1. Basic information

1.1 CRIS Number: 
1.2 Title: Supply of Equipment for Microbiology Laboratories in B&H
1.3 ELARG Statistical code: 02. 19 - Consumer and health protection
1.4 Location: Bosnia and Herzegovina

Implementing arrangements:
1.5 Contracting Authority (EC)
EC Delegation to Bosnia and Herzegovina
1.6 Implementing Agency:
EC Delegation to Bosnia and Herzegovina
1.7 Beneficiary (including details of project manager):
Ministry of Civil Affairs Health Sector, Ministry of Health and Social Welfare RS and Ministry of Health FB&H

SPO: Dr Serifa Godinjak
Ministry of Civil Affairs, Health Sector
Trg BiH 1
Tel/fax: 0037833713926; Fax:0038733719930
e-mail serifagodinjak@mcp.gov.ba

Financing:
1.8 Overall cost: 0,5Mil. Euro
1.9 EU contribution: 0,5Mil. Euro
1.10 Final date for contracting: N+2
1.11 Final date for execution of contracts: N +4
1.12 Final date for disbursements: N + 5

2. Overall Objective and Project Purpose

2.1 Overall Objective:
To enhance capacity of health care system in B&H to respond on possible threat of easy transmissible communicable diseases introducing bio-safety cabinets and providing relevant equipment to laboratories dealing with microbiological materials potentially dangerous for their staff and general population.

2.2 Project purpose:
To provide relevant B&H laboratories with equipment needed for their proper functioning according to EU and international standards.

2.3 Link with AP/NPAA / EP/ SAA
SAA in the Article 75 covering Standardisation, Metrology, Accreditation and Conformity Assessment states “Bosnia and Herzegovina shall take the necessary measures in order to gradually achieve conformity with Community technical regulations and European standardisation, metrology, accreditation and conformity assessment procedures. To this end, the Parties shall seek to: promote the use of Community technical regulations, European standards and conformity assessment procedures; … promote Bosnia and Herzegovina’s participation in the work of organisations related to standards, conformity assessment, metrology and similar functions.”

It is expected from B&H to implement newly revised WHO International Health Regulations due to come into force in June 2007 whose purpose and scope 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(Article 2), The Regulation states in the Article 5 “Each state Party shall develop, strengthen and maintain, as soon as possible, but no later than five years from the entry in the force of these Regulation for that State Party, the capacity to detect, asses, notify and report events in accordance with these Regulations.” ANNEX 1 of WHO International Health Regulations elaborates the core capacity requirements for surveillance and response. At the local community level and/or primary public health response level (point 4) IHR states capacities (b) to report all available essential information immediately to the appropriate level of healthcare response. … For the purposes of this Annex, essential information includes the following: clinical descriptions, laboratory results, sources and type of risk, numbers of human cases and deaths, conditions affecting the spread of the disease and the health measures employed.

Health care priorities in European Union are regulated in Article 152 of the EC Treaty and it states among other issues that: ..”actions shall cover the fight against the major health scourges, by promoting research into courses, their transmission and their prevention, as well as health information and education. “

2.4 Link with MIPD
The MIPD for 2007-2009 argues as a priority that “Community assistance will seek to improve the investment climate by improving national preparedness to public health threats and the systems for health monitoring and disease surveillance. ” Specific assistance to the country to face possible threat of Avian flu is also foreseen: “Support to increase bio safety in region through implementation of appropriate security measures in prevention and combat of Avian Influenza.”

2.5 Link with National Development Plan (where applicable)
The MTDS highlights limited institutional capacity. Further it points out that ageing of the population and unhealthy life style are main contributors to the epidemiological profile and communicable disease control (HIV/AIDS, STD, TB). This project will assist in building institutional capacity to response adequately on possible outbreak of communicable diseases.
Plans for Pandemic Influenza Preparedness and Control in both entities of Bosnia and Herzegovina are prepared and adopted by both entity ministries of health, in Republika Srpska in October 2005, and in Federation of BiH in March 2006. B&H Plan for Pandemic Influenza Preparedness and Control is in the procedure to be adopted by B&H Council of ministers. In order to assure that the health system in the country is ready to perform this task and to be ready on other similar threats as it is stated in the National Plan “equipping laboratories at all levels and defining standard diagnostic procedures” is needed. B&H Plan addresses the issues of case definition were Probable H5N1 case is to be notify to WHO, positive laboratory confirmation of an influenza A infection but insufficient laboratory evidence for H5N1 infection. B&H laboratory diagnostic capacity should assure implementation of WHO case definitions.

2.6 Link with national/ sectoral investment plans (where applicable)
N/A

3. Description of project

3.1 Background and justification:
When it comes to the institutional set up of the country the state level ministry responsible for health issues Ministry of Civil Affairs in particular Health Sector within the ministry has coordinating role. The responsibility for health sector is with entity and cantonal ministries, which are at the same time founders of health institutions including laboratories. Within this frame the Project will cooperate with all relevant ministries and the responsibility for the coordination of Project activities will be with Health Department in MoCA while direct counterparts will be entity and cantonal ministries. Some relatively recent developments in frame of globalisation, and outbreaks of easily transmissible diseases such as SARS and Avian Influenza have attracted attention of WHO and health authorities all over the world on preparedness of countries on early detection and proper surveillance of these kind of diseases. Health system in B&H is not properly prepared for these situations.

There are 19 laboratories dealing with microbiological materials located in hospitals and PHIs in the country. While the laboratories are quite well staffed with highly professional staff the laboratories are not properly equipped. Those laboratories should assure good laboratory practice - GLP which stress the importance of: resources: organization, personnel, emphasizing the need for sufficient facilities and equipment; rules: protocols and written procedures; characterization: test items and test systems; documentation: raw data, final report and archives; quality assurance. The laboratories should assure as well good microbiological work practices covering appropriate containment equipment, proper facility design, operation and maintenance, and administrative considerations to minimize the risk of worker injury or illness. Good microbiological work practices are not applicable at the moment due to lack of bio-safety cabinets, inappropriate equipment, protocols and procedures. Biological safety cabinets (BSCs) are designed to protect the operator, the laboratory environment and work materials from exposure to infectious aerosols and splashes that may be generated when manipulating materials containing infectious agents, such as primary cultures, stocks and diagnostic specimens.
Joint EC and WHO project “EU/WHO Support to the Healthcare Reform in BiH” (CARDS 2001 – implemented in period December 2003-September 2006) by focusing the Component on reinforcing Communicable Disease (CD) Surveillance and Response, opened good opportunity to thoroughly review existing CD surveillance and response systems in BIH (RS, FBIH and BD) along three pillars of modern CD surveillance systems, i.e. surveillance standards and procedures, information systems and organization and functioning of laboratory services.

Survey on capacities of infectious diseases laboratories in BIH was undertaken within the same Project following weaknesses are identified: the laboratories are not equipped properly, there is no network of laboratories, referral system is not adequate and does not meet the needs of population in terms of capacity, there is no regular control of quality of laboratory services (internally and externally), there are no bio-safety cabinets. In addition during development of B&H Plan for Pandemic Influenza Preparedness and Control lack of national pandemic influenza laboratory has been identified. In order to address some of above mentioned issues training was provided by WHO experts to epidemiologist and microbiologists from different microbiology laboratories. This training included bio-safety matters but it is not possible to deal with bio-safety issue properly without adequate facilities and equipment in the laboratories. On the other hand, this training contributed to the capacity building of the staff in order to be able to develop procedures and implement relevant standards. The staff in the laboratories and relevant authorities are committed to develop procedures and protocols in coming period. The lack of bio-safety cabinets is direct threat to laboratory staff and users of their services, and general population. The Project supported development of a Plan of Action for upgrading and extending laboratory capacities which was accepted by relevant ministries.

Additionally within the same Project, a detailed assessment of microbiology laboratory capacities in BIH was carried out and the following documents were produced:

1. Summary Survey of Infectious Diseases Microbiology Laboratories in B&H
2. Development of a Laboratory Network for the Surveillance of Infectious Diseases in B&H
3. Development of Influenza Diagnosis and Surveillance in BIH
4. List of Equipment of listed Microbiology Laboratories in B&H including recommended bio-safety level (Microbiology laboratory in Bihac was not included in this list since the experts could not visit it due to some technical reasons, but it will be included in the future activities)

It is obvious that all preparatory activities for upgrading of level of laboratory services have been completed (capacity building, assessment of situation and identification of needs, technical and policy documents drafted) but main obstacle is lack of bio-safety measures and adequate equipment.

This project will contribute to bridge existing gap and will assist health system to adequately respond to the possible health threats. For successful implementation of this Project crucial document is the “List of Equipment for 19 Microbiology Laboratories in
B&H” (attached to this Project Fish). This List was prepared by WHO experts for laboratories, who visited all 19 laboratories, recommended required level of bio-safety for each laboratory, and prepared lists of equipment for each laboratory needed for fulfilment of recommended standards.

3.2 Assessment of project impact, catalytic effect, sustainability and cross border impact (where applicable)

Successful implementation of the project will improve safety of staff, patients and population using health services in B&H and it will improve safety of population B&H in general and surrounding countries. The work of the laboratory will be upgraded and in accordance relevant EU and international standard. Increased capacities of laboratories will broaden scope of their activities in terms of early detection and appropriate handling with public health threat. This Project will cover referral national laboratories for pandemic influenza as well, which will be than appropriately equipped and prepared for possible outbreak of communicable disease. This will enable the national laboratories to become members of WHO network of laboratories for pandemic influenza.

3.3 Results and measurable indicators:

Results:
- Technical specification prepared
- Equipment delivered and installed in selected laboratories
- Staff trained to use the equipment
- Technicians trained to maintain and upgrade the equipment.

Indicators:
- Technical specification paper produced by month 3 of project implementation
- Tender procedure launched by month 5 of project implementation
- Equipment delivered and installed by month 18 of project implementation
- Staff in all laboratories trained (minimum 38 staff members) to use equipment by the end of Project implementation
- Technicians from each location trained (minimum 19 staff members) by the end of Project implementation

3.4 Activities:
- To undertake the needs assessment activities (visits to laboratories, prepare reports and recommendations) in order to develop technical specification of the equipment
- Draft recommendations for needs of level of bio safety in all laboratories
- Draft technical specification
- Deliver and install the equipment
- Organise training sessions for staff in laboratories and technicians on the use and maintenance of the equipment
The Project will need input of minimum two international experts to assess the needs and draft recommendation for Technical specification and for this part of activity the Technical Assistance type of activity will be needed. Equipment will be purchased, delivered and installed through a Supply Project.

3.5 Conditionality and sequencing:
During the implementation of the above EU/WHO Project the WHO experts for laboratories paid visits to all listed 19 laboratories and provisionally identified space for future bio-safety cabinets and drafted a list of the equipment.
Step I:
In order to be able to implement this Project properly it is necessary to engage an international expert who will be responsible to draft ToR for physical reconstruction of existing facilities including recommendations for standards to be met for bio-safety cabinets level II and III. For this purpose EC Delegation will by June 2007 contract an expert through another budget line (BA Assistance)
Step II:
Based on these Recommendations drafted by the expert, the project documentation for reconstruction of premises will be prepared by September 2007 through separate contract funded by EU through (BA) Assistance financial line.
Step III:
Based on the Project documentation the relevant institutions and health authorities will conduct physical reconstruction of rooms recommended to be bio-safety cabinets before launching the tender. These actions will be financed by BH institutions.

In order to be able to launch supply tender it is necessary to obtain guaranties and commitment by relevant Ministries of Health to implement and finance previously mentioned activities. In this stage of project preparation MoCA and entity Ministries support the project.

Precondition: statement by relevant ministries for availability of funds in 2008 for reconstruction purposes should be provided by October 2007.

Comment: Total budget for this Project will be split in two parts: 30,000 Euros for Technical Assistance and 470,000 for supply. Preparation of technical specification will start in parallel with physical rehabilitation of bio-safety rooms.

3.6 Linked activities
Previous EU assistance in this filed joint EC and WHO project “EU/WHO Support to the Healthcare Reform in B&H” (CARDS 2001) prepared grounds for this project. A set of documents and recommendations was produced:
1. Summary Survey of Infectious Diseases Microbiology Laboratories in B&H
2. Plan of Action for Strengthening infectious diseases laboratory capacity in B&H
3. Development of a Laboratory Network for the Surveillance of Infectious Diseases in B&H
4. Development of Influenza Diagnosis and Surveillance in BIH
5. List of Equipment for 19 Microbiology Laboratories in B&H (including recommended bio-safety level)

The project was completed in September 2006. It was strongly recommended by the WHO experts to upgrade bio safety in all laboratories dealing with infectious materials.

Global Fund is investing USD 4,832,385 in two years starting from 01 November 2006 in coordinated national response to HIV/AIDS.

The primary goal is to ensure effective and efficient implementation of the “Coordinated National Response to HIV/AIDS & Tuberculosis in a War-torn and Highly Stigmatized Settings” programme, as funded by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) implemented by UNDP as the Principal Recipient nominated by the Country Coordination Mechanism (CCM).

Additionally to that key goal, awareness raising and education are available to the final beneficiaries throughout B&H, UNDP also takes on its self the responsibility to build capacities of the B&H national institutions in this sector with the ultimate goal that in the foreseeable future national authorities take over complete management and implementation of the Global Fund grants.

With implementation of the GF grant, UNDP and partners will seek to strengthen and scale up existing services to ensure country-wide coverage of existing effective services. Additionally Global Fund is financing project dealing with improvement of services for TB control in B&H. The Project will strengthen the laboratory network for TB, the recording and reporting system, as well as monitoring and evaluation. A nationwide human resources development plan of training/re-training all the professionals involved in TB control done. The laboratory network re-organized and improved according to European standards. The NRLs strengthened. In the second phase, the laboratory network will be ready to organize a nationwide Drug resistance survey (DRS) and for the Green light committee (GLC) application. Amount and duration of financing is under negotiation, over five (5) years.

Main objective of the project is to cost-effectively reduce the burden of disease of TB in B&H:

3.7 Lessons learned

EU funded Project implemented in 2000 provided equipment for BH Laboratory for Quality Drug Control. The staff from the Laboratory was additionally trained in other EU funded project providing technical assistance. As a result of these combined activities this Laboratory become a member of EU Network of Quality Drug Control Laboratories.

Using this experience it is planned to provide technical assistance to management staff of the laboratories through another IPA funded 2007 project, Strengthening BH PHI’s which will be responsible for upgrading of diseases surveillance system in BH.
4. Indicative Budget (amounts in €)

<table>
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<th>Activities</th>
<th>TOTAL COST</th>
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<td>Laboratory in B&amp;H</td>
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<td>TOTAL</td>
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* expressed in % of the Total Cost

5. Indicative Implementation Schedule (periods broken down per quarter)

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<th>Signature of contract</th>
<th>Project Completion</th>
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<td>2nd quarter 2008</td>
<td>4th quarter 2008</td>
<td>2nd quarter 2010</td>
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</table>

6. Cross cutting issues (where applicable)

6.1 Equal Opportunity
The Project will be implemented in whole B&H in 19 microbiology laboratories.

6.2 Environment
Proper handling with potentially contagious materials/samples and with laboratory solid water/liquid and air waste will contribute to healthy environment.

6.3 Minorities
N/A
Annex I Logical Framework matrix in standard format

<table>
<thead>
<tr>
<th>LOGFRAME PLANNING MATRIX FOR Project Fiche</th>
<th>Programme name and number: Supply of Equipment for Microbiology Laboratories in B&amp;H</th>
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<td>Contracting period expires</td>
<td>Disbursement period expires</td>
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<tr>
<td>Total budget : 500,000 EUR</td>
<td>IPA budget: 500,000 EUR</td>
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### Overall objective

To enhance capacity of health care system in B&H to respond on possible threat of easy transmissible communicable diseases introducing bio-safety cabinets and providing relevant equipment to laboratories dealing with microbiological materials potentially dangerous for their staff and general population.

### Objectively verifiable indicators

- National laboratories for influenza members of international network

### Sources of Verification

- WHO report

### Project purpose

To provide relevant B&H laboratories with equipment needed for their proper functioning according to EU and international standards.

### Objectively verifiable indicators

- B&H microbiology laboratories certified by accredited bodies

### Sources of Verification

- Certificates

### Results

- Technical specification prepared
- Equipment delivered and installed in elected laboratories
- Staff trained to use the equipment
- Technicians trained to maintain and upgrade the equipment.

- Technical specification paper produced by month 3 of project implementation
- Tender procedure launched produced by month 5 of project implementation
- Equipment delivered and installed produced by month 18 of project implementation

### Objectively verifiable indicators

- Technical specification document
- Tender documentation
- PAC (Provisional Acceptance Certificates) and FAC (Final Acceptance Certificates)
- Training reports

### Sources of Verification

- Current facilities meet basic criteria (electricity, water supply, waste management, premises bio-safety cabinets)
  - The health institutions can bear the maintenance cost

### Assumptions
- Staff in all laboratories trained (minimum 38 staff members) to use equipment produced by the end of project implementation
- Technicians from each location trained (minimum 19 staff members) by the end of project implementation

<table>
<thead>
<tr>
<th>Activities</th>
<th>Means</th>
<th>Costs</th>
<th>Assumptions</th>
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</table>
| - To undertake the needs assessment activities (visits to laboratories, prepare reports and recommendations) in order to develop technical specification of the equipment  
- Draft recommendations for needs of level of bio safety in all laboratories  
- Draft technical specification  
- Organise training sessions for staff in laboratories and technicians on the use and maintenance of the equipment | Supply | 0.5 MEURO | Pre-conditions  
ToR for physical reconstruction of existing facilities including recommendation for standards to be met prepared through separate EU funded project  
Project documentation for reconstruction of premises prepared through separate EU funded project  
Relevant health institutions finance and implement reconstruction of bio-safety rooms |
## ANNEX II: amounts (in €) Contracted and disbursed by quarter for the project

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ANNEX III

Federation of Bosnia and Herzegovina

1. Act on the Protection of the Population from Communicable Diseases (“FBiH Official Gazette”, No. 29/05/);
2. Health Care Act (“FBiH Official Gazette”, No. 29/97);
3. Health Insurance Act (“FBiH Official Gazette”, No. 30/97 and 7/02);
4. Act on the Protection and Rescue of People and Property from Natural and Other Disasters (“FBiH Official Gazette”, Nos. 39/03 and 22/06);
5. FBiH Criminal Code (“FBiH Official Gazette”, No.: 36/03);
6. Pandemic Influenza Preparedness Plan of FBiH.

Republic of Srpska

1. Act on the Protection of the Population from Communicable Diseases (“RS Official Gazette”, No. 10/95);
2. Health Care Act (“RS Official Gazette”, No. 18/99, 58/01 and 62/02);
3. Health Insurance Act (“RS Official Gazette”, No. 18/99 and 70/01);
4. RS Criminal Code (“RS Official Gazette”, No.49/03, 8/04, 37/06);
5. Civilian Protection Act (“RS Official Gazette”, No. 26/02 and 39/03);

BH Brčko District

2. Health Care Act (“BiH Brčko District Official Gazette”, No 2/01);
3. Health Insurance Act (“BiH Brčko District Official Gazette “, No.1/02 and 7/02);

Reference to AP/NPAA/EP/SAA

1. WHO International Health Regulations (due to come into force in June 2007) with scope and purpose to prevent, protect against, control and provide a public health response to the international spread of disease, states: “Each state Party shall develop, strengthen and maintain, as soon as possible, but no later than five years from the entry in the force of these Regulation for that State Party, the capacity to detect, assess, notify and report events in accordance with these Regulations.”
2. SAA in the Article 75 covering Standardisation, Metrology, Accreditation and Conformity Assessment states “Bosnia and Herzegovina shall take the necessary measures in order to gradually achieve conformity with Community technical regulations and European standardisation, metrology, accreditation and conformity assessment procedures. To this end, the Parties shall seek to: promote the use of Community technical regulations, European standards and conformity assessment procedures; … promote Bosnia and Herzegovina’s participation in the work of organisations related to standards, conformity assessment, metrology and similar functions.”
3. Article 152 of the EC Treaty: ..”actions shall cover the fight against the major health scourges, by promoting research into courses, their transmission and their prevention, as well as health information and education.“
Reference to MIPD

MIPD for 2007-2009:
1. “Community assistance will seek to improve the investment climate by improving national preparedness to public health threats and the systems for health monitoring and disease surveillance.”
2. “Support to increase bio safety in region through implementation of appropriate security measures in prevention and combat of Avian Influenza.”

Reference to National Development Plan

1. MTDS – V.3. Sector priorities – Health Care
   “Reform goals in the sector: ensure an efficient and transparent health care system focused on the promotion of health and the prevention of disease”;
2. Millennium Development Goals in B&H-2015: 2.4 Action programmes for the reduction of infectious diseases:
   “Due to the new epidemiological situation emerging in the world, the World Health Organisation has requested that all countries tighten their control of infectious diseases in order to make possible the prompt detection of spreading diseases, the identification of new diseases, and to start timely activities on their prevention and eradication. Infectious diseases have a significant share in the pathology of the B&H population. The basic causes are … insufficient laboratory diagnostic”.
3. Plan for Pandemic Influenza Preparedness and Control in Bosnia and Herzegovina highlighted as necessary: …
   - “Equipping laboratories at all levels and defining standard diagnostic procedures.
   - Ensuring engagement of adequately educated staff in viral laboratories.
   - Paying particular attention to the quality control measures, as well as ensuring laboratory bio-safety

ANNEX IV

Needs assessment conducted under CARDS 2001 joint WHO and EU project "Support to the Healthcare Reform in BiH".

Reports:

1. Summary Survey of Infectious Diseases Microbiology Laboratories in B&H (document attached)
2. Development of a Laboratory Network for the Surveillance of Infectious Diseases in B&H
   **Executive summary**
   This report describes an assessment of the laboratory infrastructure for infectious diseases in Bosnia and Herzegovina (BIH), including infrastructure, management, capacity and geographical distribution.
   In June 2006, 19 Public Health Institute (PHI) and Hospital Microbiology Laboratories (HML) have been assessed in a standardized way:
   - Through on-site visits
   - Using a computerized tool called ‘BLAT’, automatically producing indicators
   - Including the mapping and GPS position of the laboratory
   - Taking digital pictures
This assessment provides practical information on the planning and establishment of a laboratory network for the surveillance of infectious diseases in BIH.

**Assessment organization**
A team of six assessors followed a specific 3 day training (both theoretical and field training, see appendix 7) and have performed the assessments of selected laboratories. Assessments logistics and organization are presented in chapter 7.

**Main strengths and weaknesses of laboratories**
Based on the assessment results, a brief summary of the strengths and weaknesses of the laboratories has been compiled:

**Major strengths of laboratories:**
- Senior staff is available
- Data and analysis recording (logbooks)
- Activity recording/specimen tracking
- Disinfection/hand washing/presence of janitors
- Quality of samples (but rarely transported)

**Major weaknesses of laboratories:**
- Buildings are often in need of renovation and requiring secure water and AC supply
- Equipment is often lacking, old or in need of maintenance
- Mechanisms for systematic laboratory quality control and quality assurance are not employed.
- Bio-safety standards are lacking including safety procedures, biosafety documentation and biosafety cabinets
- Formal training programmes for staff to update skills and expertise are lacking
- Reporting of results to external institutes/health authorities is lacking
- Specific outbreak procedures, and sometimes supplies, are lacking
- Few laboratories are supervised
- Laboratories are working alone (no real network except for TB labs)

**Recommendations:**
- Laboratories are in need of renovation and re-equipping and working space needs to be reorganized. Within this process, special attention should be paid to biosafety standards.
- All laboratories should be provided with written procedures for biosafety, the analyses they are performing and reporting of results.
- Laboratories should be provided with modern laboratory management and reporting systems.
- Laboratories should employ systematic laboratory quality control and quality assurance and be supervised in this process.
- Formal training programmes for staff to update skills and expertise should be provided as well as training in international laboratories for staff of reference laboratories.
- Procedures and supplies for participation in outbreaks should be provided.
- A web-based communication forum should be developed to facilitate networking.

3. List of Equipment for 19 Microbiology Laboratories in B&H (including recommended bio-safety level) document attached

**TA assistance**
Input of 2 experts 15 days each for preparation of technical specification