

## Short-Term Mission

### Activity 5.1 „Assessment of the laboratory infrastructure and possible accreditation“ -Laboratory-

#### Mission Report

#### Names of experts

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#### Tasks according to TOR

1. Assessment of BIH diagnostic laboratories concerning accreditation
2. Development of basic forms and documents within the object of quality management
3. Proposing a working structure and methodologies for future works
4. Identifying gaps in existing legislation and in specialisation among the present laboratories (institutes) with regard to internationally confirmed standards
5. Development of a guidance to establish examples in writing SOPs made available for discussion among the participants
6. Development of a accreditation strategy along a proposed time line comprising also visits of further experts

#### Mission details

23th Sept. 2007: Arrival at Sarajevo  
24th to 28th Sept. 2004: Institute of the Veterinary Faculty Sarajevo  
24th September 2007: - Briefing with the RTA Dr. Schollmeyer  
- Opening the visit by Ms. Almedina Zuko und introduction to the Veterinary Faculty Sarajevo  
- Evaluation of the laboratory of the department of Infectious Diseases at the Veterinary Faculty Sarajevo  
- Evaluation of the building foreseen to take up the Veterinary Institute Sarajevo outside the Faculty

- 25<sup>th</sup> September 2007: - Introduction of the plans for the new laboratory of the Veterinary Faculty.  
 - Discussion of the plans and the possibilities.  
 - Evaluation of the documents concerning sample handling and investigations of the department of infectious diseases.  
 - Visit and evaluation of the department of Pathology.
- 26<sup>th</sup> September 2007: - Meeting with the Task-Force "Laboratory". First recommendation on sample management and preparation of SOPs. Discussion of example SOP.
- 27<sup>th</sup> September 2007: - Meeting with the members of the Task-Force "Laboratory". Discussion of a time frame of accreditation. Presentation of an example of a quality management manual.  
 - Visit of the Department of Diagnostic of Infectious Diseases of Poultry. (Participating members of the Task-Force see appendix)
- 28<sup>th</sup> September 2007: - Meeting with the members of the Task-Force "Laboratory". Presentation and discussion of the needs of ISO 17025 for rooms and equipment conditions. Further on Information about the needs of the facilities by 2004/54/EG (Biosafety).  
 - Presentation of the ongoing accreditation of the veterinary institute, Bihac, by Mr. Galijasevic.

### **Condition of the laboratory units**

Within the Department of Diagnosis of Infectious Diseases and Epidemiology the facilities do not satisfy the conditions established by regulations in EN ISO 17025. Main points are inadequate room and personal hygienic measures, lacking documents on general laboratory work, missing documentation of environmental conditions being able to influence testing and test results. There is no clear regulation of responsibilities in this Department. The work of the Veterinary Institute is not independent of the policy of the Veterinary Faculty. We agree upon the recommendation of the Norway experts, that these two domains shall be made independent from each other. To establish this independence the moving of the Veterinary Institute into a building outside the Veterinary Faculty as discussed could be a solution. The respective building was assessed according to the needs of the Laboratory units mainly with respect to establish a functional infrastructure in this building. Within the laboratory units assessed further only the reconstructed rooms of the Department of Infectious Disease of Poultry accomplish the requirements of European standard.

The Task-Force agreed that in each regional laboratory a quality manager shall be named by the respective head or top management. The quality managers shall develop and co-ordinate a obligate management system to be laid down in a quality manual. Helps are given by the presentation of an exemplary Handbook of the Veterinary Institute Oldenburg and by the next visit in November 2007.

The moving of the Veterinary Institute of the Faculty of Sarajevo to outside building shall not take place before the clearing and fixing of the tasks of the departments of the Faculty, the Veterinary Institute of the Faculty and the other State Veterinary

Institutes. For example it does not make sense to reconstruct the laboratories of the Departments in the old building of the Faculty before transferring the tasks to the Veterinary Institute in a new building (see the reconstruction of the laboratory of the Department for Infectious Diseases of Poultry). The new building should be planned according to the tasks and the expected number of samples. Beside this the financing of the Institute and the Faculty must be clear and safe.

## **Special recommendations**

### **Quality manager**

All Institutes/Laboratories need a quality manager. The position of the quality manager is next to the head of the institute. But it can not be the institute leader itself. To go on with the accreditation process it is necessary to name a quality manager for each institute very soon. These quality managers should build a quality management Task-Force. (see appendix)

### **Sample and order management**

All samples and orders of all State Veterinary Institutes/Laboratories shall use the same system for this purpose. The institutes should develop an uniform order form for their submitters. This form has to contain the following information:

- |                                       |   |
|---------------------------------------|---|
| 1. sample taking veterinarian         | 2. time of sampling                       |
| 3. owner of the animals               | 4. kind of animal                         |
| 5. type of sample                     | 6. number of sample                       |
| 7. sample number                      | 8. animal identification                  |
| 9. sample handling (during transport) | 10. asked investigation                   |
| 11. date of reception (in laboratory) | 12. person                                |
| 13. quality of sample                 | 14. storage of sample until investigation |
| 15. handed to (department or unit)    |   |

Each incoming order shall get a order number. This number has to be noted on all forms and protocols belonging to the order or to the samples of the order. The number shall be logical and all State Veterinary Institutes shall use the same system for this number. We suggested a following code system. First two letters for the institute/laboratory, for example FS = Faculty Sarajevo. One more letter for the unit/department, for example P= Infectious diseases of poultry. Next the year, in the example 2007. Then the number of the week, 39= 39<sup>th</sup> week of the year. At least there is a running number of the sample in the week. An example can look like:

**FSP 2007390127**

The example means that this is 127<sup>th</sup> order for the Department of Infectious Diseases of Poultry, Faculty Sarajevo, in 39<sup>th</sup> week of 2007.

The uniform order number should be implemented very soon, in the next two month. A general sample reception desk for each institute/laboratory should be planned and established in the future.

## **Standard operating procedures (SOP)**

For all methods which are used for investigation a SOP has to be prepared. The different Institutes/Laboratories should use the same form for the SOPs. The procedures for the preparation of a SOP can be part of the quality manual, for example a master SOP. The quality manual will be a topic of the next mission in November 2007 and the second step in the ongoing accreditation. The quality manuals for the different Institutes/Laboratories should be written in cooperation within the Task-Force "Laboratory".

Further on, we recommend the same necessary items for a SOP comprising a test procedure: General information about author, responsibilities, version No and the chapters of a SOP. The chapters of a SOP can be:

1. purpose
2. principle
3. instruments and material
4. quality and kind of samples (preanalytical aspects)
5. quality and kind of controls and reference material
6. result
7. result documentation
8. validation
9. literature

(During the meeting we discussed the same examples for a SOP from the Veterinary Institute Oldenburg, LAVES, and from the Department of Infectious Diseases of Poultry. The drafts of the Department of Infectious Diseases of Poultry by Ms Kauzovic looked very good and nearly finished.)

As a further example the prerequisites necessary in a SOP for hygienic measures were presented. This SOP shall contain regulations for cleaning and disinfection of laboratory ceilings, tables, lab clothes and equipment. Handwash and respective disinfection devices must exist and must be used regularly. A plan with timely defined frequency of cleaning and disinfection must be formulated and controlled. Further on, regulations about solid infectious and noninfectious and respective liquid material (waste) must exist.

## **Bio safety**

The bio safety levels of the germs shall be respected and handled according to the international regulations. Animal pathogens (for example *Bacillus anthracis*, *Brucella* spec., *Coxiella burnetii*, HPAI-strains - H5 and H7 – are possible risks to human health. We have given the requirements for working with pathogens of the risk groups 2 and 3 in a laboratory.

## **Time frame for accreditation**

A time frame for the accreditation of the Institutes/Laboratories was suggested. This draft was discussed with the members of the Task-Force "Laboratory". All Institutes/Laboratories saw problems because of the very short time for the tasks up to the next mission in November 2007. At least all Institutes/Laboratories accepted the time frame in general. (For the time frame see the appendix)

Sarajevo, 28<sup>th</sup> September 2007

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Prof. Dr. G. Thalmann

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Prof. Dr. Dr. B. Schlatterer

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Dr. A. Moss