Ministry of Health
The Republic of Moldova

PROJECT COMPLETION REPORT
ON
THE PROJECT FOR IMPROVING MEDICAL DEVICE MANAGEMENT
IN
THE REPUBLIC OF MOLDOVA

APRIL 2017

JAPAN INTERNATIONAL COOPERATION AGENCY (JICA)

FUJITA PLANNING CO., LTD.

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Project Completion Report

Project Title: Project for Improving Medical Device Management

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Project Completion Report on
the Project for Improving Medical Device Management
in the Republic of Moldova

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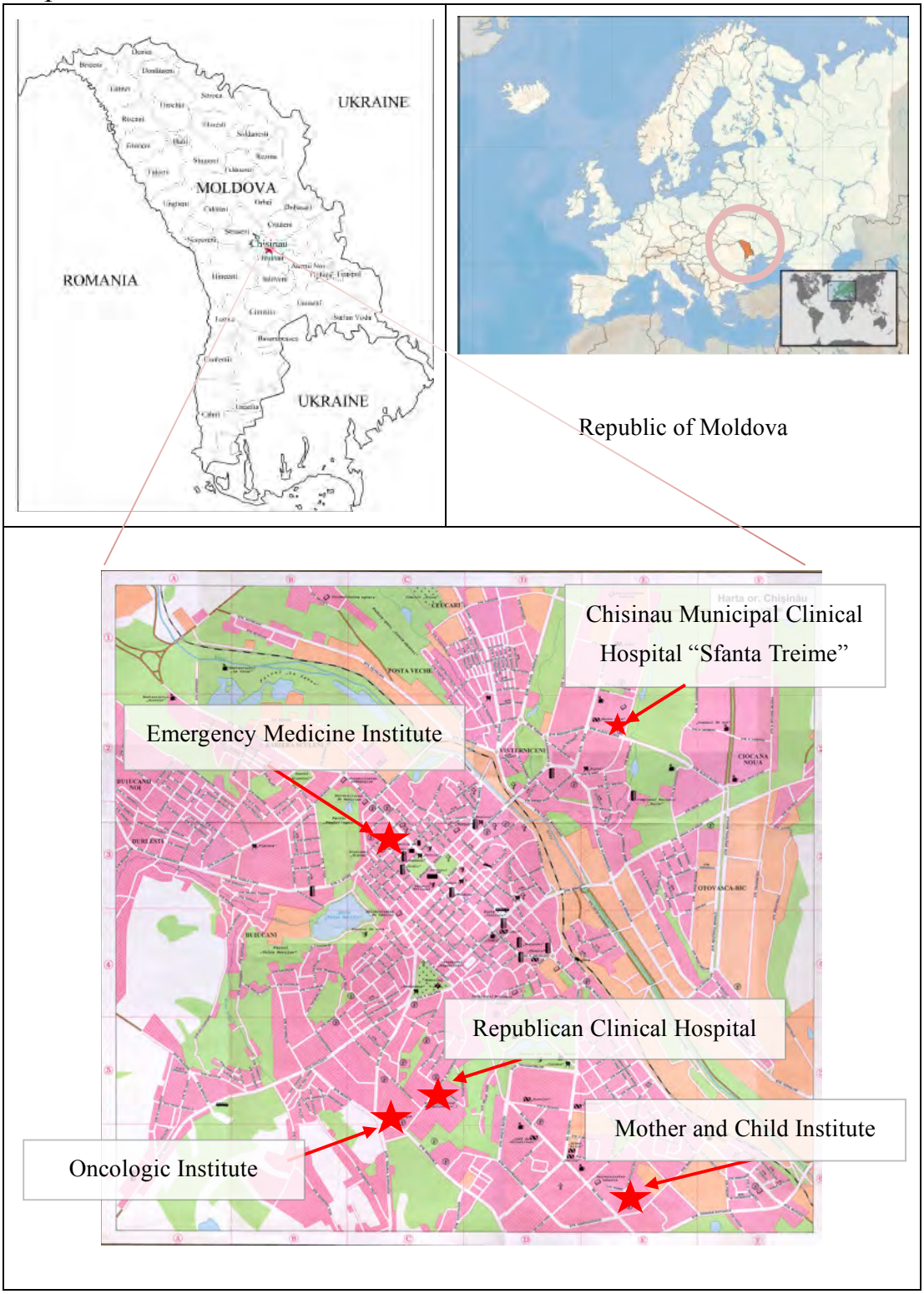
Map

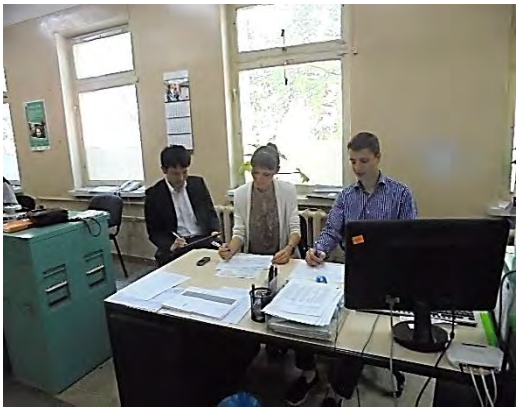


http://upload.wikimedia.org/wikipedia/commons/a/a5/Europe_location_MDA.png,
http://www.ecoi.net/file_upload/mv240_moldova_south.jpg
http://www.worldmapfinder.com/Map_OpenStreetMap.php?ID=/Jp/Europe/Moldova/Chisinau

Photos

Assessment study on current situation of medical device management

Workshop for managerial personnel (Chisinau Municipal Clinical Hospital "Sfanta Treime")



D/SBME monitoring by Japanese experts (Emergency Medicine institute)

User Training (Mother and Child Institute)

Planned Periodical Maintenance by technicians (Emergency Medicine Institute)

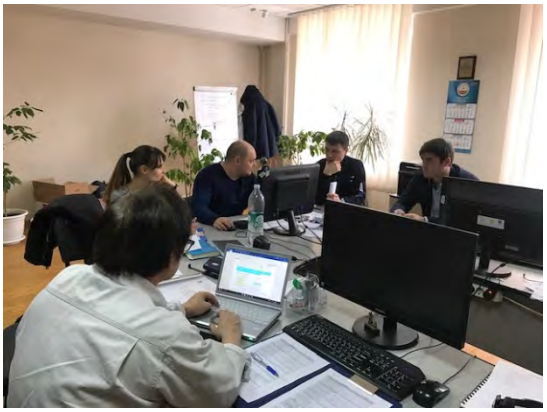
V4+Japan Cooperation Workshop on management of medical devices

1st Japan Study Tour
Discussion on lessons learnt

2nd Japan Study Tour
Feedback to Japanese Manufacturers

Training for development of Quick Guide

Working space in an ICU at pilot hospital



D/SBME monitoring by technicians
(Mother and Child Institute)

Dissemination Seminar

I. Basic Information of the Project

1. Country

The Republic of Moldova

2. Title of the Project

The Project for Improving Medical Device Management

3. Duration of the Project (Planned and Actual)

April 2015 – April 2017

4. Background (from Record of Discussions(R/D))

In the Republic of Moldova ("Moldova"), the authority has been working on the health sector reform after its independence in 1991. With the great effort by the Moldovan government and assistance from donors, the level of primary health care has become comparable to the neighboring European countries and the reform on health financing system has been making a good progress. The mandatory health insurance system covers more than 80 % of population and it contributed to reduce health finance. In addition, the progress of MDGs is on-track while reducing the number of hospitals.

However, Moldova spends about 12% of the GDP on health care including contribution to health insurance, which is rather high level and almost as same as the level in developed countries. In order to avoid the increase of medical care expenditure to an unsustainable level, further reform and streamlining of the medical care service in hospital sector is necessary, in light of the advancement of the rapid aging society. Under such condition, "Project for Improvement of Medical Care Service" by Yen Loan has been in operation to improve and streamline the medical care and public health service by introducing new medical and laboratory device into core tertiary and secondary hospitals and other facilities in Moldova.

In addition to severe conditions in the hospital sector, the insufficient number of biomedical engineer is another challenge for Moldova. Though the Law on Medical Devices (Law no. 92/26.04.12) was adopted, the health system lacks sufficient institutional and operational capacities for its implementation.

Under this circumstances, the Government of Moldova requested JICA's technical cooperation project to enhance institutional and functional capacity of health system in the field of medical device management.

5. Overall Goal and Project Purpose (from Record of Discussions(R/D))

R/D dated December 19th, 2014.

Overall Goal : The medical device management centers/units are installed in all country in accordance with the developed guidelines.

Project Purpose : The established medical device management centers/units are functional.

Amendment to R/D dated September 27th, 2016.

Overall Goal : The Departments/Sections of Biomedical Engineering[1] are established throughout the country based on the developed guidelines.

Project Purpose : The established Departments/Sections of Biomedical Engineering are functional.

6. Implementing Agency

The Ministry of Health of the Republic of Moldova (hereinafter referred to as "MoH")

[1] Hereinafter referred to as D/SBME

II. Results of the Project

1. Results of the Project

1-1 Input by the Japanese side (Planned and Actual)

Planned	Actual
(1) Amount of input by the Japanese side: 185million Japanese Yens (2) Expert dispatch: 3 persons (3) Local cost for the activities of the Japanese Experts. (4) Receipt of training participants to Japan: 16 persons (5) Equipment Provision: 15 million Japanese Yens	(1) Amount of input by the Japanese side: 172 million Japanese Yens (2) Expert dispatch: 4 persons (Mention the distinction of long- or short-term and major activity items.) - Chief Advisor/ Medical Device Management – 1 Yosuke Umemiya, 11.87 MM - Hospital Management / Medical Device Management – 2 Akio Kaneko, 8.50 MM - Training Coordination – 1 / Project Coordinator -1 / Medical Device Maintenance Management -1 Hiroshi Yoshino, 6.70 MM - Training Coordination – 2 / Project Coordinator -2 / Medical Device Maintenance Management -2 Kodai Tateno, 7.33 MM (3) Local cost for the activities of the Japanese Experts: - Cost of local staff - V4 + Japan cooperation Workshop - Seminar on the Medical Device Management within the pilot hospitals of the Project - (Dissemination) Seminar on Medical Device Management (for the non-pilot hospitals of the project). (4) Receipt of training participants to Japan: total of 16 persons - 1st Study tour to Japan Period: from January 17th to 28th, 2016

Planned	Actual
	Number of participants: 8 - 2nd Study tour to Japan Period: from July 25th to August 3rd, 2016. Number of participants: 8 Visited places: manufacturers of medical devices and hospitals with clinical engineers. (5) Equipment Provision: 15 million Japanese Yens 1) Gas Flow Analyzer, 2 pcs 2) Anesthesia Gas Analyzer, 3 pcs 3) Infusion Pump Analyzer Single Channel, 3 pcs 4) Infusion Pump Analyzer Multi Channel: 1 pc 5) Electrical Safety Analyzer, 3 pcs 6) Multiparametric Simulator, 4 pcs 7) Electric Surgical Unit Analyzer, 3 pcs 8) Defibrillator Analyzer, 3 pcs 9) Phototherapy Analyzer, 1 pcs 10) Fetal Simulator, 1 pc 11) Spirometer Calibration Syringe, 5 pcs

1-2 Input by the Moldovan side (Planned and Actual)

Planned	Actual
(1) Counterpart assignment: 4 persons - Project Director: Deputy Minister, MoH. - Project Manager: Deputy Director of Medicine and Medical Device Department, MoH. - Medicine and Medical Device Agency (hereinafter referred to as "MMDA"): 1 person - Technical University of Moldova: 1 person	(1) Assignment of the Personnel - Project Director: Minister, MoH. - Project Manager: Deputy Director of Medicine and Medical Device Department, MoH. - MMDA: 1 person - Technical University of Moldova: 1 person (2) Due to lack of space in MoH, the project office with desks and chairs, land line phone and internet was provided at the Republican Clinical Hospital instead of

Planned	Actual
(2) Project office space in MoH. (3) Employment of necessary staff for the Departments / Sections of Biomedical Engineering. (4) Cost for necessary tools in the Departments / Sections of Biomedical Engineering (5) Space to establish the Departments / Sections of Biomedical Engineering in the target hospitals (6) Functional "Information System of Medical Device Management" (SIMDM)	MoH. (3) New and/or additional staff has been employed at Republican Clinical Hospital, Oncologic Institute and Chisinau Municipal Clinical Hospital “Sf. Treime”. Emergency Medicine Institute and Mother and Child Hospital had Biomedical Engineering staff before the Project started. (4) Each pilot hospital procured the tools for Departments / Sections of Biomedical Engineering. (5) New and/or additional space for office and workshop have been provided by the hospital management at Republican Clinical Hospital, Emergency Medicine Institute, Oncologic Institute and Chisinau Municipal Clinical Hospital “Sf. Treime” while Mother and Child Hospital already had adequate office and workshop before the Project started. (6) As of March 7th, 2017, the schedule for implementing SIMDM has been facing delays and SIMDM is not yet functional. Major delays encountered were the delay in the preparation of the program and the delay in the approval process. (7) Other items borne by the counterpart government: - Running cost of the project office; electricity, air conditioning, land line phone, internet. - Running cost of the pilot D/SBMEs. - Daily allowance and/or transportation cost for the participants of, a) V4 + Japan workshop

Planned	Actual
	b) Seminar on the Medical Device Management within the pilot hospitals of the Project c) (Dissemination) Seminar on Medical Device Management.

1-3 Activities (Planned and Actual)

Activity	Contents
Activity 1-1: Establish a Technical Committee for the development of the establishment criteria of the Departments / Sections of Biomedical Engineering.	Members of the Technical Committee have been selected and the Technical Committee for the development of the establishment criteria of the Departments / Sections of Biomedical Engineering was established by the end of April 2015, within the planned schedule, with the memberships of, - Representative of Medicine and Medical Device Department, MoH, - Consultant of the Japanese Yen Project, "the for Improvement of Medical Care Service", - JICA Experts, - Representative of MMDA, - Representative of the Technical University of Moldova, formalized by the Ministry Order and worked with development of the establishment criteria of the Departments / Sections of Biomedical Engineering.
Activity 1-2: Conduct an assessment study on situation of medical device management in Chisinau and one rural region.	The target area of the assessment study on situation of medical device management (hereinafter referred to as the "Study") was

Activity	Contents
	changed from “Chisinau and one rural region” to “nation-wide” following suggestions of the Technical Committee, and the Study was conducted first by pilot study to several medical institutions and then through questionnaires and was completed by the end of October 2015 with 1 month delay from the planned schedule due to additional work volume though this delay didn’t affect the schedule of other activities. The report on the results and the analysis of the Study is attached in the Separate Volume, Copy of Products Produced by the Project.
Activity 1-3: Develop the guideline for establishment criteria of the Departments / Sections of Biomedical Engineering.	The draft of the Guidelines for installation criteria of the medical device management centers/units and the Guidelines for Roles and Responsibilities of the medical device management centers/units have been developed, discussed in the V4 + Japan workshop (workshop on effective medical device management), provided modification according to the feedbacks from the workshop, merged into one guideline, namely, the Guidelines on the Establishment Criteria, Roles and Responsibilities of Departments / Sections of Biomedical Engineering in the Public Healthcare Institutions, and approved by the MoH with the MoH Order no. 262 dated 12th of April, 2016 with 2 months delay from the planned schedule. Change of the Project Manager from the Moldovan side and the integration of the guidelines were the main reasons of the delay but, since the new Project Manager has biomedical engineering
Activity 1-4: Develop the guideline on Roles and Responsibilities of the Departments / Sections of Biomedical Engineering and clarify the functions for the Departments / Sections of Biomedical Engineering	

Activity	Contents
	background, the appointment of the new Project Manager made a positive impact on the Project. The approval of the Guidelines and the issuance of the Ministry Order was a milestone which served to raise up the activities of the project. The guidelines are available on MoH's web site[2].
Activity 2-1: Organize a workshop for managerial personnel of the pilot hospitals on introduction of the establishment criteria of the Departments / Sections of Biomedical Engineering.	Completed according to the planned schedule. The workshop for managerial personnel of the pilot hospitals on introduction of the establishment criteria, roles and responsibilities of the Departments / Sections of Biomedical Engineering has been implemented during April 14th to 25th, 2016. The report of the workshop is attached in the Separate Volume, Copy of Products Produced by the Project.
Activity 2-2: Develop a work plan to establish the Departments / Sections of Biomedical Engineering.	The work plan to establish the Departments / Sections of Biomedical Engineering in the pilot hospitals has been developed according to the planned schedule. Copy of the work plan is attached in the Separate Volume, Copy of Products Produced by the Project.
Activity 2-3: Procure the necessary equipment in the Departments / Sections of Biomedical Engineering in accordance with the guideline.	Input by the Japanese side; the procurement of necessary equipment and testing devices for the pilot D/SBMEs, has been completed by the end of April 2016, 5 months ahead of the planned schedule. This advance in the schedule enabled to start the pilot activities ahead of planned schedule, too.

[2] http://www.ms.gov.md/?q=legislatie&field_legtip_tid=13

Activity	Contents
	As for the input by the Moldovan side; the pilot hospitals allocated necessary equipment such as office furniture and engineering tools for DBME.
Activity 2-4: Provide training for the staff of the Departments / Sections of Biomedical Engineering and for other medical staff such as doctors and nurses.	The schedule of the trainings has been adjusted taking into consideration the schedule of the establishment of the pilot D/SBMEs. The change of schedule didn't have any negative impact to other activities of the Project. 1st training for the staff of the D/SBMEs was completed by the end of March, 2016 and the 1st training for other medical staffs was completed by the end of May, 2016. The 2nd training for the staff of the D/SBMEs was planned as (1) additional training for the testing devices which was conducted on October 11th, 18th and 19th and, (2) Training for Development of Quick Guide which was conducted on November 18th, 2016. The 2nd training for the other staff was conducted between November to December, 2016. The reports of the trainings are attached in the Separate Volume, Copy of Products Produced by the Project.
Activity 2-5: Support and monitor the implementation of the roles, responsibilities of the Departments / Sections of Biomedical Engineering according to the guideline.	Monthly Monitoring sessions in each pilot hospital started from June 2016, 4 months before the planned schedule. This advance enabled to have a longer monitoring period and cope with the challenges encountered such as the necessity to hold training for the newly employed staff on the development of

Activity	Contents
	the quick guide of the medical devices. Quarterly Reports of the Monitoring of the pilot DBMEs are attached in the Separate Volume, Copy of Products Produced by the Project.
	From the monitoring sessions, further understanding and collaboration from the user side of the medical devices was identified as one of the challenges. Following this feedback, the Project Execution Team decided to hold the Seminar on the Medical Device Management within the pilot hospitals of the Project for Improving Medical Device Management, targeting to medical device users, such as doctors and head nurses, to cope with this challenge. The aforementioned seminar was hold on December 12th and 13th, 2016. The report of the seminar is attached in the Separate Volume, Copy of Products Produced by the Project.
Activity 2-6: MoH issues a decree for the establishment of the Departments / Sections of Biomedical Engineering for the pilot hospitals.	MoH issued a decree, MoH order no. 262 dated 12th of April, 2016, for the establishment of the Departments / Sections of Biomedical Engineering for the pilot hospitals, and for the approval of the Guidelines on Establishment Criteria, Roles and Responsibilities of Departments / Sections of Biomedical Engineering in Public Healthcare Institutions. The issuance of the Ministry Order served to raise up the activities of the project and contribute directly to the

Activity	Contents
	establishment of the pilot D/SBMEs.
Activity 2-7: Review of the Guidelines on the establishment criteria, roles and responsibilities of the Departments / Sections of Biomedical Engineering.	The Review of the Guidelines on the establishment criteria, roles and responsibilities of the Departments / Sections of Biomedical Engineering has been completed and the revised version of the Guidelines has been approved by MoH in March 2017, and uploaded to the web site of the MoH. A copy of the Guidelines is attached in the Separate Volume, Copy of Products Produced by the Project.

2. Achievements of the Project

2-1 Outputs and indicators

(Target values and actual values achieved at completion)

Target values	Actual values achieved at completion
【Output 1】 Establishment criteria, roles and responsibilities of the Departments / Sections of Biomedical Engineering in the Public Healthcare Institutions are developed. 【Indicator】 The guidelines on the establishment criteria, roles and responsibilities of the Departments / Sections of Biomedical Engineering in the Public Healthcare Institutions are developed.	【Output 1】 The establishment criteria, roles and responsibilities of the Departments / Sections of Biomedical Engineering in the Public Healthcare Institutions are developed and the Output 1 is achieved. The guidelines on the establishment criteria, roles and responsibilities of the Departments / Sections of Biomedical Engineering in the Public Healthcare Institutions are developed and approved by MoH order no. 262 dated 12th of April, 2016.
【Output 2】 In the pilot site, the Departments / Sections of	【Output 2】 In the pilot site, the Departments / Sections

Target values	Actual values achieved at completion
Biomedical Engineering are established based on the developed guidelines in the Output 1.	of Biomedical Engineering are established based on the developed guidelines in the Output 1 and the Output 2 is achieved.
【Indicator】 The Departments / Sections of Biomedical Engineering which implement the Standard Operating Forms of the guidelines are established in all 5 pilot hospitals.	Implementation status of the Standard Operating Forms is; 100.00%[3] DBMEs are established in all 5 pilot hospitals and operating.

2-2 Project Purpose and indicators

(Target values and actual values achieved at completion)

Target values	Actual values achieved at completion
【Project Purpose】 The established Departments / Sections of Biomedical Engineering are functional. 【Indicators】 (1) number of attended cases of corrective maintenance against requests, (2) number of implemented procedures of technical planned preventive maintenance against planned number*1, (3) number of implemented training sessions for users against planned one*1, and (4) number of medical device inventoried in the database of SIMDM against total number of medical devices, are more than 90%”,	【Project Purpose】 It has been confirmed through the monitoring sessions that the established Departments / Sections of Biomedical Engineering are functional. 【Indicators】 Average of the indicators of the 5 pilot hospitals are: (1) 1,101 / 1,101 = 100%*[2], (2) 509 / 560 = 90.89%*[2], (3) 29 / 30 = 96.67%*[2], (4) 6,801 / 6,801 = 100%*[3] All four indicators achieved more than 90%. (1) All requests for corrective maintenance have

[3] Calculation method: (Total number of forms in use in the 5 pilot hospitals)*/(12 (total number of Standard Operating Forms) x 5) *in use=1, not in use=0

Target values	Actual values achieved at completion
*1: according to the annual and/or monthly plan. Status as of the date of the indicators were set （May, 2016） are as follows. (1) Republican Clinical Hospital: no registration. Mother and Child Institute 100%, Emergency Medicine Institute 100%, Oncologic Institute: number of request no registration. Chisinau Municipal Clinical Hospital “Sf. Treime” 0% (not conducted). (2) Republican Clinical Hospital 0%, Mother and Child Institute 100%, Emergency Medicine Institute 100%, Oncologic Institute 0% (no inventory existed), Chisinau Municipal Clinical Hospital “Sf. Treime” 0% . (3) Republican Clinical Hospital: no permanent activities of user training, Mother and Child Institute 100%, Emergency Medicine Institute: no permanent activities of user training, Oncologic Institute 0% (no inventory existed): no permanent activities of user training, Chisinau Municipal Clinical Hospital “Sf. Treime”: no permanent activities of user training, (4) Republican Clinical Hospital 0% (no inventory existed), Mother and Child Institute 100%,	been attended in the 5 pilot DBMEs. (2) Republican Clinical Hospital 280 / 325 = 86.15%, Mother and Child Institute 18 / 20 = 81.82%, Emergency Medicine Institute 171 / 171 = 100%, Oncologic Institute 13 / 15 = 86.67%, Chisinau Municipal Clinical Hospital “Sf. Treime” 27 / 27 = 100%. (3) Republican Clinical Hospital 4 / 4 = 100%, Mother and Child Institute 7 / 7 = 100%, Emergency Medicine Institute 6 / 6 = 100%, Oncologic Institute 3 / 4 = 75.00%, Chisinau Municipal Clinical Hospital “Sf. Treime” 9 / 9 = 100%. (4) Medical devices in all 5 pilot hospitals have been inventoried. Number of medical devices: Republican Clinical Hospital 1,966, Mother and Child Institute 1,977, Emergency Medicine Institute 1,277, Oncologic Institute 868, Chisinau Municipal Clinical Hospital “Sf. Treime” 716 *2: For the period of January to February 2017. *3: as of February 28th, 2017. Since SIMDM is not yet available as of March 7th, 2017, this indicator represents the number of medical device inventoried in any form of database against total number of medical devices.

Target values	Actual values achieved at completion
Emergency Medicine Institute 100%, Oncologic Institute 0% (no inventory existed), Chisinau Municipal Clinical Hospital "Sf. Treime" 0% (no inventory existed).	

3. History of PDM Modification

The PDM has been modified from Version 1 to Version 2 with the amendment to the Record of Discussions signed by JICA and the MoH on September 27th, 2016. Major points of the modification by the amendment are presented in continuation.

※The amended parts are shown in *italic.*

3.1. "Annex 1 Logical Framework (Project Design Matrix: PDM)" of the R/D signed on December 19th, 2014

(1) Overall Goal and its Objectively Verifiable Indicators

(2) Project Purpose

(3) Important assumption in the line of the Project Purpose

(4) Output 1 and its Objectively Verifiable Indicators

(5) Output 2 and its Objectively Verifiable Indicators

(6) Activities 1-1, 1-3, 1-4, 2-1, 2-2, 2-3, 2-4 and 2-5

(7) Inputs of the Moldovan side, 3, 4 and 5.

(8) Pre-conditions

"Annex 2 Tentative Plan of Operation" of the R/D signed on December 19th, 2014

(9) Activities 1-1, 1-3, 1-4, 2-1, 2-2, 2-3, 2-4 and 2-5

(10) Reports / Documents

(1), (2), (3), (4), (5), (6), (8), (9), and (10)	
Before (wherever the phrase below appears in the above parts of Annexes)	Amended Version
medical device management centers/units	*Departments / Sections of Biomedical Engineering*
(7)	
Before (wherever the phrase below appears in the above parts of Annexes)	Amended Version
medical device management unit	*Departments / Sections of Biomedical Engineering*

Reason: According to the international practice in this area, and the information offered by the Personnel Management Department of MoH about the basic structure of medical institutions in Moldova, the name of the organization in charge of the medical device management established by this project is modified.

3.2 "Annex 1 Logical Framework (Project Design Matrix: PDM)" of the R/D signed on December 19th, 2014

(1) Objectively Verifiable Indicators of the Overall Goal

Before	Amended Version
1. Number of the centers/units who meets the requirements in accordance with the guidelines (The concrete indicators are to be set after the development of the guidelines)	Number of the Departments / Sections of Biomedical Engineering *which implement the Standard Operating Forms of the guidelines is more than 20 throughout the country.*
Reason: Indicator has been set after the development of the guidelines. The tentative list of the sites planned to establish the Departments /Sections of Biomedical Engineering is attached as Annex 4.	

3.3. "Annex 1 Logical Framework (Project Design Matrix: PDM)" of the R/D signed on December 19th, 2014

(1) Objectively Verifiable Indicators of the Project Purpose

Before	Amended Version
1. Updated maintenance record, etc. (Indicators to measure the state of functioning of the units are to be determined after the development of the guidelines)	*In the pilot hospitals, percentage of (1) number of attended cases of corrective maintenance against requests, (2) number of implemented procedures of technical planned preventive maintenance against planned number, (3) number of implemented training sessions for users against planned one, and (4) number of medical device*

	inventoried in the database of SIMDM against total number of medical devices, are more than 90%.
Reason: Indicators have been set after the development of the guidelines.	

3.4 "Annex 1 Logical Framework (Project Design Matrix: PDM)" of the R/D signed on December 19th, 2014

(1) Objectively Verifiable Indicators of Output 1

Before	Amended Version
The guidelines for installation criteria of the medical device management centers/units and for roles and responsibilities of the medical device centers/units are developed.	*The guidelines on the establishment criteria, roles and responsibilities of the Departments / Sections of Biomedical Engineering in the Public Healthcare Institutions* are developed.
Reason: The "guidelines for installation criteria of the medical device management centers/units" and "for roles and responsibilities of the medical device centers/units" are merged into "the guidelines on the establishment criteria, roles and responsibilities of the Departments / Sections of Biomedical Engineering in the Public Healthcare Institutions" in the course of the approval following the suggestion from the MoH.	

3.5 "Annex 1 Logical Framework (Project Design Matrix: PDM)" of the R/D signed on December 19th, 2014

(1) Means of Verification of Output 1

Before	Amended Version
2. The Guideline 3. The Guideline	2. *The guidelines on the establishment criteria, roles and responsibilities of the Departments / Sections of Biomedical Engineering in the Public Healthcare Institutions.*

Reason: The “guidelines for installation criteria of the medical device management centers/units” and “for roles and responsibilities of the medical device centers/units” are merged into “the guidelines on the establishment criteria, roles and responsibilities of the Departments / Sections of Biomedical Engineering in the Public Healthcare Institutions” in the course of the approval following the suggestion from the MoH.

3.6 “Annex 1 Logical Framework (Project Design Matrix: PDM)” of the R/D signed on December 19th, 2014

(1) Objectively Verifiable Indicators of Output 2

Before	Amended Version
The medical device management centers/units with required number of Biomedical engineers/technicians are established in all 5 hospitals in the project site.	The Departments / Sections of Biomedical Engineering *which implement the Standard Operating Forms of the guidelines are established* in all 5 pilot hospitals.
Reason: Modification is made to focus on the actual work of the Departments/Sections of Biomedical Engineering than the number of staff.	

3.7 “Annex 1 Logical Framework (Project Design Matrix: PDM)” of the R/D signed on December 19th, 2014

(1) Activities 2-6

(2) Important Assumption in the line of the Activities

“Annex 2 Tentative Plan of Operation” of the R/D signed on December 19th, 2014

(3) Activities 2-6

(2)	
Before	Amended Version
MoH issues the decree for the installation of the medical device management centers/units	(none)

(1) and (3)	
Before	Amended Version
(none)	*MoH issues a decree for the establishment of the Departments / Sections of Biomedical Engineering for the pilot hospitals*
Reason: The above sentence is shifted from Important Assumption in the line of Activities to Activities since this matter is not an external factor.	

3.8 "Annex 1 Logical Framework (Project Design Matrix: PDM)" of the R/D signed on December 19th, 2014

(1) Activities 2-7

"Annex 2 Tentative Plan of Operation" of the R/D signed on December 19th, 2014

(2) Activities 2-7

Before	Amended Version
(none)	*Review of the Guidelines on the establishment criteria, roles and responsibilities of the Departments / Sections of Biomedical Engineering.*
Reason: The above sentence is added as one of the activities considering that it is an important activity in the later stage of the Project which has been planned before the start of the project. The plan of operation of this activity is written in the Annex 2, Plan of Operation ver.2 (amended version)	

3.9 "Annex 1 Logical Framework (Project Design Matrix: PDM)" of the R/D signed on December 19th, 2014

(1) Inputs of the Moldovan Side

Before	Amended Version
(none)	*6. Functional "Information System of Medical Device Management" (SIMDM)*

Reason: SIMDM is a key and base system for the daily and routine work of the Departments / Sections of Biomedical Engineering.

3.10 "Annex 1 Logical Framework (Project Design Matrix: PDM)" of the R/D signed on December 19th, 2014

(1) Remarks in the line of the Project Purpose

Before	Amended Version
(none)	・*MoH issues the decree for the establishment of the Departments / Sections of Biomedical Engineering throughout the country.*
Reason: A decree from the MoH is an important factor to expand the outputs of the Project to nationwide.	

The Record of Discussions and the amendment to the Record of Discussions is attached in Annex 4.

4. Others

4-1 Results of Environmental and Social Considerations (if applicable)

Not applicable

4-2 Results of Considerations on Gender/Peace Building/Poverty Reduction (if applicable)

Not applicable

III. Results of Joint Review

1. Results of Review based on DAC Evaluation Criteria

(1) Relevance

1) Relevance with policy documents

The relevance of the project in relation to the healthcare policy and development needs of the Republic of Moldova is high as described in continuation.

The National Health Policy 2007-2021

The general and specific objectives of the National Health Policy focus on to strengthening of the population's health, namely by increasing life expectancy at birth and lengthening the healthy life, ensuring life quality and diminishing the difference in terms of health for all social groups, strengthening the inter-sector partnership, promotion of health and disease prevention, etc.

In order to strengthen the health of people, the healthcare system needs to use the appropriate tools for that, one tool being the delivery of quality medical services, which is possible nowadays only by using quality medical devices. The endowment with quality medical devices will prove out to be efficient for the medical act only when these medical devices will be sustainable in time. In order to ensure the durability of medical devices, medical institutions need to implement an efficient medical device management. Thus, the implementation of the Project for Improving Medical Device Management is highly relevant for the healthcare sector of the Republic of Moldova.

The Healthcare System Development Strategy for the period of 2008-2017 and the Plan of actions for the Strategy implementation

The Healthcare System Development Strategy is part of the country's social and economic policy, detailing basic goals and priorities, and is a platform for future actions of strengthening the performances of the healthcare system. The goal of the Strategy is the continuous improvement of the population's health, decreasing the financial risks associated with health services, reducing the inequalities in the use and distribution of the healthcare services and improves user satisfaction.

One focus point of the Healthcare System Development Strategy is the continuous improvement of the efficiency of the hospital infrastructure, endowment with modern and cost-efficient medical equipment, and implementation of new technologies. The maintenance of the hospital infrastructure form the medical devices point of view greatly depends on the capacity of the system to perform necessary tasks in this field. The project is highly relevant for the Healthcare System Development Strategy, as it improved the capacity of the local

healthcare system in the field of infrastructure sustainability.

Policy documents which refer to the field of medical device management include:

The Strategy on Medical Device Management

The Strategy on Medical Devices Management (hereinafter referred to as "the Strategy") is clearly specifying the importance of medical device management in the healthcare sector. The main purpose of the strategy is to create a framework in which the medical devices would be treated according to their importance. The Strategy specifies that the main feature of medical devices is that these needs to be safe and efficient. Since Moldova is a country which is new to the concept of medical device management, the implementation of the Project is highly relevant to this country. The draft version of the Strategy corresponded for the period of 2014 to 2020 but was not approved due to several changes of the government. In the meantime, MoH decided to review the Strategy and drafted up the revised Strategy which corresponds to the period of 2017 – 2022. The revised Strategy is in its approval process which is expected to complete soon.

Law No. 92 as of 26.04.2012 on medical devices

The purpose of this Law is to regulate the activity of the actors involved in the healthcare system as to ensure the quality and safety of the medical devices and thus as a general impact, improve the quality of medical services. Since Moldova has quite recently developed this legal framework, all actors need a continuous improvement of their capacities in order to ensure that medical devices are safe for the population. In this respect, the implementation of the Project is highly relevant to the Law no. 92.

2) Country development needs:

Upgrade of the hospital infrastructure and quality of medical devices.

One of the important areas that required extensive upgrade in Moldova was the medical equipment field, since more than 80% of the existing medical devices were already morally and physically outdated[4], a large part of these devices being a legacy from the Soviet Union era. Moldova started making investment to procure modern medical device, one of these investments being the "Project for Improvement of Medical Care Service" supported by Japan as ODA loan.

The Project purpose is in line with this need, since it supported the establishment of the

[4] Source: Final Report of the Preparatory Survey for the Project for the Improvement of Medical Care Service in the Republic of Moldova, JICA

departments of biomedical engineering and upgrade of the skills of the staff of these departments on how to maintain medical devices as to make them functional and sustainable.

Support in capacity building in the field of medical device management

During the implementation of the Yen Loan Project, the Moldovan side understood that the existing capacities to handle the newly procured medical devices were not sufficient to ensure the sustainability of this equipment. Project pilot hospitals started requesting for support in dealing with the technical aspect of the medical device exploitation. These requests have reached the Ministry of Health, Department of Health of Chisinau Municipality and Medicines and Medical Devices Agency which in their turn supported the perspective of a technical support from the Japanese side in order to enhance the capacities to further adequately support the procured equipment.

The project is in line with this need, since it considered the capacity building of the local staff in the field of medical device management.

Harmonization with the European Legislation

The need of a technical cooperation project in the field of medical devices became more acute once the Association Agreement between Moldova and European Union was signed in 2014. This implied the harmonization of the Moldovan legislation with the European one that target also for the improvement of the health of the population and thus in line with the Project considering that medical device management is important for maintaining the medical devices in appropriate condition which are indispensable for the delivery of healthcare services. The harmonization of the legislation on medical devices meant also amending Law 92 as of 26.04.2012 on medical devices that provides the primary legal framework for the transposition and implementation of three European Directives[5] to the national legal framework, thus enabling the alignment of national standards to the European ones.

3) Appropriateness of the approach:

Selection of the pilot sites

In the timeframe of 2013-2015 the Ministry of Health in collaboration with JICA implemented the "Project for Improvement of Medical Care Service" as ODA loan in 5 pilot hospitals of Moldova through which an important number of advanced medical devices were delivered and installed.

[5] Directive 90/385/EEC regarding active implantable medical devices (AIMD), Directive 93/42/EEC regarding medical devices (MDD), Directive 98/79/EC regarding in vitro diagnostic medical devices (IVDD)

In April 2015 when the Project for Improving Medical Device Management as a technical cooperation project started its activities, in 3 out of the same 5 pilot hospitals the preventive maintenance and user training were not performed and there was and is a need to have staff to take care of medical device management to ensure the function and the sustainability of the medical devices introduced by the "Project for Improvement of Medical Care Service" and all other medical devices within Moldovan medico-sanitary institutions. Thus, the implementation of the technical cooperation project was highly relevant.

Relation between the inputs, activities, outputs, project purpose and overall goal

The approach of the Project in relation with the inputs and the activities planned was appropriate and led to get satisfactory actual results and achievements of the outputs and the project purpose. However, since the timing to set the indicators of the overall goal was before the start of the pilot activities, and the planned period of the pilot activities was only 6 months, consideration and measures against the challenges such as absence of the field level implementation body and the central structure to be in charge towards the achievement of the overall goal of national expansion of the D/SBMEs could not be taken in timely and an adequate manner.

Trend of Aid by other Development Partners

In the medical device management field, Swiss Agency for Development and Cooperation (hereinafter referred to as "SDC") is supporting the development of SIMDM as one of the component of REPEMOL (Regionalization of the Pediatric Emergency and Intensive Care Services in Moldova) though REPEMOL is scheduled to end by October 2017. It is not confirmed any other support in the field of medical device management from other development partner.

The distribution of the foreign support in the healthcare sector was focused on investment, which included reconstruction and refurbishments, procurement of medical technologies and supplies, etc., and on technical assistance, which included mainly capacity building related to medical skill improvement. Besides SDC, none of the foreign partners focused on medical device management as an important component of the healthcare system. In this respect, the implementation of the technical cooperation project with JICA support was highly relevant.

Technical advantage of Japan

Past aid efforts in the healthcare sector of Moldova by Japan are "the Project for Improvement of Medical Equipment for Mother and Child Republican Hospital", "the Project for Improvement of Maternal and Child Health Care System in the Second Level Hospitals"

"the Project for Introduction of Clean Energy by Solar Electricity Generation System", and the Project "Improvement of medical and healthcare service".

Japan focused on the endowment of hospitals with medical devices. At the same time, the decision to implement the technical cooperation Project, namely the project for Improving Medical Device Management, made Japan one of the few development partners which focused the input on the need to support the capacity building at the technical level in the field of medical device management.

As a conclusion to the above presented perspectives, the Project for Improving Medical Device Management was highly relevant for the healthcare sector of the Republic of Moldova.

(2) Effectiveness

The effectiveness of the project is high which is proved by the achievement level of the project purpose, outputs and their indicators.

Although there was a delay in the last stage of the drafting of the Guidelines, all planned outputs were produced, and the product of the outputs, the Guidelines and the establishment of the 5 pilot D/SBMEs, led directly to the achievement of the project purpose by the time of project completion. The issuance of the Ministry Order 262 by MoH on the approval of the Guidelines and the establishment of the pilot D/SBMEs was a milestone of the Project which served to raise up the activities of the Project. On the other hand, SIMDM which was planned as one of the input from the Moldovan side hasn't be available as planned during the project period and the pilot hospitals had to cope with the medical device inventory using spread sheet programs.

With regards to the important assumption "not many technicians who receive the training leave the post", there were a few technicians who left the post during the period of the project and went to the private sector but since this number was not big, so it did not affect the activities of the project. In this context, the preset important assumption was appropriate. Achievement levels of each indicator for the project purpose and the outputs are presented in Table-III.01

Table-III.01. Achievement level of the each of the indicators for project purpose and outputs

Indicators for the project purpose and the outputs	Achievement level
【Project Purpose】 (1) number of attended cases of corrective maintenance against requests, (2) number of implemented procedures of technical planned preventive maintenance against planned	【Indicators】 Average of the indicators of the 5 pilot hospitals are: (1) 1,101 / 1,101 = 100%*[2],

Indicators for the project purpose and the outputs	Achievement level
number*[1], (3) number of implemented training sessions for users against planned one*[1], and (4) number of medical device inventoried in the database of SIMDM against total number of medical devices, are more than 90%", *1: according to the annual and/or monthly plan. Status as of the date of the indicators were set (May 2016) are as follows. (1) Republican Clinical Hospital: no registration. Mother and Child Institute 100%, Emergency Medicine Institute 100%, Oncologic Institute: number of request no registration. Chisinau Municipal Clinical Hospital "Sf. Treime" 0% (not conducted). (2) Republican Clinical Hospital 0%, Mother and Child Institute 100%, Emergency Medicine Institute 100%, Oncologic Institute 0% (no inventory existed), Chisinau Municipal Clinical Hospital "Sf. Treime" 0% . (3) Republican Clinical Hospital: no permanent activities of user training, Mother and Child Institute 100%, Emergency Medicine Institute: no permanent activities of user training, Oncologic Institute 0% (no inventory existed): no permanent activities of user training, Chisinau Municipal Clinical Hospital "Sf. Treime": no	(2) 509 / 560 = 90.89%*[2], (3) 29 / 30 = 96.67%*[2], (4) 6,801 / 6,801 = 100%*[3] All four indicators achieved more than 90%. (1) All requests for corrective maintenance have been attended in the 5 pilot DBMEs. (2) Republican Clinical Hospital 280 / 325 = 86.15%, Mother and Child Institute 18 / 20 = 81.82%, Emergency Medicine Institute 171 / 171 = 100%, Oncologic Institute 13 / 15 = 86.67%, Chisinau Municipal Clinical Hospital "Sf. Treime" 27 / 27 = 100%. (3) Republican Clinical Hospital 4 / 4 = 100%, Mother and Child Institute 7 / 7 = 100%, Emergency Medicine Institute 6 / 6 = 100%, Oncologic Institute 3 / 4 = 75.00%, Chisinau Municipal Clinical Hospital "Sf. Treime" 9 / 9 = 100%. (4) Medical devices in all 5 pilot hospitals have been inventoried. Number of medical devices: Republican Clinical Hospital 1,966, Mother and Child Institute 1,977, Emergency Medicine Institute 1,277, Oncologic Institute 868, Chisinau Municipal Clinical

Indicators for the project purpose and the outputs	Achievement level
permanent activities of user training, (4) Republican Clinical Hospital 0% (no inventory existed), Mother and Child Institute 100%, Emergency Medicine Institute 100%, Oncologic Institute 0% (no inventory existed), Chisinau Municipal Clinical Hospital "Sf. Treime" 0% (no inventory existed).	Hospital "Sf. Treime" 716 *2: For the period of January to February 2017. *3: as of February 28th, 2017. Since SIMDM is not yet available as of March 7th, 2017, this indicator represents the number of medical device inventoried in any form of database against total number of medical devices.
【Output 1】 The guidelines on the establishment criteria, roles and responsibilities of the Departments / Sections of Biomedical Engineering in the Public Healthcare Institutions are developed	100% (The guidelines on the establishment criteria, roles and responsibilities of the Departments / Sections of Biomedical Engineering in the Public Healthcare Institutions are developed and approved by the MoH Order no. 262 dated 12th of April, 2016.
【Output 2】 The Departments / Sections of Biomedical Engineering which implement the Standard Operating Forms of the guidelines are established in all 5 pilot hospitals	Implementation status of the Standard Operating Forms is: Implementation status of the Standard Operating Forms is: 100%[6] DBMEs are established in practice in all 5 pilot hospitals and operating.

Achievement level of each output and project purpose which clearly show the high effectiveness of the project are presented in Table-III.02. The indicators of the project purpose

[6] Calculation method: (Total number of forms in use in the 5 pilot hospitals)*/(12 (total number of Standard Operating Forms) x 5) *in use=1, not in use=0

represent the works of the established DBMEs that are also stipulated in the Guidelines, namely, (1) corrective maintenance (repair), (2) planned preventive maintenance, (3) user training, and (4) inventory of the medical devices. Thus, the achievement of these indicators represents the functionality of the established DBMEs. At the same time, the achievement of the indicators is not due to external factor but a direct result of the Project which established the pilot DBMEs. The Project's contribution for the achievement of each indicators which was made through the Activity 2-4 and 2-5 is, (1) introduction of registering system of the request and the attended cases of corrective maintenance, (2) introduction of PPM activity, (3) introduction of user training activity including training for the Engineers to improve the capacity for the same training, and (4) emphasizing the importance of inventory of medical devices.

Table-III.02. Achievement level of each of the outputs and project purpose

Outputs and project purpose	Result by evaluation criteria for Effectiveness
【Project Purpose】	High: (1) 1,101 / 1,101 = 100% , (2) 509 / 560 = 90.89% , (3) 29 / 30 = 96.67%, (4)* 6,801 / 6,801 = 100 % All four indicators achieved more than 90%.
【Output 1】	High: actual figure is 100%.
【Output 2】	High: actual figure is 100%.

(3) Efficiency

All planned activities have been implemented within the planned project cost and the planned project period, at the same time, the outputs and the project purpose have been achieved by the completion of the project, hence proving the high efficiency of the project. As presented in Table-III.03, the actual project cost spent is 172 million Japanese Yens, less than planned cost which is 185 million Japanese Yens, and the actual project period is from April 2015 to April 2017, the same as planned.

As for the input by the Japanese side, the provision of equipment (testing device of medical devices) assisted the achievement of the output of establishment of pilot DBMEs in the equipping aspect and helped to implement the preventive and corrective maintenance activities of the pilot D/SBMEs, the implementation of the trainings, workshops and seminars contributed

to the capacity building of the staff of the pilot hospitals and to get understanding and cooperation from the management and medical staff of the pilot hospitals to the project activities and the necessity of medical device management and D/SBME. Expert dispatch contributed to the output of the development and revision of the Guidelines, and was also necessary and sufficient to cover the project activities and to achieve the project targets. The study tours to Japan which were implemented twice during the Project period with the purpose to study the latest situation for medical device management in Japan through visiting medical devices manufacturer, hospitals, etc., successfully achieved the objective, contributed to gain understanding of the participants on medical device management and thus assisted to achieve the outputs and purpose of the Project. The team of the 1st study tour to Japan consisted of managerial personnel and engineers, namely, the deputy minister of MoH, the deputy director of the Department of Health of Chisinau Municipality, the representative of MMDA and 5 engineers from the pilot hospitals. This visit and the encounter of precisely these representatives gave the opportunity to the managerial personnel to notice the importance of the medical device management and biomedical engineering. At the same time they noticed that Moldova has qualified biomedical engineering human resources. For the engineers that participated in the study visit this was an opportunity to explain to the managerial personnel what are their activities and the importance of their assistance for the quality of the medical act and also to express the challenges they are facing in their work. The team of the 2nd study tour consisted of technical managerial personnel and medical device users, namely, the representative of Medicine and Medical Device Department of MoH who has biomedical engineering background, the representative of the Technical University of Moldova, the representative of MMDA and 5 doctors from the pilot hospitals. This combination and interaction between them enabled the technical managerial personnel to see the field from the perspective of medical device users, and allowed the doctors to acquire understanding and cooperative attitude towards medical device management.

Table-III.03. Planned and actual project cost and period

Item	Planned	Actual
Project cost	185 million Japanese Yens	172 million Japanese Yens
Project period	April 2015 – April 2017	Same as planned (April 2015 – April 2017)

(4) Impact

The impact at the time of the completion of the project is expected to be fair or relatively low considering unless the challenges described in continuation will be timely coped with in an

adequate manner.

The target set for the overall goal can be expected to be achieved as the project effect by the Moldovan side in a long term, not in a short term such as 3 years, since necessary information to establish further D/SBME are defined and included in the Guidelines developed through the project. The Guidelines contain the establishment criteria, the roles and responsibilities of the D/SBME, the standard operation procedures and the standard operating forms of D/SBME. The experiences MoH and the pilot hospitals gained through the project will be useful for the further establishment of D/SBMEs.

The achievement of the overall goal, the expansion of D/SBMEs will contribute to maintain the medical devices in adequate and functional status. Medical devices in adequate and functional status then will contribute to the delivery of quality healthcare service, thus Impact to the Republic of Moldova's development plan can be expected.

The project focused on the development of the Guidelines, the establishment of D/SBMEs at the pilot hospitals, and to introduce medical device management to the pilot D/SBMEs to make them functional. However, for the nationwide expansion of the D/SBMEs it is required to consider having a body, which can support the establishment of further new D/SBMEs and train the new staff on the implementation of medical device management, which at the present time is lacking in Moldova.

On the other hand, as it was pointed out in the time of the Detailed Planning Survey, the small number of human resources in the field of biomedical engineering will be a challenge for further establishment of D/SBMEs.

The overall goal does not deviate from the purpose of the Project although during the implementation of the project several challenges have been observed. (1) The timely establishment of a system to train and support the establishment of new D/SBMEs, and (2) the timely establishment of a system to secure enough absolute number of technical engineering human resources such as Biomedical Engineers are challenges that may become factors which may impede the achievement of the overall goal if not dealt properly.

The important assumption of "the budget to establish the D/SBMEs in the country is secured" from the project purpose to the overall goal is appropriate even at the stage of completion of the project. However, it is preferable to consider the challenges mentioned above as the important assumptions.

As for the effects and influence other than overall goal envisaged, from the challenge on the absolute number of the biomedical engineers described above, MoH requested to the Technical University of Moldova and the Ministry of Education the increase in number of admission of students with scholarship, with the condition to work in the public sector at least 3 years after graduation, for the biomedical engineering specialty course in the Technical

University of Moldova thus contribute to the acknowledgement of the career of biomedical engineering in the society of Moldova. Furthermore, the implementation and existence of the Project has positively influenced the modification of the Law 92, the revision of the Strategy on Medical Device Management, regulating the vigilance of medical devices, the development of additional regulation on the periodical verification, and the revision of the MoH Order No. 100. As for the pilot hospitals, the Project helped to enhance the understanding on the medical device management and biomedical engineering in the user side, and the works of the established DBMEs are contributing to reduce the cost to maintain the medical devices.

(5) Sustainability

The sustainability at the time of the completion of the project is estimated to be fair since there are several factors that may affect the continuity of the results as described below.

Although the project purpose and all outputs have been achieved by the time of the completion of the Project, risk factors that may affect the sustainability of the Project exist in all levels. Medicine and Medical Device Department of MoH has been the key player from the Moldovan side and at present counts with personnel with knowledge and understanding on medical device management but this situation may change considering that the shortage of human resources is a common challenge in the public sector of Moldova. As for the management personnel of the pilot hospitals, the current directors and management personnel have or gained understanding and are supporting the pilot DBMEs, the effect and force of MoH order No.262 and the understanding of the other personnel of the pilot hospitals towards medical device management gained through the Project activities may function and work in positive direction, however, if to consider the experience of Mother and Child Institute who had their department downgraded to a section even during the support of REPEMOL and recovered the status of department by the efforts of the execution team of the Project, future change of management personnel may have serious influence to the sustainability of the Project. With regards to the staff of the pilot DBMEs, the chief of the Emergency Medicine Institute and the Oncologic Institute are yet new in their position and unfortunately don't have enough experience which can also be a weak point for the sustainability.

The Back-up from the policy and institutional aspects required for continuation of the project effect is established, and the initiative to support future expansion is also secured by "the Strategy on medical device management (2017 – 2022)" which describes the national strategy on medical device management and is about to be approved, the Ministry Order 100 which defines the number of staff including the ones for the D/SBME, and "the Guidelines on the establishment criteria, roles and responsibilities of D/SBME" which has been approved by the Ministry Order No. 262 and which describes the establishment criteria and standard operating

procedures of the D/SBME together with the standard operating forms.

The project contents do meet the development needs of the society which is aiming for the improvement of the quality of the delivery of the healthcare service, and thus the project have prospects to be continued and developed on a continuous basis.

From the Structure of the implementing agency perspective, the Medicine and Medical Device Department of MoH has been taking lead of the activities of the project, thus, the project ownership is secured sufficiently. However, considering that MoH which is a policy making body had to combine the function of the implementing body, the experience gained by the project may not serve effectively once MoH returns in its original function as the policy making body. MMDA which is the implementing body of the policies originally was the Medicine Agency and the function related to medical device has been added recently, 2013. In this context、 the capacity of MMDA is yet under building stage and cannot be said that has enough capacity to be in charge of implementing all medical device management related necessities. The possibility of MoH to return to its original function is high, thus, it is important to ensure to make function the implementation body.

As for the skills of the implementing agency, the Medicine and Medical Device Department of MoH has been involved and been working during the project implementation period and gained the knowledge and skill for the continuation of the project and can extend and disseminate the skill.

With regards to the finance of the implementing agency which is the MoH, the future new D/SBMEs, as continuation of the project, will be created within the public healthcare institutions which don't have direct budgetary relation with the implementing agency, meaning, each medical institution which intend to create a D/SBME and its founder is in charge of secure the necessary cost for the D/SBMEs. However, MoH is the policy making body of the public health sector thus can secure the necessary financial resources required for the continuation of the project effect in the future by setting appropriate and necessary regulations. In this context, there is a good possibility to secure necessary financial resources.

2. Key Factors Affecting Implementation and Outcomes

The implementation of the project activities encountered several factors that acted like challenges, namely:

(1) Lack of the approved Strategy on Medical Device Management
(2) Lack of Informational System on Medical Device Management (SIMDM)
(3) Insufficient number of biomedical engineering human resources available on the Moldovan Market

(4) The biomedical engineering occupation was not registered in the list of positions that can be employed in the medical system (MoH Order No. 100 on the establishment of medical personnel number which is to work in the budgetary sector)
(5) Low salaries of the specialists in charge of medical devices from the public sector
(6) Available budget for the establishment of the pilot D/SBME
(7) Decreased implementation power/capacity of the Medicines and Medical Devices Agency (MMDA) of the Republic of Moldova
(8) Lack of training courses that would "recondition" existing technical engineering human resources into biomedical human resources

Details of (1) to (7) above are written in 3. Evaluation on the results of the Project Risk Management.

As for **(8) Lack of training courses that would "recondition" existing technical engineering human resources into biomedical human resources**, the Republic of Moldova is a post-communist country which has many technical engineering human resources available, especially from older generations of people. In the conditions in which there are few biomedical engineers on the market, but at the same time there are more general technical resources available, there was no training system that would enable the existing technical resources to learn a new aspect of engineering and retrain them into biomedical engineers. This situation had a negative impact on the availability of skilled and competent technical resources to be employed in the pilot hospitals.

During the advancement of the project activities, the project team together with the Technical University of Moldova assessed the need of such training courses. Currently, the Technical University is developing a program that would allow the human resources with other technical background to get retrained in the biomedical engineering field and to be able to handle medical devices within the medical institutions.

3. Evaluation on the results of the Project Risk Management

(1) Lack of the approved Strategy on Medical Device Management

The lack of the approved Strategy was one of the challenges in establishing the set of activities in line with the country's direction of development in the field of medical devices. Although the Project tried and implemented its activities through close coordination and collaboration among the project execution team, while the country has no established direction in this field, it is quite difficult to presume what are the expectations of the country in relation to the results that had to be achieved by the project. This challenge has been pointed out from the very beginning of the Project, the Moldovan side intended to brush up and approve the 1st

version of the Strategy during the period of the project but finally decided to update the Strategy which is now in its final stage of the approval of the Government.

Although there was no approved Strategy during the project period, as for the proper project activities, MoH offered sufficient support and guidance in this field, so that the implementation of activities would go smoothly and undisturbed according to the Project Work Plan.

(2) Lack of Informational System on Medical Device Management (SIMDM)

SIMDM is a component which was developed by the support of SDC within REPEMOL Project and had to be implemented during the technical cooperation project period. This system was planned and included as an input from the Moldovan side, and was meant to create the basis of information related to the inventory of medical devices. This would have been a major support for our project in the process to calculate the necessary staff needed to manage medical devices and to grab comprehensively the status of medical devices in our pilot project institutions, but also around the country. Unfortunately, SIMDM was not yet implemented.

Since the implementation of SIMDM was and still is in continuous delay, the project team had to reorient the D/SBME activities in such a way so that these activities wouldn't depend on the availability of SIMDM. As a result the pilot hospitals started using other spreadsheet programs to hold the record of the medical device inventory and works implemented by the departments. Additionally, a set of Standard Operating Forms have been developed in order to be used (paper-based or electronically) in order to keep track of the activities implemented within D/SBME. This approach allowed the D/SBME to manage their activities more efficiently than before and also avoid the dependence on SIMDM for a smooth implementation of the biomedical engineering works.

(3) Insufficient number of biomedical engineering human resources available on the Moldovan Market

The establishment of the Departments of Biomedical Engineering involved the selection and employment of the appropriate biomedical engineers to work in the pilot hospitals. As a matter of fact, the specialty of "biomedical engineer" is quite new for Moldova, as it was established in 2006, and the first promotion of biomedical engineers was in 2010. Another important factor to consider is that the admission number for this specialty is quite low, about 40 students per year, out of which only 50% graduate. Considering that the establishment of the pilot D/SBME started in 2016, it meant that the absolute number that the Technical University of Moldova could have trained and graduated as biomedical engineers would be around 120 specialists. After making a market analysis, it was found that more than 50% of these people

were working abroad, and the ones who remained in Moldova, were mostly employed in the private sector which could provide better salaries for these specialists. This situation was an important challenge on the way to create strong, sustainable and competent teams for the pilot D/SBME in our project.

The situation concerning the shortage of biomedical engineering resources has been approached from more aspects. First of all, the Japanese expert team determined that there are technical resources available in the hospitals and which take care of medical devices, but which are not with biomedical engineering background. These are good professionals who need to be kept in the medical device management since their knowledge, skills and capacities are of big help to the D/SBME. The Annex on the calculation of the D/SBME staff was developed in the way to also consider these resources and thus increase the capacity of the D/SBME to handle the big variety of technical works they are in charge of. In addition, by the coordination among the Project team, the Technical University of Moldova and the pilot hospitals, some available biomedical engineering human resources including 4th grade students of the biomedical engineering course of the Technical University of Moldova have been involved and allocated to the pilot DBMEs.

In relation to the needs of biomedical engineering resources on the country level, the MoH has issued a request to the Ministry of Education, which specified the increase of the number of admission places for the Faculty of Biomedical Engineering. This increase would provide more human resources in this field in the next years, thus giving the possibility for the public sector healthcare facilities to employ the necessary number of people.

(4) The biomedical engineering occupation was not registered in the list of positions that can be employed in the medical system (MoH Order No. 100 on the establishment of medical personnel number which is to work in the budgetary sector)

Since one of the project activities was the creation of the Departments of Biomedical Engineering in the 5 core medical institutions of the country, this activity involved the employment of biomedical engineers in these hospitals. Since the employment of staff and the categories of occupations that can be employed in the public healthcare sector institutions is regulated by law, it was a challenge for medical institutions to employ specialists in the position of biomedical engineer, because this position was not mentioned in MoH Order no.100. This situation became a problem for the 5 pilot institutions of the project, but also for any medical institution in the country which wanted to employ one or more biomedical engineers.

In order to facilitate the employment of biomedical engineers in the pilot hospitals, MoH has issued the Order no.262 as of 12.04.2016 on the establishment of the Departments/Sections of Biomedical Engineering which approved the Guidelines on the establishment criteria, roles

and responsibilities of the D/SBME within the public healthcare institutions together with the Annex which specified the calculation of the number of biomedical and technical engineers to be employed in the medical institutions in the Republic of Moldova. MoH specified that through Order no.262, the pilot hospitals can employ biomedical engineers. At the same time, MoH started the revision process of the Order no.100, in order to include the profession of biomedical engineer in the official staffing list of the healthcare institutions. The Japanese expert team worked on the revision of the Annex for the calculation of no. biomedical engineering staff, which will be the basis of the modifications operated in Order no.100. The modification of Order 100 will be soon finalized, in order to allow any medical institution in the country to employ biomedical engineers officially.

(5) Low salaries of the specialists in charge of medical devices from the public sector

Public healthcare sector in the Republic of Moldova is lacking financing. This is the major cause of having low salaries for the professionals employed in the public healthcare sector, regardless of the medical or non-medical profile of the employees. The existent engineers working in the field of medical device management in the public hospitals were very few. The low salary was the very first obstacle in the willingness of other engineers to join the public healthcare institutions, thus leaving hospitals with little support in managing medical devices in an efficient way. This aspect remains as future continuous challenge for the Moldovan side.

To deal with this problem and other similar situations related to salary issues in the healthcare field, MoH has modified the Regulation on the calculation of salaries for the staff employed in the healthcare system. As a result, the salaries of the biomedical engineers increased with approximately 1000 MDL per month, which is about 30 % from their old salary. Additionally, the chiefs of the D/SBME have had an important and motivating increase of salary. These operated changes made the specialty of biomedical engineering bit more attractive for the potential employees of the public healthcare sector.

(6) Available budget for the establishment of the pilot D/SBME

Since the establishment of the pilot D/SBME started in the middle of the fiscal year of 2016, according to local regulation, the medical institutions were not prepared to allocate the necessary resources to support and facilitate the creation of the departments. This resulted in delays in allocation of necessary resources to procure necessary furniture, OA and tools and also allocation of necessary financially covered staffing units for the departments.

The pilot hospitals have made an important effort to allocate necessary resources in order to establish the D/SBME. The adjustment of the hospitals was quite quick with the result of

successful allocation of space, furniture, and some of the most necessary tools. OA and some particular tools were a challenge for the hospital budgets because of the high prices of these items. Nevertheless, the hospitals managed quite well to allocate the minimum necessary resources to ensure the activity of the D/SBME until the next planning of budget for 2017. The planned budget for 2017 included the procurement of necessary items that couldn't be acquired in the middle of 2016, when the establishment of the D/SBME took place.

(7) Decreased implementation power/capacity of the Medicines and Medical Devices Agency (MMDA) of the Republic of Moldova

MMDA, the implementing body in the field of medical devices, could be presumed as the partner of the project. However, because of the fact the medical device component has been included to MMDA in 2012 and the actual staff allocation started gradually from 2013, there were various issues in the capacity of implementation of activities in MMDA. Thus, the Moldovan side decided to have MoH as a counterpart which actually is a policy making body.

Because MMDA was considered to have insufficient capacity to implement this project, MoH took over the role of the implementing agency, and thus the necessary support for the project expert team was provided from MoH side.

4. Lessons Learnt

During the implementation of the project activities the following ideas have been concluded:

(1) Necessity of the presence of a perseverant and persuasive execution team as driving force

The presence of a perseverant and persuasive execution team has been one of the main factors to ensure that the project activities were implemented appropriately and at a high level. e.g. The medical device engineers that existed in the pilot hospitals before the actual start of the project activities were at the beginning very reluctant to the implementation of the project activities, since they have struggled much with their management of the hospital in order to demonstrate that medical device management is needed for the hospital and they didn't succeed much. Since their effort didn't meet any success, they thought that the project methods would also fail. Nevertheless, the project team insisted on the implementation of various activities to all the involved parties at all levels. While at the beginning the intentions of the execution team were disregarded as having low priority in comparison with other serious struggles of the medical institution, due to the perseverance and persuasiveness of the project team, the efforts turned out to get efficient results and good outcomes. The Moldovan side acknowledged this approach as being one of the core aspects that supported the achievement of good project

results.

(2) Impact of the Japanese expert team's work style and approach to the Moldovan side

The work approach of the Japanese expert team has set a model for the other team members in reference to work approach.

e.g. The project team had a very persuasive approach towards the beneficiary representatives at all levels. This gave out good results. This approach was implemented by the engineers in their struggle to equip the newly created workshops with the necessary tools. Since hospitals are facing financial difficulties, the procurement of engineering tools is neither the top, nor the second priority for the hospital management. Nevertheless, engineers insisted on their need providing sufficient reasons that the tools are needed in order for them to be able to do their job more efficiently. This approach turned out to be appropriate, and gradually the stocks of tools improved.

(3) The subordination to authority

The subordination to authority in the post-communist countries is quite high. This circumstance can be used to more easily implement activities, raising the level of the efficiency of input. In practical aspects related to Moldova, it was determined that a certain idea has a higher rate of success and implementation if it comes from high authority figures such as Ministry of Health or foreign donor representatives.

e.g. The proper idea of the establishment of the Departments/Sections of Biomedical Engineering was supported by the Moldovan side, but concrete measures were delayed to implement this in practice by the management of the pilot hospitals due to various quite practical reasons. Thus, the project team appealed to the Ministry of Health for support. MoH issued an order by which the pilot institutions are obliged to establish the Departments according to the Guidelines developed in this respect. The pilot hospitals have shortly complied with the Order. This example practice was implemented by the project team anytime the team faced some unwillingness or difficulties from the beneficiaries of the project activities

(4) Close interaction with the beneficiary side

Close interaction with the beneficiary side improves the quality of work. From the psychological perspective, closer interaction with the beneficiary hospitals in terms of monitoring the activities and problem solving in a supportive manner as to show that people are not alone in their struggle showed great results in respect to task fulfillment.

e.g. The implementation of various project activities at the beginning of the project gave medium results. Pilot sites' representatives were involving in the activities, but not enough so

that the outcomes could reach the expected level. Once the team started involving more in the actual situation of the pilot sites, namely finding out what other struggles the project pilot hospitals faced, it helped the project team adjust the activities in such way as to meet the actual needs of the beneficiaries from the project purpose perspective. Once the pilot sites representatives acknowledged the project effort to really understand and cope with their needs, they started to involve more actively and commit more efficiently, so that soon project activity results reached expected level.

(5) Collaboration among the team and teambuilding activities

Collaboration among the team and teambuilding activities are major factors in the improvement of the quality in the implementation of activities. The effort of the Japanese side to create more cohesion among the team members of the Moldovan side was a successful idea that created a synergy effect in relation to the outcomes of the implemented activities. The establishment of a local team in terms of good and smooth interaction among the local team members is a prerequisite for quality implementation and sustainability of project activities. Capacity building in the field of team approach to solving encountered problems had turned out to be one of the key activities that ensured the quality of the works within the project.

e.g. Once the project team started their activities with the medical device engineers from the 5 pilot sites, the project team noticed that the engineers mostly didn't know each other. Their interaction, if any, was very seldom. When the project activities started, the project team saw that the engineer team was very diffuse and there was a great lack of cohesion among the engineer team. The project team came up with the incentive to organize more meeting that would involve all engineers from the project sides, where the engineers would interact more closely and create connections among themselves. This idea gave good results and soon the level of communication among the engineer team improved, they started to act as an engineering team, no matter which hospital they belonged to. Solving different engineering problems was also one issue that engineers tackled as a team already. This coherent team of engineers started to perform better in the project activities, with a strong sense that they are not alone in this field and they have also other people in the field that they can rely on.

(6) Commitment and involvement from the Japanese expert team

Commitment and involvement from the Japanese expert team has set a model for the other team members in reference to work approach. The fact that Japanese team involved and committed itself to the activities and to the solving of the difficult situations the beneficiary side was encountering gave a good example to the Moldovan side. In some timing the Moldovan side started to also involve more deeply in the activities and adopted a good portion of the

commitment of the Japanese side. Thus, better results were reached in respect to the project activities and outcomes.

(7) Taking Advantage of the study tours to Japan

One of the lessons learnt is that the study tours to Japan are important opportunities to have intensive and close communication among the participants that may lead to have more effects in addition to the set purpose. It is worth taking advantage of this lesson, try to get additional results by mixing participants from different levels, backgrounds and positions such as the Project Director/Manager, other high-level government officials, and the people working in the field level.

e.g. The participation of the deputy Minister to the 1st tour which came as an initiative from the Moldovan side, and the spontaneous intensive communication among the participants for being out of Moldova for about 10 days in a country with language barrier and passing most of the time together as a group, led the study tours gain additional positive effects such as 1) employment of a biomedical engineer in MoH's project manager position, 2) set up of the room for biomedical engineers inside the Intensive Care Unit at Chisinau Municipal Clinical Hospital "Sf. Treime", and 3) further understanding and closer interaction among the participants (the policy making personnel, the medical device users and the engineers), which helped the implementation of the Project.

IV. For the Achievement of Overall Goals after the Project Completion

1. Prospects to achieve Overall Goal

The necessary set up and information to achieve the overall goal are available by (1) "the Strategy on medical device management (2017 – 2022)" which supports the national strategy on medical device management and is expected to be approved soon, by (2) the Ministry Order 100 which defines the standard of the number of staff in the healthcare institutions including the staff of D/SBME, and by "the Guidelines on the establishment criteria, roles and responsibilities of D/SBME". Furthermore, as stated in the "Remarks" of the Revision of the Project Design Matrix, MoH, is in plan to issue the order for the establishment of the D/SBMEs throughout the country. Issuance of the order is possible, however this has to be considered from the perspective of the possibility of implementation. This Ministry Order is expected to have a direct and strong impact. Hence, in a long term, not in 3 years, there is a good possibility to achieve the overall goal of "the Departments/Sections of Biomedical Engineering are established throughout the country based on the developed guidelines" with its indicator "Number of the Departments / Sections of Biomedical Engineering which implement the Standard Operating Forms of the guidelines is more than 20 throughout the country". However, to ensure the achievement of the overall goal it will be necessary to pay attention and cope timely with the challenges mentioned in (4) Impact and (5) Sustainability, 1. Results of Review based on DAC Evaluation Criteria, III. Results of Joint Review, namely, (1) the absence of a field level body, system and structure to implement, train and support the creation of new D/SBMEs and, (2) the small absolute number of the biomedical engineers in the Moldovan market.

2. Plan of Operation and Implementation Structure of the Moldovan side to achieve Overall Goal

The plan of operation of the Moldovan side to achieve the overall goal is presented in table-IV.1. The implementation structure of the Moldovan side for the achievement of the overall goal is shown below.

(1) Monitoring and supervising body: Medicine and Medical Device Department, MoH
(2) Field level activity implementation body: "Core BME center"
(3) Supportive organizations: Technical University of Moldova, the Ministry of Education

Table-IV.1 Plan of operation

No.	Activity	Target period	Responsible
1. Expansion of D/SBME network			

No.	Activity	Target period	Responsible
1-1.	Strengthening the medical device management capability of the 5 pilot hospitals of the project to concretely establish the D/SBME activities such as technical Planned Preventive Maintenance (PPM), user trainings, and annual planning as stable and sustainable activities, and be able to cover the needs and demands of the hospital attached to in full scale.	May 2017 – April 2019	MoH as supervising body and the 5 pilot hospitals as the implementing body
1-2.	Monitor, evaluate and if necessary select from the 5 pilot DBMEs of the project the DBME to be the "Core BME center" that will provide support for the establishment of new D/SBME for nationwide expansion of D/SBME.	May 2017 – August 2018	MoH
1-3.	Reinforce and strengthening the "Core BME center" selected in 2 above to be able to function to provide support for the establishment of new D/SBMEs.	September 2018 – June 2019	MoH
1-4.	Training for the staff of new D/SBME at the "Core BME center".	February 2019 -	MoH as supervising body and the "Core BME center" as the field level implementing body
1-5.	Establishment of the first 5 new D/SBMEs as 1st group for nationwide expansion.	June – July 2019	Ditto
1-6.	Operation and monitoring (Plan, Do, Check, Adjust) of the D/SBMEs established in 1-5.	June 2019 – December 2020	Ditto

No.	Activity	Target period	Responsible
1-7	Establishment of 2nd group of D/SBME for nationwide expansion.	January – February 2020	Ditto
1-8	Operation and monitoring (Plan, Do, Check, Adjust) of the D/SBMEs established in 1-7.	January 2020 – April 2021	Ditto
2. Increase of technical engineering human resources including biomedical engineers			
2-1	Increase of technical engineering human resources at the Technical University of Moldova	From September 2018 -	MoH, MoE, the Technical University of Moldova
2-1-1	Increase of number of admission at the Technical University of Moldova	By June 2017	Ditto
2-1-2	Allocation of 2nd grade students to D/SBME	From September 2018 -	Ditto
2-1-3	Allocation of 3rd grade students to D/SBME	From September 2019 -	Ditto
2-1-4	Allocation of 4th grade students to D/SBME	From September 2020 -	Ditto
2-1-5	Allocation of graduates to D/SBME	From September 2021 -	Ditto
2-2	Trainings for existing engineering human resource from different specialty background. (if necessary to secure human resource)	From September 2019 -	Ditto

3. Recommendations for the Moldovan side

One of the lessons learnt from the project implementation is the importance and effectiveness of the presence of a persistent and insistent execution team which made able to convince the necessity and advantage of having in-house medical device engineering division to other stuff of the medical institution such as management and medical users that are indispensable actors to achieve and establish the D/SBMEs in each healthcare institution maintain and sustain the medical device management activities. The recommendation for the Moldovan side is to take into consideration this point while planning and implementing of each

every stage of the expansion of the D/SBME network towards the achievement of the overall goal, try and establish a persistent and insistent execution team whether internally and/or with foreign support.

4. Monitoring Plan from the end of the Project to Ex-post Evaluation

MoH will report to JICA the status and the progress, every 6 months after the completion of the Project.

ANNEX 1: Results of the Project
(List of Dispatched Experts, List of Counterparts, List of Trainings, etc.)
ANNEX 2: List of Products (Report, Manuals, Handbooks, etc.) Produced by the Project
ANNEX 3: PDM (All versions of PDM)
ANNEX 4: R/D, M/M, Minutes of JCC (copy) (*)
ANNEX 5: Monitoring Sheet (copy) (*)
(Remarks: ANNEX 4 and 5 are internal reference only.)

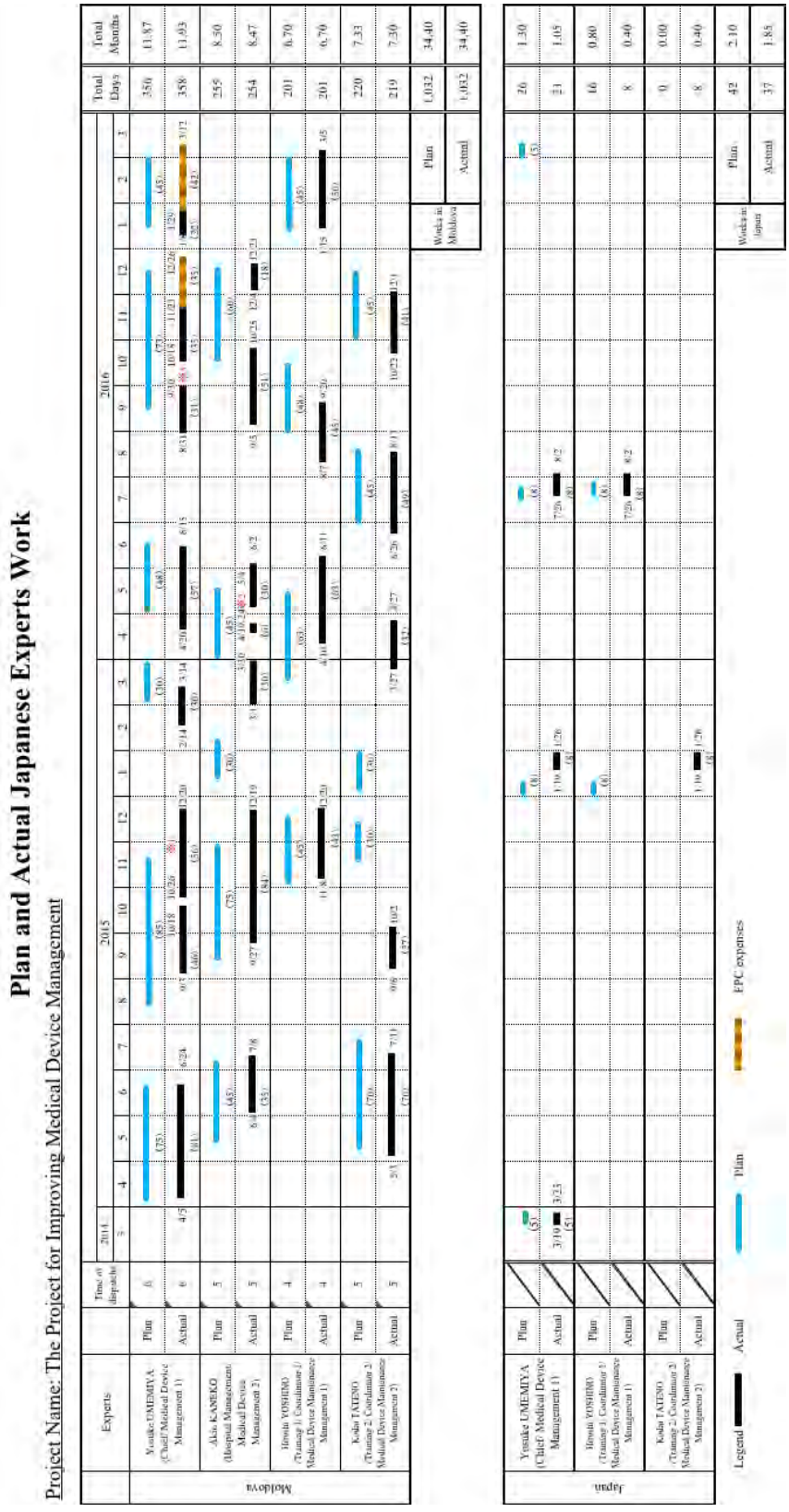
Separate Volume: Copy of Products Produced by the Project

ANNEXES

ANNEX 1. Results of the Project

Annex. 1 Results of the Project
（List of Dispatched Experts, List of Counterparts, List of Trainings, etc.）

1. Dispatched Experts



2. List of counterparts: 4

No	Name	Position	Organization
1	Ms. Ruxanda GLAVAN	Minister	Ministry of Health
2	Mr. Gheorghe GORCEAG	Deputy Director of Medicine and Medical Device Department Project Manager	Ministry of Health
3	Mr. Dorian VISTERNICEANU	Head of Standard Section, Medicine and Medical Device Agency	Medicine and Medical Device Agency
4	Prof. Victor ŞONTEA	Chief of Department for Microelectronics and Biomedical Engineering, Technical University of Moldova	Technical University of Moldova

3. List of Workshops and Trainings

Total expenditure：JPY 3,920,937 (JICA)

No.	Workshop /Training	Date	Duration	No. of participants	Expenditure (JICA)
1	V4 + Japan Cooperation Workshop on management of the medical devices	8th and 9th December, 2015	2 days	127	8,158.25€[1] (¥980,621)
2	Workshop for managerial personnel	14th, 18th, 19th, 22nd and 25th April, 2016	5 days	239	0 円
3	Training for the staff of D/SBME	23rd to 25th March, 2016 11th, 18th and 19th October, 2016	6 days (3 days x 2 times)	26	6,031.32MDL (¥33,654)
4	Training for the other medical staff	11th, 15th, 24th to 27th December, 2015	6 days 1 day x 6 times	164	0 円
5	Training for Developing Quick Guide	18th and 19th October, 2015	2 days	7	12,193.70MDL (¥68,039)
6	Workshop for the Medical Device Management within the Pilot Hospitals	12th and 13th December, 2016	2 days	114	8,413.33€[2] (¥1,014,888)
7	Dissemination Seminar	28th February and 1st March 2017	2 days	211	15,172.50€[3] (¥1,823,735)

*Calculated as 1 EUR = 120.20 JPY

[1] 8,158.25 = 7468.25 (Rent) + 390 + 300 (Interpreter 1/2)
[2] 8413.33 = 7,723.33 (Rent) + 360 + 360 (Interpreter 1/2)
[3] 15,172.50 = 14,452.50 (Rent) + 360 + 360 (Interpreter 1/2)

3.1 Japan Study Tour: 16 people

1st Japan Study Tour

No.	Name	Institution	Position	Name of Course	Duration
1	ROTARU Valentina	MoH	Deputy Minister	Japan Study Tour	19th to 26th January, 2016
2	SCRIPCARI Adrian	Medicine and Medical Devices Agency	Head of section certification,		
3	RÎMIȘ Constantin	DoH, Chisinau Municipal Council	Head of Health Department		
4	RUSU Gheorghe	Republican Clinical Hospital	Bio-engineer		
5	PÎSLARU Corneliu	Mother and Child Institute	Head of Department,		
6	SIDELNICOV Iulii	Oncologic Institute	Engineer Physicist		
7	GORCEAG Gheorghe	Emergency Medical Institute	Chief of Medical Technologies		
8	COȚAGA Anatol	Municipal Clinical Hospital Sfanta Treime	Medical Equipment and		

2nd Japan Study Tour

No.	Name	Institution	Position	Name of Course	Duration
1	GORCEAG Gheorghe	MoH	Deputy Chief of the Medicine and	Japan Study Tour	26th July to 2nd August, 2016
2	ȘONTEA Victor	Technical University of Moldova	Head of the Microelectronics		
3	ȚERNA Eduard	Medicine and Medical Devices Agency	Acting chief of the Medical Device		
4	BOTIZATU Alexandru	Republican Clinical Hospital	Head of the Reanimation and		
5	COȘPORMAC Viorica	Mother and Child Institute	Chief of the Department of		
6	MURA Sergiu	Oncologic Institute	Head of the Operation Bloc		
7	BELÎI Adrian	Emergency Medicine Institute	Head of the Reanimation and		
8	GUȚU-BAHOV Cornelia	Municipal Clinical Hospital Sfanta Treime	Head of the Reanimation and		

ANNEX 2. List of Products

Annex 2. List of Products (Reports and Deliverables)

List of Project Reports

	Deliverables	Language/ Q'ty*
1	Monitoring Sheet Ver. 1 （Including Work Plan）	EN: 2 pcs., RO: 1 pc.
2	Monitoring Sheet Ver.2	EN: 2 pcs., RO: 1 pc
3	Monitoring Sheet Ver.3	EN: 2 pcs., RO: 1 pc.
4	Monitoring Sheet Ver.4	EN: 2 pcs., RO: 1 pc.
5	Monitoring Sheet Ver.5	EN: 2 pcs., RO: 1 pc.
6	Project Completion Report	JP: 5 pcs., EN: 5 pcs., CD-ROM: 2 pcs.

List of Technical Assistance Deliverables

	Deliverables	Language/ Q'ty*
1	the Guideline for Roles and Responsibilities and Installation Criteria of Medical Device Management Centers/Units	EN: 10 pcs. RO: 10 pcs.
2	Training Materials for staffs of the Medical Device Management Centers/Units	EN: 10 pcs. RO: 10 pcs.
3	Training Materials for other Medical Staffs	EN: 10 pcs. RO: 10 pcs.

List of Reports for Workshop and Trainings

	Deliverables	Language
1	Report on the Assessment Study of current situation of Medical Device Management	EN
2	V4 + Japan Cooperation Workshop Report	EN
3	Report on the Workshop for the managerial personnel	EN
4	Report on the training for the staff of the D/SBME	EN
5	Report on the training for the other medical staff	EN
6	Report on the Japan Study tour	EN
7	Report on the Training Development of Quick Guide	EN
8	Report on the Medical Device Management within the Pilot Hospitals	EN
9	Report on the Dissemination Seminar	EN

ANNEX 3. PDM (All versions of PDM)

Project Monitoring Sheet I （Revision of Project Design Matrix）

Project Title: Project for Improving Medical Device Management Version 1

Implementing Agency: Ministry of Health Dated 22 May, 2015

Target Group: Medicine and Medical Device Department of MoH, Medicine and Medical Device Agency, All Medical Institutions and their Biomedical Engineers/Technicians

Period of Project: April 2015 ～April 2017 （2 years）

Project Site: Throughout the country Pilot Site: Chisinau (5 hospitals; The Republican Clinical Hospital, The Mother and Child Institute, The Emergency Medicine Institute, The Oncologic Institute, Chisinau Municipal Clinical Hospital "Sfanta Treime")

Narrative Summary	Objectively Verifiable Indicators	Means of Verification	Important Assumption	Achievement	Remarks
Overall Goal The medical device management centers/units are installed throughout the country in accordance with the developed guidelines.	1. Number of the centers/units who meets the requirements in accordance with the guidelines (The concrete indicators are to be set after the development of the guidelines)	1. Report of the Medicine and Medical Device Department of MoH 2. Observation			
Project Purpose The established medical device management centers/units are functional.	1. Updated maintenance record, etc. (Indicators to measure the state of functioning of the units are to be determined after the development of the guidelines)	1. Project Report 2. Observation	・The budget to install the Medical Device Management Center/Unit in the country is secured.		
Outputs 1. Installation criteria and roles and responsibilities of the medical device management centers/units are developed.	The guidelines for installation criteria of the medical device management centers/units and for roles and responsibilitiesof the medical device centers/units are developed.	1. Report of the assessment study 2. The guideline for the installation criteria of the medical device management centers 3. The guideline for the roles and responsibilites of the medical device management centers	・Not many technicians who receive the training leave the post		
2. In the pilot site, the medical device management centers/units are established in accordance with the developed guidelines in Output1.	The medical device management centers/units with required number of Biomedical engineers/technicians are established in all 5 hospitals in the project site.	1. Project Report 2. Observation			

Annex 3

Activities	Inputs		Important Assumption
	The Japanese Side	**The Moldovan Side**	
1-1 Establish a technical committee for the development of the installation criteria of the medical device management centers/units 1-2 Conduct an assessment study on the situation of medical device management in Chisinau and one rural region 1-3 Develop the guideline for installation criteria of the medical device management centers/units 1-4 Develop the guideline for Roles and Responsibilities of the medical device management centers/units and clarify functions for the medical device management centers/units 2-1 Organize a workshop for managerial personnel of the pilot hospitals on introduction of the installation criteria of the medical device management centers/units 2-2 Develop a work plan to establish the medical device management centers/units 2-3 Procure the necessary equipment in the medical device management centers/units in accordance with the guideline 2-4 Provide trainings for the staffs of the medical device management centers/units and for other medical staffs such as doctors and nurses 2-5 Support and monitor the implementation of the role and responsibilities of the medical device management centers/units according to the guideline	1. Japanese Experts (Chief/Medical Device Management, Hospital management, Training/Coordinator) 2. Local cost for the activity of Japanese Experts 3. Training in Japan 4. Provision of the equipment(office equipment, etc)	1. Collaboration with Counterparts 2. Project office space in MoH 3. Employment of necessary staff for the medical device management unit 4. Cost for necessary tools in the medical device management unit 5. Space to install the Medical Device Management Center/Unit in the target hospitals	・MoH issues the decree for the installation of the medical device management centrs/units **Pre-Conditions** ・The national poicy on medical device management does not change ・Necessary technical staff for the medeical device management centers/units are employed **<Issues and countermesures>**

Annex 3

Project Monitoring Sheet I （Revision of Project Design Matrix）

Project Title: Project for Improving Medical Device Management Version 2

Implementing Agency: Ministry of Health Dated 30 September, 2016

Target Group: Medicine and Medical Device Department of MoH, Medicine and Medical Device Agency, All Medical Institutions and their Biomedical Engineers/Technicians

Period of Project: April 2015 ～April 2017 （2 years）

Project Site: Throughout the country

Pilot Site: Chisinau (5 hospitals; The Republican Clinical Hospital, The Mother and Child Institute, The Emergency Medicine Institute, The Oncologic Institute, Chisinau Municipal Clinical Hospital "Sfanta Treime")

Narrative Summary	Objectively Verifiable Indicators	Means of Verification	Important Assumption	Achievement	Remarks
Overall Goal The Departments / Sections of Biomedical Engineering are established throughout the country based on the developed guidelines.	Number of the Departments / Sections of Biomedical Engineering which implement the Standard Operating Forms of the guidelines is more than 20 throughout the country.	1. Report of the Medicine and Medical Device Department of MoH 2. Observation		Pilot activities at pilot facilities, which will serve as a base of the overall goal, are on going	
Project Purpose The established Departments / Sections of Biomedical Engineering are functional.	In the pilot hospitals, percentage of (1) number of attended cases of corrective maintenance against requests, (2) number of implemented procedures of technical planned preventive maintenance against planned number, (3) number of implemented training sessions for users against planned one, and (4) number of medical device inventoried in the database of SIMDM against total number of medical devices, are more than 90%.	1. Project Report 2. Observation	・The budget to establish the Departments / Sections of Biomedical Engineering in the country is secured.	Departments / Sections of Biomedical Engineering are established in all 5 pilot hospitals and operating. Average of the 5 pilot hospitals for the indicators are; (1) 98.18%, (2) 62.45%, (3) 48.44%, (4)* 86.92% *Since SIMDM is not yet available, this indicator represents the number of medical device inventoried in any form of database against total number of medical devices.	・MoH issues the decree for the establishment of the Departments / Sections of Biomedical Engineering throughout the country.
Outputs 1. Establishment criteria, roles and responsibilities of the Departments / Sections of Biomedical Engineering in the Public Healthcare Institutions are developed.	The guidelines on the establishment criteria, roles and responsibilities of the Departments / Sections of Biomedical Engineering in the Public Healthcare Institutions are developed.	1. Report of the assessment study 2. The guidelines on the establishment criteria, roles and responsibilities of the Departments / Sections of Biomedical Engineering in the Public Healthcare Institutions	・Not many technicians who receive the training leave the post	The guidelines on the establishment criteria, roles and responsibilities of the Departments / Sections of Biomedical Engineering in the Public Healthcare Institutions are developed and approved by MoH.	
2. In the pilot site, the Departments / Sections of Biomedical Engineering are established based on the developed guidelines in Output 1.	The Departments / Sections of Biomedical Engineering which implement the Standard Operating Forms of the guidelines are established in all 5 pilot hospitals.	1. Project Report 2. Observation		Departments / Sections of Biomedical Engineering are established in all 5 pilot hospitals and operating. Implementation status of the Standard Operating Forms is; 63.33%* * (Total number of forms in use in the 5 pilot hospitals)/(12 (total number of Standard Operating Forms) x 5)	

Annex 3

Activities	Inputs		Important Assumption
	The Japanese Side	**The Moldovan Side**	
1-1 Establish a technical committee for the development of the establishment criteria of the Departments / Sections of Biomedical Engineering 1-2 Conduct an assessment study on the situation of medical device management in Chisinau and one rural region 1-3 Develop the guideline on establishment criteria of the Departments / Sections of Biomedical Engineering 1-4 Develop the guideline on roles and responsibilities of the Departments /Sections of Biomedical Engineering and clarify their functions. 2-1 Organize a workshop for managerial personnel of the pilot hospitals on introduction of the establishment criteria of the Departments /Sections of Biomedical Engineering 2-2 Develop a work plan to establish the Departments / Sections of Biomedical Engineering 2-3 Procure the necessary equipment in the Departments / Sections of Biomedical Engineering in accordance with the guideline 2-4 Provide trainings for the staff of the Departments / Sections of Biomedical Engineering and for other medical staff such as doctors and nurses 2-5 Support and monitor the implementation of the roles and responsibilities of the Departments / Sections of Biomedical Engineering according to the guideline 2-6 MoH issues a decree for the establishment of the Departments / Sections of Biomedical Engineering for the pilot hospitals 2-7 Review of the Guidelines on the establishment criteria, roles and responsibilities of the Departments / Sections of Biomedical Engineering	1. Japanese Experts (Chief/Medical Device Management, Hospital management, Training/Coordinator) 2. Local cost for the activity of Japanese Experts 3. Training in Japan 4. Provision of the equipment(office equipment, etc)	1. Counterparts 2. Project office space in MoH 3. Employment of necessary staff for the Departments / Sections of Biomedical Engineering 4. Cost for necessary tools in the Departments / Sections of Biomedical Engineering 5. Space to establish the Departments / Sections of Biomedical Engineering in the target hospitals 6. Functional "Information System of Medical Device Management" (SIMDM)	**Pre-Conditions** ・The national policy on medical device management does not change ・Necessary technical staff for the Departments / Sections of Biomedical Engineering are employed **<Issues and countermesures>**

Annex 3