

1. 協議議事録（ミニッツ）・PDM・評価報告書

MINUTES OF MEETINGS
BETWEEN
JAPANESE TERMINAL EVALUATION TEAM
AND
AUTHORITIES CONCERNED OF THE GOVERNMENT OF
THE SOCIALIST REPUBLIC OF VIETNAM
ON
JAPANESE TECHNICAL COOPERATION PROJECT
FOR
CAPACITY DEVELOPMENT FOR NATIONAL INSTITUTE OF HYGIENE AND
EPIDEMIOLOGY TO CONTROL EMERGING AND RE-EMERGING
INFECTIOUS DISEASES IN VIETNAM

The Japanese Terminal Evaluation Team (hereinafter referred to as "the Team") organized by the Japan International Cooperation Agency (hereinafter referred to as "JICA"), headed by Ms. Naoko UEDA conducted the study from 10 to 25 November, 2008, for the purpose of the terminal evaluation of the project for capacity development for National Institute of Hygiene and Epidemiology (hereinafter referred to as "NIHE") to control emerging and re-emerging infectious diseases in Vietnam (hereinafter referred to as "the Project").

During the study, the Team had a series of discussions with the authorities concerned of the Vietnamese government, jointly evaluated the achievement of the Project, and exchanged views for future direction of the Project.

As a result of the study and discussions, both sides agreed upon the matters in the documents attached hereto.


Hanoi, 25 November, 2008

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THE ATTACHED DOCUMENT

I. INTRODUCTION

The Project started on 20 March, 2006 with the cooperation period of three (3) years. The purpose of the Project is that "NIHE has capacity to examine highly hazardous transmissible pathogens properly in the BSL-3 laboratory that meets international standard".

II. TERMINAL EVALUATION

The terminal evaluation was carried out in accordance with the Project Design Matrix (PDM) version 2 dated on 14 September, 2007 as attached as Appendix 1. Both Vietnamese and Japanese sides reviewed the achievement of the activities and the outputs of the Project based on the results of interviews with the personnel concerned with the Project and the Project records.

The result of the evaluation was described in the Joint Terminal Evaluation Report as shown in Appendix 3.

III. CONCLUSIONS

The Project has successfully produced visible outcomes. These outcomes include establishment of the Biosafety Department, and the Biosafety Regulation, the Biosafety Level (BSL)-3 Standard Operational Procedure (SOP), and SOPs for laboratory technique on Influenza, which are aligned with the WHO Biosafety Manual. The training on Biosafety and BSL-3 laboratory has been conducted. As a result, engineer staff members carry out routine work in operation and maintenance for the BSL-3 laboratories according to SOPs. And also, trained researchers began conducting laboratory test at the BSL-3 laboratories. These activities built the basic system of Biosafety management.

However, achievement of the Project Purpose is not optimal at the time of the terminal evaluation. It is because some activities remain to be completed to achieve the Project Purpose. In order to meet the international standard, those uncompleted activities should be carried out and strengthened, which can lead to ensure 1) safety operation and maintenance of the BSL-3 laboratories, 2) quality and safety test performance, and 3) management of registration of highly hazardous transmissible pathogens.

There are some unpredictable factors that delayed the progress of the activities. Even though the Project continues to make every effort to pursue attainment of the Project Purpose, it reveals to be inevitable to complete all necessary activities within the current project period.

Therefore, it is highly recommended to extend the project's cooperation term for one and a half year so as to achieve the Project Purpose by implementing the remaining activities.

IV. RECOMMENDATIONS

Based on the review on the achievement of the activities and the outputs of the Project, both sides confirmed the recommendations as follows:

Biosafety management

1. The level of the capacity and leadership of the Biosafety Department needs to be enhanced further to have a better collaboration with other user departments.
2. To make Biosafety activities more practically applied among all users, Information, Education and Communication (IEC) materials should be developed and utilized.

Operation and Maintenance

3. NIHE's ability to ensure safety operation and maintenance of the BSL-3 laboratories should be further improved especially in terms of emergency response and evacuation training, regular inspections, and operation and maintenance data analysis.
4. It should be considered to recruit and train more full-time engineers at the Biosafety Department to exclusively operate and maintain BSL-3 laboratories for 24-hour-operation.

Laboratory activities

5. Training manuals and SOPs with focus on specific pathogens including rabies, anthrax, tuberculosis, rickettsial diseases and others, needs to be developed (Activity 3-1).
6. Laboratory practice under supervision for testing and diagnosis by internal and external experts should be improved (Activity 3-4).
7. Management system including SOPs for registration of highly pathogenic agents should be strengthened (Activity 3-6).

Extension of the Project period

8-1. Based on the result of the evaluation, both sides confirmed that it is strongly recommended to extend the project's cooperation term for one and a half year. The necessities of the extension are as follows:

- 1) In order to make the NIHE's capacity meet the international standard, uncompleted activities should be carried out and strengthened, which can lead to ensure safety management of the BSL-3 laboratories.
- 2) Some activities to carry out were identified and suggested in the implementation process. These specific activities are the following: a) more advanced training to operate and maintain the High-tech Center (HTC) BSL-3 laboratories, b) training on emergency response, c) data analysis for operation and maintenance, d) development of training manuals with focus on each pathogen, and so on. They are in fact within the existing PDM framework and are indispensable to meet the international standard and to achieve the Project Purpose.

8-2. Some unpredictable factors that delayed the progress of the activities are as follows:

- 1) It took more time to transfer, install, adjust and operate the mobile BSL-3 laboratory than anticipated due to unpredictable reasons both in Japan and Vietnam.
- 2) The HTC BSL-3 laboratories took also several months from completion of the facility to its full operation using pathogens. Once the operation began, some problems of the facilities and equipment were reported, which are in the process of solving.

- 3) The engineer staff, who was trained at the mobile BSL-3 laboratory, required more time than anticipated to be trained further on operation and maintenance specifically for the HTC BSL-3 laboratories.
- 4) Due to the factors mentioned in 1) to 3) above, technical assistance and on-the-job-training using the BSL-3 laboratories had been limited during the delayed period.
- 5) NIHE staff would not experience annual inspection during the current project's period, because launching of the full operation of the HTC BSL-3 laboratories was delayed to June 2008. As the technical assistance is indispensable to conduct such a large scale inspection which will be conducted in June 2009, practical experience of the annual inspection with technical assistance is vital for NIHE staff.

8-3. Activities to be completed during the extended period

During the extended project period more emphasis should be put on accomplishment of the activities under Output 2 and 3 within the framework of the current PDM as follows:

1) Output 2

Activity 2-2

- More advanced training to operate and maintain the HTC BSL-3 laboratories
- Training on emergency response

Activity 2-3

- Regular inspections
- Data analysis for operation and maintenance

2) Output 3

Activity 3-1

- Adding a section of sharing a laboratory with different pathogens to existing SOPs and training manuals
- Development of SOPs and training manual with focus on each pathogenic agent to test at the BSL-3 laboratories

Activity 3-2

- Training for researchers based on the manual above

Activity 3-4

- Upgrading quality of laboratory practice under supervision for testing and diagnosis by internal and external experts for avian influenza

Activity 3-6

- Strengthening management system for registering highly pathogenic agents

Tentative plan of operation of activities above for the extended period is attached in Appendix 2.

8-4. Recommended inputs during the extended period

Japanese side

- Long and short-term experts
- Training in Japan
- Provision of equipment
- Local cost

Vietnamese side

- Counterpart officers
- Equipment and materials
- Local cost

For the future

9. Collaboration between NIHE and Japan is strongly encouraged in the future as well through optimizing best practices of the Project.

V. WAY FORWARD

If the extension of the project's cooperation term is approved by concerned authorities of Japan and Vietnam, both sides will confirm the extension by the Record of Discussions before the termination of the current cooperation term.

Appendix:

1. PDM (ver.2 dated 14 September, 2007)
2. Recommended tentative plan of operation for the extended period
3. Joint Terminal Evaluation Report

Project title: Capacity Development for NIHE to Control Emerging and Re-emerging Infectious Diseases in the SRV

Target Area: National Institute of Hygiene and Epidemiology (NIHE) Target group: BSL-3 Related Staff in NIHE

Narrative Summary	Objectively Verifiable Indicators	Means of Verification	Important Assumptions
<p>Super Goal Emerging and re-emerging diseases are controlled in the Socialist Republic of Vietnam.</p>	<p>Number of human cases of any emerging or re-emerging diseases in Vietnam is minimized.</p>	<p>Report/record of MOH</p>	
<p>Overall Goal BSL-3 Laboratories are fully functioned and maintained in NIHE</p>	<p>Numbers of registered researchers and actual users working with BSL-3 pathogens as well as number of diagnosis/investigation/research performances increase.</p>	<p>Report/record of NIHE</p>	<p>Policies of the Socialist Republic of Vietnam on control of emerging and re-emerging infectious diseases do not change significantly.</p>
<p>Project Purpose NIHE has capacity to examine highly hazardous transmissible pathogens properly in the BSL-3 laboratories that meets international standard.</p>	<ul style="list-style-type: none"> The system of biosafety management is established and properly implemented and all necessary records are being produced according to the regulations. 	<p>Report/record of NIHE</p>	<p>Staff and budget are properly allocated for operation and maintenance of BSL-3 laboratories.</p>
<p>Outputs 1 Biosafety regulation/system in NIHE which includes management and operation of BSL-3 laboratories is established.</p>	<ul style="list-style-type: none"> Institutional Biosafety Regulation of NIHE is developed. Staff involved in biosafety laboratory works take training of new biosafety regulation. 	<p>Document Training record</p>	<p>BSL-3 laboratories are installed in NIHE by grant aid.</p>
<p>2 The Capacity of NIHE to operate and maintain BSL-3 laboratories is established.</p>	<ul style="list-style-type: none"> Establishment of operation and maintenance division, function of the division and job description of the staff are authorized by NIHE. 	<p>Document (developed manuals, records, etc)</p>	
<p>3 The Capacity of NIHE to conduct laboratory testing of highly hazardous transmissible pathogens in BSL-3 laboratories is established.</p>	<ul style="list-style-type: none"> All necessary documents are developed and implemented. Ex. Maintenance procedure documents, maintenance documents (register, records, etc.), preventive (periodical) maintenance records 	<p>Training record</p>	

Activities	Inputs		Trained NIHE staff members do not leave
	Japan	Vietnam	
<p>1 Biosafety regulation/system in NIHE which includes management and operation of BSL-3 laboratories is established.</p> <p>1-1. Propose revision on national biosafety regulation</p> <p>1-2. Develop Institutional Biosafety Regulation in NIHE</p> <p>1-3. Establish and strengthen Biosafety Department which manage the implementation of biosafety</p> <p>1-4. Strengthen Biosafety Committee</p> <p>1-5. Develop Laboratory Operation Manual and Standard Operational Procedure (SOP)</p> <p>1-6. Organize biosafety training courses</p> <p>2 The Capacity of NIHE to operate and maintain BSL-3 laboratories is established.</p> <p>2-1. Establish Operation and Maintenance Division within Biosafety Department.</p> <p>2-2. Conduct training of operation and maintenance of BSL-3 laboratories for maintenance/laboratory staff.</p> <p>2-3. Establish regular maintenance system for BSL-3 laboratories.</p> <p>2-4. Establish logistics system for spare parts and repair works for BSL-3 laboratories.</p> <p>3 The Capacity of NIHE to conduct laboratory testing of highly hazardous transmissible pathogens in BSL-3 laboratories.</p> <p>3-1 Develop training manual of testing high pathogenic viruses in BSL-3 laboratories.</p> <p>3-2 Conduct training on biosafety for technical staff based on the training manual.</p> <p>3-3. Review training manual regularly after training courses.</p> <p>3-4. Improve laboratory practice under supervision for laboratory testing for diagnosis.</p> <p>3-5. Develop and implement SOP for testing highly transmissible pathogens in BSL-3 laboratories.</p> <p>3-6. Strengthen management system for registration of highly pathogenic agents.</p>	<p>Experts</p> <p>(1) Chief Advisor</p> <p>(2) Virology</p> <p>(3) Coordinator</p> <p>(4) Biosafety</p> <p>(4) Laboratory Testing</p> <p>(5) Laboratory Maintenance</p> <p><i>Other necessary fields.</i></p> <p>Full-time project staff</p> <p>(1) Secretary</p> <p>(2) Interpreter</p> <p>Training in Japan</p> <p>(1) Biosafety</p> <p>(2) Laboratory Testing</p> <p>(3) Laboratory Maintenance</p> <p><i>Other necessary fields.</i></p> <p>Equipment and materials</p> <p>(1) Laboratory Equipment for Training</p> <p>(2) Equipment for Laboratory Maintenance</p> <p>(3) Other equipment mutually agreed upon as necessary.</p> <p><i>* The equipment to be provided will be subjected to change due to the budgetary conditions of the Japanese side</i></p> <p>Local cost</p> <p>(1) Training textbooks, and materials</p> <p>(2) General expenses of the project office</p>	<p>Counterpart officers</p> <p>(1) Director</p> <p>(2) Coordinator</p> <p>(3) Chief of Biosafety Department</p> <p>(4) Chief of Virology Department</p> <p>(5) Chief of Medical Material and Equipment Division</p> <p>(6) Chief of Department of Administration</p> <p>(7) Chief of Department of Training and Research Management</p> <p>(8) Secretary</p> <p>Project staff</p> <p>(1) Staff of Biosafety Department</p> <p>(2) Staff of Virology Department</p> <p>(3) Staff of Medical Material and Equipment Division</p> <p>(4) Staff of Department of Administration</p> <p>(5) Staff of Department of Training and Research Management</p> <p>Equipment and materials</p> <p>(1) Project Office</p> <p>(2) Vehicle</p> <p>(3) Laboratory Equipment</p> <p>Local cost</p> <p>(1) Building and civil work</p> <p>(2) Public utility (electricity, water, etc)</p>	<p>NIHE creates a new department who is in charge of the Project and provides personnel and budget necessary for the Project.</p>

Appendix 2 Recommended Tentative Plan of Operation for Extension Period

Year Japanese Fiscal Year Month	2009												2010					In charge						
	JFY2009												JFY2010					NIHE	JICA					
	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8			9				
Monitoring & Evaluation Output 2	★JCC														★JCC	★Evaluation								
2-2 More advanced training to operate and maintain the HTC BSL-3 laboratories			↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑		↑							LE, SE (BS & Lab, Maintenance)	
2-2 Training on emergency response				↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑		↑							LE, SE (BS & Lab, Maintenance)	
2-3 Regular inspections			↑													↑							LE, SE (BS & Lab, Maintenance)	
2-3 Data analysis for operation and maintenance				↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑		↑							LE, SE (BS & Lab, Maintenance)	
Output 3																								
3-1 Adding a section of sharing a laboratory with different pathogens to existing SOPs and training manuals		↑		↑												↑								
3-1 Development of SOPs and training manual with focus on each pathogenic agent to test at the BSL-3 laboratories		↑		↑												↑								LE, SE (BS)
3-2 Training for researchers based on the manual above				↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑		↑							LE, SE (Lab, Testing)	
3-4 Upgrading quality of laboratory practice under supervision for testing and diagnosis for avian influenza				↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑		↑							SE (Lab, Testing)	
3-6 Strengthening management system for registering highly pathogenic agents				↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑		↑							LE, SE (BS)	

Note: --▶ done by OIT or on NIHE's own
 ↑ assisted by technical cooperation
 BS: Biosafety, MME: Materials and Medical Equipment
 LE: Long-term Experts, SE: Short-term Experts, JCC: Joint Coordinating Committee

**JOINT TERMINAL EVALUATION REPORT
ON JAPANESE TECHNICAL COOPERATION PROJECT
FOR
CAPACITY DEVELOPMENT FOR
NATIONAL INSTITUTE OF HYGIENE AND EPIDEMIOLOGY
TO CONTROL EMERGING AND
RE-EMERGING INFECTIOUS DISEASES
IN VIETNAM**

25 November 2008

**NATIONAL INSTITUTE OF HYGIENE AND EPIDEMIOLOGY,
VIETNAM
JAPAN INTERNATIONAL COOPERATION AGENCY, JAPAN**

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ABBREVIATIONS

BS	Biosafety
BSL	Biosafety Level
HPAI	Highly Pathogenic Avian Influenza
HTC	High-tech Center
IEC	Information, Education and Communication
GMT	Good Microbiological Techniques
JARCOM	JICA- Asean Regional Cooperation Meeting
JCC	Joint Coordinating Committee
JICA	Japan International Cooperation Agency
MME	Materials and Medical Equipment
NIHE	National Institute of Hygiene and Epidemiology, Vietnam
NIID	National Institute of Infectious Diseases, Japan
ODA	Official Development Assistance
PDM	Project Design Matrix
PO	Plan of Operation
RD	Record of Discussions
RT-PCR	Reverse Transcriptase – Polymerase Chain Reaction
SARS	Severe Acute Respiratory Syndrome
SOP	Standard Operational Procedure
VND	Vietnamese Dong
WHO	World Health Organization

1. Introduction

1.1 Background and Summary of the Project

In Vietnam, emerging diseases has occurred such as Severe Acute Respiratory Syndrome (SARS) in 2003 and Avian Influenza since 2004. Especially regarding Avian Influenza, there have been more than 50 deaths and concern for spread of infections is growing. In order to maintain health and safety of people in Vietnam and in neighboring countries, measures to control the disease were urgently needed to be taken.

Under these circumstances Japan International Cooperation Agency (JICA) conducted a project formulation survey for the purpose of analyzing the capability of testing and diagnosis of National Institute of Hygiene and Epidemiology (NIHE) and of elaborating a future possible cooperation. In the survey, the current measures for controlling emerging infectious diseases were analyzed and the needs of the Vietnamese government were identified. As a result of the discussions between the Vietnamese and Japanese sides, official request was submitted for the grant aid for Biosafety Level (BSL) 3 laboratories in the NIHE High-tech Center (HTC), which was approved in 2006. The construction of the laboratories was completed in January 2008.

Together with the request for the grant aid, a request was submitted for the Technical Cooperation Project on capacity development of NIHE to safely manage and operate those BSL-3 laboratories and to examine highly hazardous transmissible pathogens. Receiving the request, JICA dispatched the preliminary study team for the purpose of clarifying and agreeing on the project framework in December, 2005. Based on the result of the study, the Project has started on 20 March, 2006 for three years.

In November 2006 a mobile BSL-3 laboratory was installed for the purpose of training and technical assistance has been provided for operating the laboratory safely. In the mid-term evaluation study conducted in September 2007, some achievements were identified such as approval of the NIHE Biosafety Regulation and capacity development of maintenance staff. Currently with the assistance by two Japanese experts in the project site and some short-term experts dispatched in the fields of biosafety, maintenance and laboratory testing, project activities are being done for safely operating the BSL-3 laboratories in the NIHE High-tech Center.

A terminal evaluation aims to evaluate the progress of activities and achievements of outputs of the Project, identify its outstanding challenges and outcomes, and confirm the direction and future plan of the Project.

1.2 Joint Evaluation Team

Japanese side

Name	Job Title	Organization and Position	Period in Vietnam
Ms. Naoko UEDA	Team Leader	Director, Infectious Disease Control Division, Human Development Department, JICA	Nov.19-26, 2008
Dr. Masato TASHIRO	Laboratory Testing	Director, Department of Virology III (Viral Diseases & Vaccine Control), National Institute of Infectious Diseases (NIID)	Nov.22-26, 2008
Dr.Kazuyoshi SUGIYAMA	Biosafety	Director, Division of Biosafety Control and Research, NIID	Nov.19-26, 2008
Ms. Tomomi IBI	Cooperation Planning	Staff, Infectious Disease Control Division, Human Development Department, JICA	Nov.13-26, 2008
Ms. Makiko KINOSHITA	Evaluation Analysis	Global Link Management Inc.	Nov.9-26, 2008
Dr. Tetsuo YONEYAMA		Chief Advisor of the Project	
Mr. Kenji IKARI		Project Coordinator of the Project	

Vietnamese side

Name	Project Position	NIHE Position
Dr. Nguyen Tran Hien	Project Director	Director
Dr. Nguyen Thi Hong Hanh	Coordinator	Deputy Director
Dr. Le Thi Quynh Mai	Counterpart & Administrative Personnel	Head of Virology Department
Dr. Nguyen Thanh Thuy	Counterpart & Administrative Personnel	Head of Biosafety Department
Mr. Nguyen Trong Phu	Counterpart & Administrative Personnel	Head of Materials and Medical Equipment Department

1.3 Method of Evaluation

The terminal evaluation was conducted in accordance with the JICA Guidelines for Project Evaluations

(2004), following these steps:

- 1) Achievements of the Project were assessed based on the Project Design Matrix (PDM) version 2, adopted on 14 September, 2007 (Annex 1). The results of the Outputs and the Project Purpose were analyzed vis-à-vis the Verifiable Indicators. The Inputs and Activities were evaluated in comparison with the plan and the results of the Outputs. Framework of the evaluation is indicated in the Evaluation Grid shown in Annex3.
- 2) Contributing and impeding factors to the achievement of the Project were analyzed by reviewing the project design and project implementation process.
- 3) The design, implementation process, and outcomes of the Project were analyzed from the viewpoints of the five evaluation criteria: relevance, effectiveness, efficiency, impact and sustainability.
- 4) Recommendations for the Project for the remaining period were formulated.

Both quantitative and qualitative data were collected and utilized for analysis. Data collection methods used by the Team were as follows:

- Document review
- Questionnaire survey to the counterparts and the Japanese experts
- Key informant interviews (See Annex 23)
- Direct observation of the Project site

Five evaluation criteria are summarized as follows:

1) Relevance

Relevance of the Project is reviewed by the validity of the Project Purpose and the Overall Goal in connection with the policies of the Government of the Socialist Republic of Vietnam and the needs of the country, as well as with the Japan's assistance policy to Vietnam.

2) Effectiveness

Effectiveness is assessed by examining the extent to which the Project has achieved its Project Purpose, and clarifying how the Outputs have contributed to the achievement of the Project Purpose.

3) Efficiency

Efficiency of the Project is analyzed by looking at how the Inputs and Activities have contributed to the production of the Outputs, analyzing the quality, quantity and timing.

4) Impact

Impact of the Project is assessed through analyzing either positive or negative influences of the Project.

5) Sustainability

Sustainability of the Project is assessed in terms of organizational, financial and technical aspects by

examining to what extent the outcomes of the Project to be sustained after the Project is completed.

2. Achievement and Implementation Process

2.1 Inputs

2.1.1 Inputs by the Japanese side

1) Experts

Long-term experts: A total of four long-term experts were assigned to the Project in three area of expertise, totaling 76 man/months. They are two Chief Advisors, the Expert in Virology, and the Project Coordinator. The previous Chief Advisor completed his assignment in April 2008, and a new Chief Advisor replaced the position in June 2008. The Expert in Virology completed his duty in August 2008. As for the short-term experts, a total of 34 short-term experts (9 experts in 2006, 15 experts in 2007, 10 experts in 2008) was dispatched as of the end of October 2008, totaling 23 man/months (=692 days).

The detail list of Japanese experts is shown in Annex 4 (List of Dispatched Experts).

2) Counterpart Training

2)-1 Counterpart Training in Japan

A total of 12 NIHE staff members participated in the counterpart trainings in Japan as of October 2008 including three members who are currently attending the training courses. The following list shows titles of training courses and the number of Counterparts attended the course in respective course.

Title of Training Course	Number of CPs
Biosafety Training	6
Laboratory Training (Virology)	2
Laboratory Training (Bacteriology)	1
Laboratory Training (HIV/AIDS)	1
Laboratory Maintenance Training	2

To date, all trainees continue to work in NIHE in their training positions.

The details are shown in Annex 7.

2)-2 Counterpart Training in Vietnam

Local trainings were carried out, some are more theory based, others are more practical and on-the-job training approach. Most trainings were facilitated by the Japanese experts, but some of the courses were done by the Biosafety (BS) Department.

The details are shown in Annex 8.

3) Provision of equipment

A total amount of the machinery and equipment provided by Japan to the Project is worth US\$ 466,972 as of October 2008. In addition, the Project purchased additional machinery and equipment worth US\$80,480. Therefore, a grand total of the provision of equipment is estimated to be US\$547,452.

The details are shown in Annex 5 (List of Equipment provided by JICA).

4) Operational expenses

A total of VND 2,940,194,000 or US\$183,068 equivalent was disbursed as direct operational expenses of the Japanese side since the beginning of the Project up to October 2008. The expenditure includes general project office management cost (e.g. office supplies and communication cost), local training cost (e.g. laboratory training and project management training), equipment (e.g. Mobile BSL-3 laboratory anteroom equipment and office equipment), and any other consumable expenditures for Mobile BSL-3 laboratory.

The details of the operational expenses are shown in Annex 6 (Project Management Cost provided by JICA).

2.1.2 Inputs by the Vietnamese side

1) Counterpart personnel assigned to the Project

Director and Vice Directors of NIHE were appointed as Project Director and Project Coordinators respectively. Eight departments of NIHE are assigned to be counterparts, and those are Departments of 1) Biosafety, 2) Materials and Medical Equipment, 3) Virology, 4) Bacteriology, 5) Molecular Immunology and Biology, 6) Community Health and Network, 7) Training and Research Management, and 8) Administration. The Project closely works with BS Department in day-to-day operation.

The details of the Counterpart of the Project are shown in Annex 11 (List of Counterpart of the Project).

2) Provision of the project office and equipment

The Vietnamese side provided two office rooms and equipment to the Project in NIHE.

The details are shown in Annex 12 (List of Facility and Equipment provided by NIHE).

3) Operational expenses

The Vietnamese side provided VND 1,285,900,000 or US\$ 78,542 as operational expenses of the Project. Besides utility cost for project office, Mobile BSL-3 laboratory and HTC BSL-3 laboratory, installation fee for Mobile BSL-3 laboratory was assisted by the Vietnamese side.

The details are shown in Annex 13 (Budget Allocation by NIHE).

2.2 Activities and Outputs

2.2.1 Achievement of activities under Output 1

“Biosafety regulation/system in NIHE which includes management and operation of BSL-3 laboratories is established.”

It is confirmed that all activities under Output 1 have been implemented without major problems as originally planned. It should be noted that even if BS Department was a newly established department; it took on heavy tasks to introduce a concept and system of “Biosafety” for BSL-3 laboratories to NIHE.

As many key persons including NIHE’s director recognize, one of the major achievements would be especially development of the NIHE’s Biosafety Regulation and manuals such as Laboratory Operation Manual and Standard Operational Procedure (SOP). It is the first Biosafety Regulation which includes management and operation of BSL-3 laboratory in Vietnam as the country did not have BSL-3 laboratory installed domestically before the Project. As the BSL-3 laboratories are now in full operation, the Biosafety Regulation has also been revised according to the locality, which led to development of the 2nd version of the Biosafety Regulation.

Another achievement to remark is that BS Department developed capacity to conduct the certified Basic Biosafety Training in a good collaboration with user departments, which allows participating researchers to become registered ones to use BSL-3 laboratories. Without completing the training course, any researchers are not eligible to use BSL-3 laboratories for their research activities.

Achieving almost all activities under Output 1, it can be concluded that the basis of the Biosafety system is firmly established; nonetheless it seems the Biosafety activities are not fully applied in practice among all users yet. In other words, BS Department began to implement Biosafety activities and training based on the Regulation and SOPs, nevertheless Biosafety practice is not widely spread among users.

Towards the end of the Project, it can be considered further to make the Biosafety system more functional. One of the possible areas to consider is to introduce behavior change approach by utilizing Information, Education and Communication (IEC) materials in the Biosafety activities. It was found out from the interview that it could take some time to grasp a new concept and change their habits especially when it comes to more complicated procedures to follow at the BSL-3 laboratories. Moreover, not all researchers start using the BSL-3 laboratories soon after participating in the training course; some may use the lab a long after the training course, which in that case the Biosafety concept can be faded away by the time to use the laboratories. Therefore, user friendly materials to explain the Biosafety concept are more appealing as a reminder. Also, the Biosafety Regulation can be simplified or summarized and distributed to all user departments. Posters and brochures can also be placed at the BSL-3 laboratories to insist on its importance and practice. More ideas are created for the new concept towards ideal behaviors.

Lastly but most importantly of all above is to continue to enhance management capacity and leadership of BS Department. At the time of the mid-term evaluation, it was suggested to strengthen leadership capacity of the Department. At this time, it is observed to be apparent that BS Department increased coordinating capacity as well as leadership; for instance the Department conducts Biosafety trainings in collaboration with other users, chair various joint meetings, and develop a plan of the effective usage of the mobile and HTC BSL-3 laboratories. However, as the time goes on with more collaboration work, expectation for BS Department in coordination and leadership continues to be high.

Activities	Achievement
1-1 Propose revision on National Biosafety Regulation	National Biosafety Regulation is currently being formulated by the Ministry of Health. The Project and NIHE are expected to provide technical feedback and suggestions in collaboration with the National Institute of Infectious Diseases in Japan.
1-2 Develop Institutional Biosafety Regulation in NIHE.	NIHE Biosafety Regulation was developed and enforced (1 st version) in July 2007. The 2 nd version was approved in November 2008. (ANNEX) 2. Project Activity List
1-3 Establish and strengthen BS Department which manages the implementation of the Biosafety Regulation	Biosafety Department was established in September 2006 as a new department in NIHE, and two new personnel were assigned to the Project (Head of the Department and staff of the Supervision Division). Two new personnel were posted as engineers at BS Department in Nov 2006, and, one more engineer and staff at the Supervision Division were added in May and August 2008 respectively. Five members of BS Department and one member of the Material & Medical Equipment (MME) Department attended the counterpart training on <i>Biosafety Training</i> in Japan. Two members of the MME Department are currently participating in the counterpart training on <i>Laboratory Maintenance Training</i> in Japan. In order to strengthen Biosafety control, the first BSL-3 laboratory management meeting was held in June 2008. Participants consist of staff of BS Department and researchers from the Virology and Bacteriology Departments, etc. Since then, five meetings were held on a regular basis to discuss various issues including 1) plan of mobile and new BSL-3 laboratory usage, 2) how to use Personal Protective Equipment, 3) animal laboratory usage, 4) emergency case in BSL-3 laboratory. The head of BS Department chairs all meetings. (ANNEX) 2. Project Activity List 7. List of Counterpart Training in Japan 14. Content of BSL-3 laboratory management meeting

<p>1-4 Strengthen Biosafety Committee</p>	<p>Biosafety Committee was established in January 2007, consisting of NIHE director, vice director, Head of BS Department, Head of the Virology and other management members.</p> <p>The Biosafety Committee meeting was held twice in 2007, 1) to discuss on the strategic plan of biosafety, 2) to discuss on the contents of the NIHE Biosafety Regulation.</p> <p>In 2008, the Biosafety Committee had a meeting once so far to discuss on 1) the progress and future plan of the Biosafety related activities, 2) drafting of the 2nd version of the NIHE Biosafety Regulation.</p> <p>(ANNEX) 2. Project Activity List</p>
<p>1-5 Develop Laboratory Operation Manual and Standard Operational Procedure (SOP)</p>	<p>In order to operate the mobile BSL-3 laboratory properly, the following procedure manuals were developed in three languages (Japanese, English, Vietnamese) <u>Standard Operational Procedure (SOP) for Mobile BSL-3 Laboratory</u> (1st version and 2nd version) <u>Instruction for Utilization of Biosafety Cabinet</u></p> <p>As for operating the HTC BSL-3 laboratory properly, the following procedure manual was developed in three languages (Japanese, English, Vietnamese) <u>Operational Manual and Standard Operational Procedure (SOP) for High Tech Center (HTC) BSL-3 laboratory</u></p> <p>(ANNEX) 9. List of Publication</p>

<p>1-6 Organize Biosafety Training courses</p>	<p>Japanese experts conducted 25 Biosafety related trainings for NIHE staff with the cumulative number of 427 participations (347 researchers and 80 others) attending the trainings as of October 2008.</p> <p>The breakdowns are the following (with the cumulative number) In 2006, 9 trainings conducted for 205 staff In 2007, 10 trainings conducted for 170 staff In 2008, 4 trainings conducted for 37 staff</p> <p>Since March 2008, trained staff of BS Department prepared and carried out the certified Biosafety training course.</p> <p>Based on Training Manual for Basic Biosafety and Use of BSL-3 Laboratory, 2-day training on Basic Biosafety and Use of BSL-3 Laboratory has been implemented by BS Department with lecturers from BS and other user departments.</p> <p>Training Contents Day 1: Biosafety Concept and Regulation Day 2: Operation and Maintenance of BSL-3 Laboratory and its practice</p> <p>From March to October 2008, the training was held four times and a total of 100 staff members attended including 68 NIHE researchers. The training course is planned to be held regularly.</p> <p>Training participants, who completed the Basic Biosafety Training course with the certificate, become registered researchers who are eligible to use pathogens at BSL-3 laboratory. As of October 2008, 18 trained researchers used BSL-3 laboratory after the training.</p> <p>(ANNEX) 8. List of Local Training 21. Numbers of registered researchers and actual users working with BSL-3 pathogens</p>
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Output 1 “Biosafety regulation/system in NIHE which includes management and operation of BSL-3 laboratories is established.”

Verifiable Indicators	Achievement
<p>Institutional Biosafety Regulation of NIHE is developed.</p>	<p>NIHE Biosafety Regulation was developed and approved in July 2007(1st version). The 2nd version was approved in November 2008.</p>
<p>Staff involved in biosafety laboratory works take training of new Biosafety Regulation.</p>	<p>Five members of BS Department and one member of the Material & Medical Equipment Department participated in the counterpart training on Biosafety Training in Japan.</p> <p>Japanese experts conducted local trainings for personnel from BS Department and the other user Departments on Biosafety. The cumulative number of 412 participations including 347 researchers attended the training.</p> <p>Trained staff of BS Department with a lecturer from the user department conducted 2-day training on Basic Biosafety and Use of BSL-3 Laboratory. A total of 100 staff members including 68 researchers completed the course and were granted the Training certificate.</p>