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12. - 14. November 2007

Report on
Activity 5.3 "Technical and organisational laboratory training" CARDS Twinning Project BA05 IB AG 01, Banja Luka, 12. - 14. 11. 2007
Seminar 1/1: Principles of quality management and accreditation.

Participants in Banja Luca (12./13. November 2007):

- Ante Vidović, Mostar Qual. Manager
- Berislav Preininger, Zenica
- Darko Despotović; Head of institute in Banja Luka
- Dilajla Jukić, Bihać
- Iva Lamešić, Tuzla
- Kenan Čaklovica, Vet. Faculty Sarajevo, Member of the QM Team
- Leila Atlić, Tuzla
- Milan Andrijanić, Director Mostar
- Slobodan Dojčnović, Banja Luka
- Savo Botinović,Banja Luka
- Violeta Santrač, Banja Luka, Quality manager

- Zorana Mehmedbašić, Sarajevo (State Vet.-Office; SVO BiH)

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Tajić Lea, Sarajevo, Interpreter Twinning Projekt

Summary
Overall since the last visit in November 2006 on the purpose of accreditation of laboratories only marginal progress in the practical implementation of accreditation procedures has been achieved. But it was encouraging to see that quality managers have been recently appointed for all laboratories concerned. Just as well the proactive laboratory in Bihać has already successfully passed the on site assessment. This means a great progress towards accreditation which was demonstrated during a visit.
The discussed and approved to-do list prepared for this workshop in the Twinning project includes four main topics. These are (1) the preparation of a first draft for a quality manual according to the example given by the laboratory in Bihać and LAVES, (2) a translation of the checklist under www.DAP-gmbh.de/documents for use and alignment in every laboratory, (3) distribution and use of the BATA requirement list for accreditation to every laboratory and (4) a critical evaluation of the scope/content of accreditation needed in every single laboratory. The memorandum of understanding was adopted and signed by the Head of the laboratories. Concerning discussions related to the contents of the reporting forms, the SVO is asked to discuss with different organisations the structure of a uniform format and to develop an electronic form optionally on the basis of LAVES-documents. The discussion on forms between laboratories is limited to December 10th, 2007.

Still a further support of laboratories by the central government is needed to define the legal tasks, obligations and material/financial requirements of the laboratories.
This could be combined with the assessment of tasks needed and performed in the laboratories. Due to the fact that not all activities performed in the laboratories are needed in all places, a concentration of certain skills and tasks in certain laboratories may preserve resources and enhance expertise and capacity.
It is to be mentioned that support by external consultant agencies during the accreditation process cannot replace the laboratories' own activities.

I. OPENING WELCOME, INTRODUCTION

Presentation of the agenda by Zorana Mehmedbasic (SVO, Sarajeva)

II. PRESENTATION OF DARKO DESPOTOVIC ON THE"INSTITUTE DR VASO BUTOZAN"

1) History of the Institute "Dr Vaso Butozan":
Foundation (1934), aims, activities

2) Structure of the Institute "Dr Vaso Butozan":

48 scientific employees
31 technical employees
3 not qualified employees

Table: Structure of the institute "Dr Vaso Butozan"

Head			managing/advising group (5 Pers., appointed by the state)		
			Director		
Departments	Microbiology	Epizootio-logy	Qual. control of milk product	out post Bijeljina	Administration

3) Plans for the future "Institute Dr Vaso Butozan":

improvement of laboratory quality
research
good laboratory practice
introduction of new methods
qualification of employees
new external parts of the institute

current problems: rooms, organisation of documents

III. DISCUSSION OF THE REPORT FORM

Problem: Reports from each laboratory are requested by many different governmental organisations with different requirements. Organisations are: Kantons, animal movement data unit, SVO, central government etc. Due to similar content of the requests, laboratories aim for coordinated and uniformed answers.

Agreement:

1) SVO is asked to discuss with different organisations the structure of a uniform format,
2) an electronic form should be developed for the future,
3) LAVES-documents will be used as templates for future development,
4) Discussion between laboratories concerning the proposed forms is limited to December 10th, 2007 to avoid further adjournment of final decision on the forms by the SVO.

IV. REPORTS FOR THE DIFFERENT LABORATORIES IN BIH CONCERNING THE PROGRESS IN ACCREDITATION

Report from the University of Sarajevo (Organigramm see annex 1):
2 main departments for intra laboratory control, education superior to 5 subordinated units:

1) animal disease
2) food hygiene, animal feed, environmental protection
3) research on pharmaceuticals/remedies, toxicology
4) reproduction and genetics
5) poultry

Remarks: QM should be introduced and work independently, with direct access to the head of the institute. Presented documents should be improved i.e. for media production, maintainance of installations and equipment etc. LAVES templates for SOPs were already distributed to the established QM for further improvement.

Report from the Veterinary Institute Tuzla (Organigramm (from 2004) see annex 2):
Two departments existing for animal disease (microbiology, chemistry) and for food control (microbiology and serology). Until now no further documents prepared. Quality manual is currently not introduced in the laboratory.
Remarks: none

Report from the Zeničko-Dobojski Kanton Laboratory (Organigramm see annex 3):
Purpose of the laboratory was food control (microbiology and serology). Unit for serology was recently closed by FBiH administration because of problems with rooms. Laboratory is part of the Cantonal Ministry of Agriculture. Possibly consulting company will be contracted in order to assist in accreditation process of laboratory.
Remarks: none

Report from the Veterinary Institute Mostar (Organigramm see annex 4):
Documents for GTZ audits were prepared in the past and will be used for the actual accreditation. The aim is to use these documents in the discussion for the future development of quality assurance (QA) documents by the new elected quality managers (QM) in BiH.
Remarks: Existing documents should be used for further development of SOPs and preferable guided by one central QM in BiH.

Report from Banja Luka Laboratory (Organigramm see presentation above):
The agenda of the laboratory in the past were: QM team building, having organigrammes prepared for accreditation, having methods prescribed for accreditation. But none of the aims were reached in the past except establishment of a QM-team. It was not clear whether a whole building or single methods will be the aim of the accreditation.
Remarks: For clarification of terms it was elucidated that accreditation means: Having competence for a certain topic. Concerning all laboratories present the central question remains: Should every laboratory have every method in its scope? Can every laboratory have the competence and manpower for all methods claimed?

Report from Bihać laboratory (Organigramm not presented):
The obligation for the start of the accreditation process by the ministry was to fulfil the standard ISO 17025. With the assistance of a member of BATA accreditation organisation the Bihać laboratory has already started and finished the accreditation process. In a pre-audit the technical competence was given but minor changes are requested for improvement. Calibration of laboratory equipment was seen as one problem.
Remarks: It seems to be helpful to coordinate the activities for accreditation in BiH for all laboratories to benefit from the experience of the different (specialised) laboratories in BiH.

V. PRESENTATION OF THE ACCREDITATION ACTIVITIES IN BIHAĆ

Quality manager from Bihać presented their strategy for accreditation. The chosen structure of the documents is:

1. the handbook named in Bihać "rules of procedure",
2. SOP are called "procedures" and

3. "forms".

The preparation for accreditation procedure for the Bihać institute has lasted until now for 6 months because of experience gained in the past years for accreditation according to ISO 9001. After 6 month of preparation in the Bihać institute delegates from BATA accreditation organisation have visited the Bihać institute to observe the status of accreditation on the spot.
For the structure of the quality manual BATA has asked to design it following precisely the the standard ISO 17025. It remains unclear whether in Bihać currently detailed procedures developed for microbiology. In BiH no reference is possible to national standards like DIN because they do not exist in BiH. Also some conditions are required and requested by the federal government concerning legal matters (tasks, legal status etc.). Main list of SOPs is added to the manual. Rooms are described. The independence of the institute has been clarified and an organigramm has been set up. A list of employees and qualifications is existing, description of tasks of the heads of the unit is established as well as list of laboratory instruments and maintenance.

From representatives of the laboratories comments on the presentation by the Bihać laboratory were made concerning the practicability of the Bihac accreditation documents and practical examples were requested.

Following this intervention, the experts from Bihać explained in general the accreditation procedure according to ISO 17025. The accreditation procedure can be divided in two main areas as follows:

A. Management obligation
general structure of accreditation documents (this is part of the handbook)

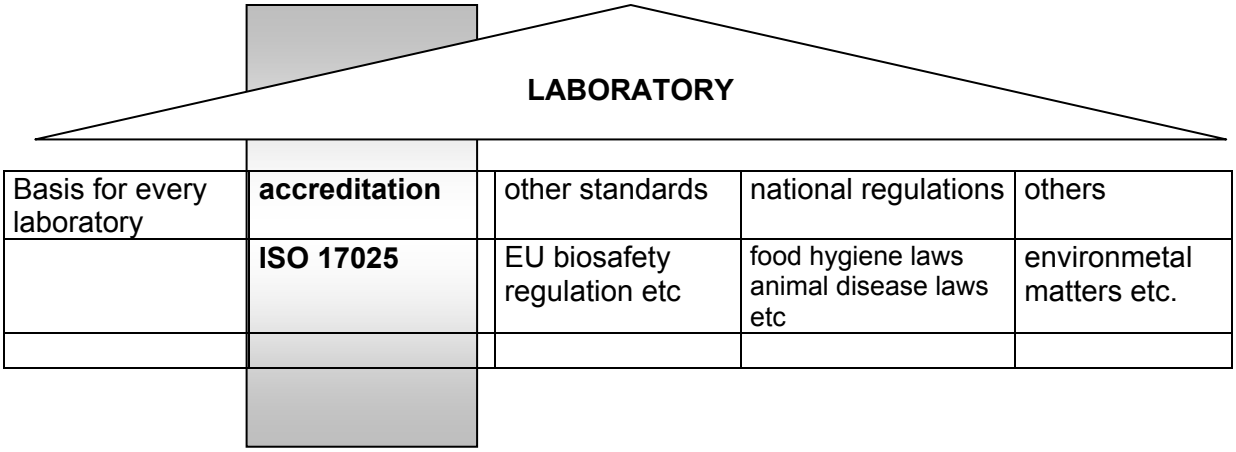
B. Technical requirements
method validation
equipment supervision
continuing education
internal quality assurance
report format

The standards however will give no obligations on laboratory safety and standards. The only obligation is that methods should not interfere each other (for his purpose is a hygiene plan for laboratories is needed, to prevent cross contamination and possible human infection by handling with pathogens). But following national and international standards laboratory safety is part of other regulations.
The clear intention of an accreditation is to demonstrate the accreditation unit (BATA) the own laboratory competence on reference methods. If a method is not part of a norm the method has to be validated in the laboratory.

Example:
Internal control:
This includes for example in the case of an ELISA method the ELISA detector itself and pipettes used. The pipettes can be validated in the own laboratory unit, the precision of ELISA reader has to be orientated on the required precision (i.e. 1% or 2%). The precision can be validated with internal standards.
For reference methods the controls of the test supplier (company) have to be used. Further to this a pool of own reference material has to be established in the laboratory to control on the long run not only the test system but also the own laboratory results and skills. This can be documented in control charts (this is to fulfil the obligation for control cards an daily control). For chemical analysis this procedure is widely known and for an ELISA a maximum deviation in the results should be defined.

External control:
External control of the competence of a laboratory concerning a certain method should be performed in ring trials via reference laboratories. Until now ring trials in BiH are performed for animal disease control. Ring tests are planned together with German laboratories as well as internal ring trial of laboratories concerned.
Internal control between selected participating laboratories can be organised between interested laboratories.

VI. ACCREDITATION ACTIVITIES / FURTHER DOCUMENTS NEEDED FOR LABORATORIES



Basis for every laboratory	**accreditation**	other standards	national regulations	others
	ISO 17025	EU biosafety regulation etc	food hygiene laws animal disease laws etc	environmetal matters etc.

Website: **www.DAP-gmbh.de**
Documents and checklists are available in German and English under www.DAP-gmbh.de/documents. A detailed checklist shown on the website on the accreditation procedure follows the structure of ISO 17025 with respect to the tasks and possibilities as well as the deficiencies of the respective laboratory. The website is not a theoretical but a practical transfer of the formal requirements of ISO 17025.

According to ISO 17025 every laboratory document should be "directed" (to a person and laboratory) and "active" (information on number of the version, date of coming into effect). These specifications should be obvious for every document. The document should have a list of content, the number of the version and a how it is distributed (name and date). This obligation of ISO 17025 can be fulfilled in a structured first page of every document. The text of a document should start on page two.
The document should be headed by the name of the procedure and the institute issuing the document. On the bottom of the document it is advisable to have the name of the author, the person issuing the document and the respective dates.

VII. DISCUSSION OF THE QUALITY MANAGEMENT HANDBOOK FOLLOWING SELECTED ITEM FROM THE LIST OF QUESTIONS LISTED UNDER WWW.DAP-GMBH.DE/DOCUMENTS

The following comments were added to the aims and items stated in the document.

Quality manager (QM)
Important obligations of the QM are the direct contact to the head of the institute and the independent function and work of the QM. If the QM is in a function as head of laboratory the

deputy QM should be from a different unit than the QM. This is to ensure the independence of internal audits and prevent self auditing.
The heads of the laboratories should also have deputies. For every employee a description of tasks and skills should be available. Tasks should be assigned to certain persons.
Newly introduced persons in the laboratory should be instructed before starting to work in the respective laboratory. "Start of work plans" are advisable for these persons who have the authorisation from both sides to assign the new person to defined tasks.
Documents should be directed in the laboratory. Hand written changes in laboratory prescriptions are possible but have to be formally approved before accreditation.
If testing is submitted to subcontractors the results have to be clearly marked in the reports issued.
The correction of mistakes and deviations should be performed according to defined rules and should include the QM and the head of laboratories concerned. Corrective actions have to be documented to avoid future mistakes.
External controls, control cards and participation on ring trials, performance tests and other quality assurance methods could be part of accreditation. Also laboratory meetings, further education and written documents are indispensable.

Laboratory records
Every information helpful for interpretation of result given is needed for laboratory records. This is important for tracing back of samples, transparency of procedures and in case of any problems concerning the method applied.
Forms, control cards and automated data can be accepted as records. Records have to be signed by the person responsible, "readable/in a clear written form" and stored for a certain time. In case of mistakes corrections have to be clearly marked but the original record(s) concerned have to be still available for verification purposes.

Internal audits
A laboratory needs a program for the performance of internal audits. Checklists from the standard ISO 17025 are helpful to perform an audit. All parts of a laboratory must be subjected to an audit. Protocols should document the deficiencies and corrective actions by the head of laboratories.

Technical requirements
Personal
See also previous. Plans for annual continuing educational training needed.

Building and environment
Control of building and environment are necessary with respect for the methods applied. Examples: High temperatures (i.e. 35°C) outside may affect incubation temperature of ELISA tests prescribed at room temperature (approx. 22°C). Also bacterial load in the air can affect the bacteriological results counted on nutrient media.
The access to laboratories should be limited to the persons in charge to prevent contamination or pollution and to ensure confidentiality.

Hygiene
The laboratory should set up measures to ensure standards to prevent any negative influence on the methods performed.

Methods for validation
1. Reference is given to national and international standards. Such test are accepted as validated. The laboratory has to ensure the correct testing methods by using standards, control programs etc.
2. For tests which are not standardised, a validation is needed and has to be applied in the laboratory. This validation is orientated on performance parameter like precision,

detection limit etc. within the scope of the intended use of the method. This validation has to be documented and assessed.

It is also possible to modify a given method in a laboratory procedure or to use a method for another purpose. This has also to be validated and documented

On the example of Brucella diagnostic in BiH, possible methods for validation of methods are discussed. The application of ring trials could be helpful to distinguish between useful and less useful methods.

It is known that methods present different levels of sensitivity and specifity. Under these terms they are selected for animal disease detection. But it is not the purpose of accreditation to select and decide between given methods upon their application in the field. For example, the immunofluorescence technique is known as a valid method to diagnose Classical Swine Fever in regions where this disease is present and clinically visible in animals. The immunofluorescence test is not the useful method to be applied for regions considered as free from Classical Swine Fever because molecular biological methods are more sensitive than the immunofluorescence technique.

Methods applied in laboratories should be available in written forms in manuals. For practical reasons it is suggested to have instructive flow charts for the daily use in laboratories.

Laboratory equipment

Basis for accreditation is a list of equipment including identity, type etc. used for accredited methods. The key question regarding the inclusion of equipments in the list is if it is needed for the respective accredited method.

The description of equipment should also include corrective actions or measures if a deviation in the performance of the equipment happens. The inspection/check interval should consider the specific needs of an equipment (i.e. pipettes, ELISA - system). Maintenance has to be documented preferable with control cards. An example for a control card is discussed and should include for example, an incubator, information on temperature and date of control.

Table: Example of a control chart for an incubator (37,0°C), min Temp. 36,0C, max temp 38°C

	Day/month/year									
Temp.	21.9.	22.9.	23.9.	24.9.	25.9.	26.9.	27.9.	28.9.	29.9.	30.9.07
38,0										
37,5				**x**						
37,0	**x**	**x**	**x**		**x**	**x**	**x**	**x**		
36,0										
35,5										
35,0										

Under defined circumstances it is possible to use one piece of equipment (i.e. Real time (RT)-PCR) by more than one working group/user (residue control unit/microbiological unit) in different rooms, if the procedure for use and access is defined for every user. It is not necessary to use separate RT-PCR by every single group.

Re-guiding to standard (i.e. for temperature)

Calibration i.e. of incubators is a measure to standardise incubators on "correct" temperature performance by identification of their individual temperature deviation. The calibration can be performed easily by a single, central and official standardised thermometer for every incubator in the laboratory. The standardisation of calibrated thermometers by an official authority is often valid for many years and can be used therefore for a long time.

For microbiological work, international reference cultures of bacteria could be used for standardisation of methods. For residue analysis, standardised chemical substances are available for calibration.

Management of samples
Samples are generally delivered to the laboratory. The suitability of the sample for investigation has to be checked at arrival at the laboratory. Complaints on the samples have to communicate to the sender. Incoming samples have to be identified individually and without doubt. This system of sample registration has to be documented in written form.

Quality assurance of results
This includes the performance of validated methods and final control of raw data and the results by a competent person.

Reporting of results
Samples have to be individually identified and every result concerning the samples must be undoubtedly assigned to the respective sample. Results have to be laid down in a report.
In case of the need to issue a new report this has to correspond to the original.
Comment: Although it is difficult to define complaints in this field which have to be followed on a regular basis complaints should be handled according the given accreditation standards of the laboratory to identify the mistake itself, the reason for the mistake and the possible follow-up measure. The quality manager should receive this procedure in written form and has to consider it for further comments. A new report has to be issued in case of failure identified.

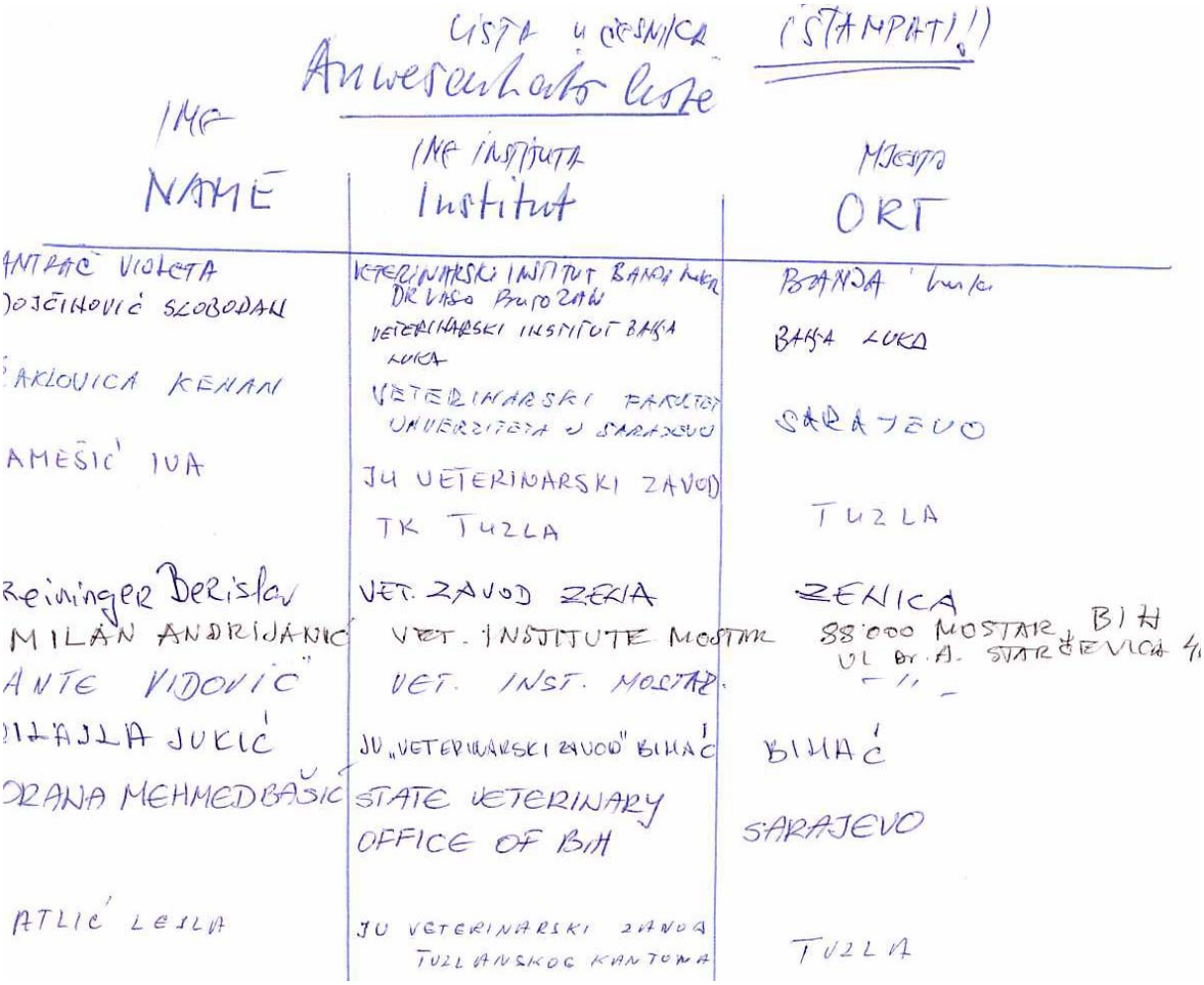
VIII. VISIT OF THE LABOTATORY IN BIHAĆ:

The laboratory activities have started in Bihać 2004 to facilitate food and zoonoses control in the entity of approx. 30 000 inhabitants. Currently 18 persons work in the two laboratory units for food hygiene and serology.
Already 13 000 cattle and 6 300 sheep are tested on brucellosis and in 2006 approx. 6000 food samples were tested.
After the presentation of general information concerning the laboratory structure during a round tour in the laboratory, the progress towards accreditation was demonstrated in every unit.

IX. TO-DO LIST FOR THE TWINNNIG PARTNERS IN BIH:

1. A first draft for a quality manual according the example given by the laboratory in Bihac and LAVES has to be developed in every laboratory
2. A translation of the checklist under www.DAP-gmbh.de/documents has to be provided for use and alignment in every laboratory
3. Distribution and use of the BATA requirement list for accreditation to every laboratory
4. Critical evaluation of the scope/content needed of accreditation in every single laboratory

List of attendance



LISTA U CIRILICI (ŠTAMPATI!)

Anwesenheits liste

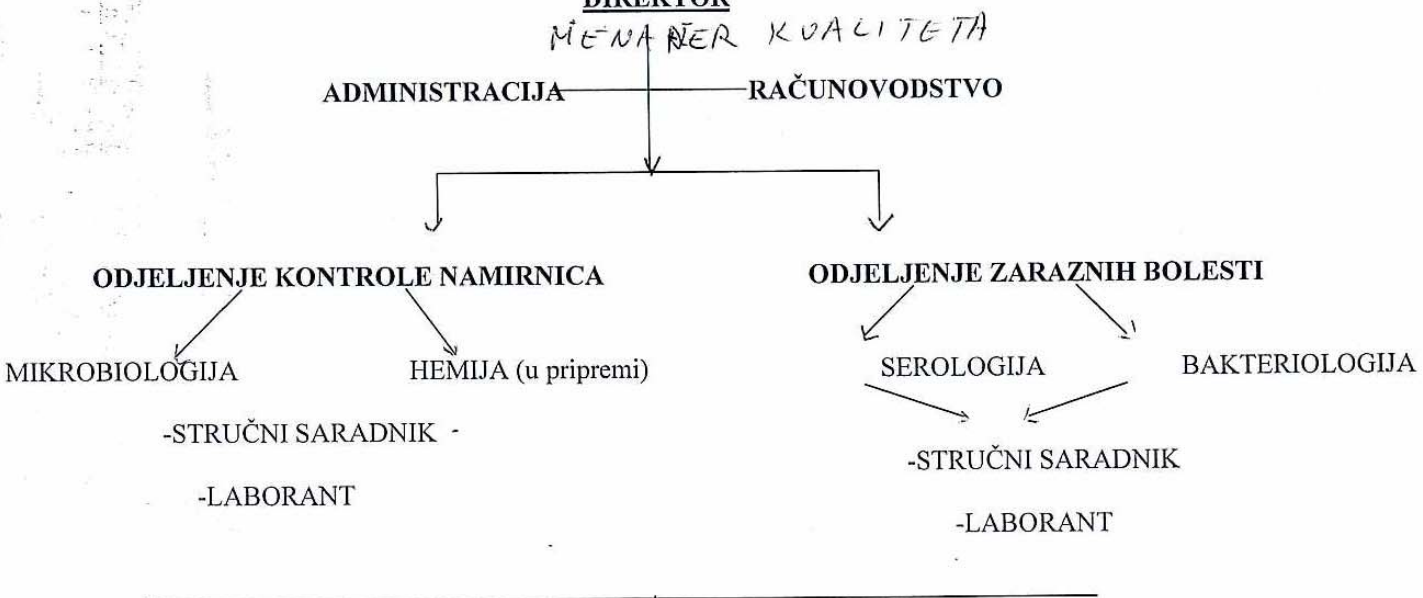
IME NAME	IME INSTITUTA Institut	MJESTO ORT
ANTRAĆ VIOLETA	VETERINARSKI INSTITUT BANJA LUKA DR VASO BUTOZAN	BANJA LUKA
DOJČINOVIĆ SLOBODAN	VETERINARSKI INSTITUT BANJA LUKA	BANJA LUKA
ĆAKLOVICA KENAN	VETERINARSKI FAKULTET UNIVERZITETA U SARAJEVU	SARAJEVO
AMEŠIĆ IVA	JU VETERINARSKI ZAVOD TK TUZLA	TUZLA
Reininger Berislav	VET. ZAVOD ZENICA	ZENICA
MILAN ANDRIJANIĆ	VET. INSTITUTE MOSTAR	88'000 MOSTAR BIH UL BR. A. STARČEVIĆA 4
ANTE VIDOVIĆ	VET. INST. MOSTAR	— " —
IZAJLA JUKIĆ	JU „VETERINARSKI ZAVOD" BIHAĆ	BIHAĆ
DRANA MEHMEDBAŠIĆ	STATE VETERINARY OFFICE OF BiH	SARAJEVO
ATLIĆ LEJLA	JU VETERINARSKI ZAVOD TUZLANSKOG KANTONA	TUZLA

ANNEX 1

ORGANIZACIJSKA ŠEMA VETERINARSKOG INSTITUTA

	Organigram Verzija 01 (Datum 28.12.2004. godine)	Strana 1 od 1

Annex 2



Izradio:	Provjerio:	Odobrio:
Datum:	Datum:	Datum:
Potpis	Potpis:	Potpis:

BOSNA I HERCEGOVINA
FEDERACIJA BOSNE I HERCEGOVINE
Zeničko-dobojski kanton
Ministarstvo za poljoprivredu, šumarstvo i vodoprivredu

Annex 3