly maintain the chain of custody may prevent the evidence in question from being introduced at trial. Consequently, chain of custody is an essential step when considering forensic analyses. Records of samples addressed to the lab and results thereof are best kept concomitantly on paper (lab logbook) and electronic database. Paper backup is justified by potential breakdown of electricity supply in the field. Pictures of relevant samples, request for analysis and results can also be justified according to the scenario and type of mission.

    - References:
        - http://www.netc.navy.mil/dpo/nasp/pdfs/Section_III_pdf/ANNEX%2012%20-%20SAMPLING%20AND%20EVIDENCE%20COLLECTION.pdf
        - CRBN Action Plan: 52009DC0273 - Communication from the Commission to the European Parliament and the council on Strengthening Chemical, Biological, Radiological and Nuclear Security in the European Union – an EU CBRN Action Plan /* */ http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52009DC0273

e. *Need for advanced forensics research:* Importance of preserving forensic evidence in a CBRN event, chain of custody which also implies finding suitable solutions for discrepant constraints regarding decontamination and preservation of forensic evidence. Preserving the integrity of reagents and clinical and environmental samples collected in the field may require to strictly respecting the cold chain throughout the mission, from departure to arrival in the reach back laboratory. This is also crucial when complementary or confirmatory tests need to be carried out in external stationary / reference lab, or, at home in the national reachback facility. This is of course essential when forensic analyses are considered as part of the duty of the deployed analytical capacity. In that respect, it is of note that crucial connections exist between the FP7-GIFT (Generic Integrated Forensic Toolbox for CBRN incidents) and FP7-MIRACLE projects regarding best practices for CB forensics.

References:

- 'Standardization of laboratory analytical methods' (http://www.cbrnecenter.eu/project/slam/ (SLAM)) , worked to validate sampling and analysis procedures. SLAM also reviewed existing standards, identifying similarities, necessary requirements and best practices for sampling, transport and analysis.
- Biological Incident Response & Environmental Sampling - a European Guideline on Principles of Field Investigation; EU Commission, DG Health and Consumer Protection, Health Threats Unit, Oct 2006: http://ec.europa.eu/health/ph_threats/com/preparedness/docs/biological.pdf

d. *Need for further research in human factors:* Return on experience points out that working in difficult conditions in the field (temperature, humidity, long working hours, in personal protective equipment, and with the need for quick and reliable results) is associated with stress and fatigue, worsen by routine continuous operations in a confined space, with a heavy workload for a limited number of operators, for an extended period of time, on potentially life-threatening CB samples and in hazardous working conditions.

7. Two major “showstoppers” that may prevent military logistic support and refrain civilian deployment: MEDEVAC and staff members security

7.1. Need for MEDEVAC

This is by far the most difficult issue to be solved when the deployment is very remote, outside the EU. Lack of guarantee for a rapid medical evacuation of proven or presumably infected / wounded / CB contaminated national volunteer’s is one of the main factors refraining national authorities for involving their available own capacity in CB disasters outside the EU. Unlike the military deployment which implies the contribution of a medical team in site and the organization of air or vehicle evacuation as a preamble to the mission, *civilian humanitarian actions are often carried out without prior detailed MEDEVAC plan*. This

remains a major showstopper for European Defence Departments considering that rapid evacuation (golden hour) of military volunteers or militaries designated to ensure the logistics support is a prerequisite to accept the deployment. Moreover, few Armed forces are really able to provide this type of capacity during civilian humanitarian operations. *When the deployment is organized on the basis of a bilateral partnership,* the *MEDEVAC plan is often discussed and prepared on this basis* ideally in close coordination with organisms or institutions that supported the host country.
Return on experience pinpoint illustrates the many efforts deployed by the EC (DG ECHO) to organize an international capacity enabling immediate evacuation of international workers from Ebola affected areas in West Africa. *However, EU mechanism of MEDEVAC is still under scrutiny*. *This is certainly a gap which needs to be better covered in the future*.
It is also important to pinpoint that any international humanitarian organisation can request the evacuation of its international staff but whether military volunteers deployed by the national authorities fall under the same rules of evacuation is currently unclear . *The MEDEVAC mechanism needs therefore to be tightly coordinated by the Emergency Response Coordination Centre* (ERCC) of the European Commission (*Directorate General for Humanitarian Aid and Civil Protection, DG ECHO*) and *WHO* and *considered globally for civilian as well as militaries involved in humanitarian support*. Moreover, to decrease health risk, it is recommended to adopt the *military preparation which makes compulsory a complete medical evaluation before deployment*. Specific health measures have to be according to the nature of the CBRN risks (e.g., the local epidemiological data at the site of deployment, endemic and epidemic diseases, what is available in terms of preventive and curative measures against the CBRN threats? What are the vaccinations which are compulsory with respect with the national legislations?).

- References:
  - Information Regarding Care and Evacuation of International Responders. December 12, 2014. http://www.usaid.gov/Ebola/medevac
  - EBOLA Medical Evacuation. Mechanism for WHO, UN Agency and NGOs staff. Presented by WHO Medevac Coordinator in SL. Mathieu Vandal. Work: 079.76.16.15 / Medevac Emergency only: 079.76.16.58. vandalm@who.int. National Emergency Response Center on 09JAN2015. https://extranet.who.int/Ebolafmt/sites/default/files/documents/WHO%20Medevac%20presentation%20NERC%2009JAN15.pdf

7.2. Ensure security of the staff members

This is a second major showstopper for Defence Departments as protection of military volunteers or militaries designated to ensure the logistics support is a priority to accept the deployment. This problem needs to be seriously considered at the light of past incidents which, although limited in scale, may substantially prevent national authorities from deploying a national military or civilian capacity. Considering that humanitarian interventions and military deployment are not necessarily compatible, this showstopper should also be globally taken into consideration and assessed based on available information from the media, the intelligence services and if necessary, by a RECCE “intelligence “team sent to the area ideally a few days before the deployment and, if impossible, contemporary to the deployment (the latter was provided during the Belgian deployment in Guinea and reassessed after a few weeks). Once deployed on site, it is indeed important to reassess the health, safety,

environmental and security risks at the light of the reality and constraints observed at the local site of deployment but also by cross-checking with locals, and with representatives of ONG and international institutions already deployed on site. This is applicable to accommodation, food, water, work conditions, local transport from the resting to the working place, contact with local people, facts and rumours.

ANNEX: Focus on some technological needs for improving CBRN sampling detection and identification

1. New trends in biological detection and identification systems in the field

Rapid Diagnostic Tests (RDT), isothermal and multiplex amplification and new portable identification tool with comprehensive panels of targets are all desirable innovations for *investigating biological threats reliably, quickly and rapidly*.

Rationale: Simplex analyses are usually justified in a context of pre-awareness, i.e., clinical and/or epidemiological evidence of an existing outbreak, with typical clinical or biological symptoms. *However, there are many situations where there is no pre-awareness (unknown samples, atypical gastrointestinal, respiratory or neurological syndrome….).* Health care problems related to *CB exposition and contamination then implies a differential diagnosis requiring technological operators to carry out a set of diagnostic tests*. Whereas laboratories in these situations perform successive identification tests for excluding potential agents one by one, this is indeed very complicated in a deployed facility as not all reagents are available, but also because this diagnostic strategy causes extra work for the staff, while being also time consuming and costly, leading therefore to detrimental delays in decision-making. In biological scenarios, , unambiguous identification using new technologies (like high-throughput sequencing) may, in the future, help to better and quickly apprehend useful genetic features for responding to a pandemic situation (virulence, airborne transmission, drug resistance…). Ideally, b*iological identification* requires *multiplexing and miniaturization*. *Isothermal amplification* is another way to rapidly confirm relevant results. Finally, *new solutions allowing testing a panel of agents, for instance those associated with clinical syndromes, whilst enabling an unambiguous identification of unknown agents should be promoted*. Additionally, *in-field electronic microscopy with identification through highly automated image recognition or remote video transmission* would be of clear added value when the presence of viral particles of an unknown sample is considered. These new developments should however be innovation-driven based on needs from the field, return on experience of lab-operators, training centers, and current or forthcoming derived research projects focusing on recognized needs.

2. New trends in chemical detection

- Ambient mass spectrometry without sample preparation (for chemicals, toxic drugs)
- Novel identification systems for explosives and narcotics.
- Innovations in rapid chemical exposure diagnostics.
- New detection instruments for inorganic compounds/gases in air: identification and quantification at sub ppm level.
- New detection instruments for volatile organic compounds, toxic industrial chemicals and chemical warfare agents in air: identification and quantification at sub ppm level. Portable GCMS
- Sensors for distant analysis of air samples

- Field analysis methods and instruments to determine (screening) elements and heavy metals in airborne particulate matter and solids (portable XRF; ….).

3. New trends in radiological detection and identification

Technologies for RN detection and identification are well developed today and there are many commercial solutions readily available. But there are some areas that still need improvement or new solutions. The gold standard today for exposure determination in humans is time consuming and laborious. A rapid method based on blood samples or some other tissue has still to be developed. Detection of alpha contamination on humans is difficult with hand held instruments, the only method available, new techniques and instruments is a field for innovation. When it comes to identification of radioactive substances, new algorithms that give less false identification is needed, especially for hand held instruments based on low resolution spectrometry:

- Need for portability: there is a need to develop handheld portability devices complementary to heavier equipment used for confirmation;
- Need for rapid test systems to quickly determine radiological exposure.
- Need for detecting alpha-contamination in urban environment and on contaminated persons
- Need for mapping contaminated areas and radioactive sources
- Need for matching radiological fingerprints with existing databases of sources (also unification of databases into one large database)
- A combined training of forensic and radiological personnel is recommended to prevent loss of traces as well as expert support for field operations and decision making

4. CB sampling

As for RN-threats, there are many available commercial solutions. Nevertheless, the following observations have come up with roundtables an workshops during the MIRACLE project:

- Common CB sampling procedures
- Need for portability
- Advanced sampling techniques such as canisters.
- Integrated detection and identification methods
- Use mobile measuring capacity to map contamination and/or find hidden sources
- Use of electronic noses as warning or monitoring instruments
- Obtaining evidence from CB heavily contaminated objects