

APPLICATION FORM FOR JAPAN'S TECHNICAL COOPERATION

1. Date of Entry: Day 1 Month August Year 2018
2. Applicant: Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia
3. Technical Cooperation (T/C) Title: Capacity Development of Medical Equipment Maintenance
4. Type of the T/C※Select only one scheme.

- Technical Cooperation Project / Technical Cooperation for Development Planning
 Science and Technology Research Partnership for Sustainable Development (SATREPS)
 Individual Expert Individual Training

5. Contact Point (Implementing Agency): Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia

Address: 144 Ak.Tsereteliave., 0119, Tbilisi, Georgia;

Contact Person: Maia Lagvilava, Deputy Minister

Tel. No.: (+995 32) 251 00 26 Fax No. _____

E-Mail: info@moh.gov.ge

6. Background of the T/C

For more than a decade in Georgia there have been no mechanisms for the regulation of medical devices. The only existing requirement of the current legislation regarding medical devices (licensing requirements for medical practices and hospital permits) refers to the device release date: medical devices should not be issued before 1998. Placement on the market, registration, assessment of conformity and surveillance of the medical devices are currently out of state regulation and accordingly, there is no competent body/authority responsible for the regulation of medical devices. In order to meet the obligations under the Deep and Comprehensive Free Trade Area Agreement (DCFTA) between Georgia and the European Union, it is necessary to establish a market surveillance system, relevant to the EU best experience. However, with the establishment of a supervision system in the medical device market (2022), it is necessary to maintain the best practices of storage and services of medical devices in medical institutions.

Georgia's possibilities are quite limited in this direction, as there is a serious lack of qualified personnel with proper management and maintenance of medical equipments, which affects the quality of services provided by medical institutions. One of the most important challenges in the health care system of Georgia is to improve the quality of medical care, and thus increase the knowledge and skills of medical staff in the direction of proper maintenance / exploitation of medical devices.

Nowadays, when one of the priorities of the Georgian government is the improvement of the legislation in the field of medical equipment, creating relevant regulatory body and supporting medical institutions to make proper functioning of medical techniques and devices, it is extremely important to learn the best practices of states that have great experience in the modern medical technological achievements and development. Therefore, shearing the best practice from Japan to Georgia bears decisive role, due to its leadership in manufacturing of medical equipment and delivering quality medical service.

7. Outline of the T/C

(1) Overall Goal

Establishment of best medical practice of medical equipment maintenance service in Georgian medical facilities.

(2) T/C Purpose

For the April 1, 2020, there is enough human resources in Georgia to maintain medical / equipment maintenance /service for the best practices in the field of training.

(3) T/C Outputs

By May 1, 2019, the personnel who will pass the preparation, is selected;
By June 1, 2019, the training-program of Georgian personnel has been developed;
By November 1, 2019, the staff has undergone a training program;
By April 1, 2020, personnels are familiar with the best practices of the medical / equipment maintenance service in Japan, and the capacity of the staffs in medical equipment management and maintenance is enhanced

(4) T/C Site

(In case there is any particular candidate site, please give specifics such as the name of the target area for the T/C and attach a rough map to the documents submitted. The attached map should be at a scale that clearly shows the project site.)

Japan

National training centre of the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia

(5) T/C Activities

- Selection of Georgian specialists for the training;
- Elaborating training-program for Georgian personnels by Japanese side;
- Training for Georgian personnels by Japanese side through lecture, field practice, discussion with following aims;
 1. To understand the current situation and the challenges in the field of medical equipment management and maintenance in Georgia
 2. To recognize and compare the differences in the systems between Georgia and Japan
 3. To gain basic knowledge of selection , procurement and disposal of medical equipment
 4. To obtain basic skills and knowledge on the management and maintenance of medical equipment
 5. To formulate short to mid-term Action Plans
- Get acquainted with the best practices of Japan in the field of maintenance of medical devices through the site visit in Japan.

(6) Input from the Recipient Government

Project manager: Marina Darakhvelidze, Head of Health Care Department.

Support staff: Regulation Division of Health Care Department.

Office space: National Training Centre.

Activities:

- Selecting Georgian specialists for training
- Process coordination
- Implementing actions plans after the training and site visit

(7) Input from the Japanese Government

Activities:

- a) Preparation of training programs for the best practice of medical equipment maintenance services.
- b) The training program which will be conducted by the Japanese side in Japan.
- c) Study visit to Japan to get familiar with the best practices system for medicalequipment maintenanceservice.

8. Implementation Schedule

Month - May Year -2019; Month- March Year 2020.

9. Description of an Implementing Agency

Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia – number of staff – 281

There is no special unit in the Ministry responsible of medical equipment maintenance.

(1) Prospects of further plans and actions/ Expected funding resources for the Project:

The Ministry intends to provide resource prepared within the project to maintain medical equipment storage / service in Georgian medical institutions for organizing trainings to establish best practices. Since most medical institutions in Georgia are private, the training costs are covered by these institutions.

(2) Activities in the same sector of other donor agencies, the recipient government and NGOs and others:

(Please pay particular attention to the following items:

- Whether you have requested the same project to other donors or not.*
- Whether any other donor has already started a similar project in the target area or not.*
- Presence/absence of cooperation results or plans by third-countries or international agencies for similar projects.*
- In the case that a project was conducted in the same field in the past, describe the grounds for requesting this project/study, the present status of the previous project, and the situation regarding the technology transfer.*
- Whether there are existing projects/studies regarding this requested project/ study or not. (Enter the time/period, content and concerned agencies of the existing studies.)*

We have no application for other donor project in this direction.

11. Global Issues (Gender, Poverty, Climate change, etc.)

Harmonization of Medical Devices National Regulations with the EU Legislation under the Association Agreement between the European Union and Georgia.

12. Environmental and Social Considerations

(In case of Technical Cooperation Project (including SATREPS) / Technical Cooperation for Development Planning, please fill in the attached screening format.)

(Note) If JICA considers that the environmental and social considerations are required to the T/C, the applicants agree on JICA's information disclosure of the T/C for public hearing in accordance with JICA guidelines for environmental and social considerations as stated in Question 11 of the attached Screening Format.

13. Others

Signed: Maia Lagvilava

Title: Deputy Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia

On behalf of the Government of Georgia

Date: 20.08.2018

Screening Format (Environmental and Social Considerations)

Please write "to be advised (TBA)" when the details of a project are yet to be determined.

Question 1: Address of project site:

144 Ak.Tsereteliave., 0119, Tbilisi, Georgia.

Question 2: Scale and contents of the project (approximate area, facilities area, production, electricity generated, etc.)

2-1. Project profile (scale and contents): **Increase the knowledge and skills of medical staff in the direction of proper storage / exploitation of medical device.**

2-2. How was the necessity of the project confirmed?

Is the project consistent with the higher program/policy?

YES: Please describe the higher program/policy.

(Harmonization of Medical Devices National Regulations with the EU Legislation under the Association Agreement between the European Union and Georgia)

NO

2-3. Did the proponent consider alternatives before this request?

YES: Please describe outline of the alternatives

()

NO

2-4. Did the proponent implement meetings with the related stakeholders before this request?

Implemented Not implemented

If implemented, please mark the following stakeholders.

Administrative body

Local residents

NGO

Others ()

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Question 3:

Is the project a new one or an ongoing one? In the case of an ongoing project, have you received strong complaints or other comments from local residents?

New Ongoing(with complaints) Ongoing (without complaints)

Other

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Question 4:

Is an Environmental Impact Assessment (EIA), including an Initial Environmental Examination (IEE) Is, required for the project according to a law or guidelines of a host country? If yes, is EIA implemented or planned? If necessary, please fill in the reason why EIA is required.

Necessity (Implemented Ongoing/planning)

(Reason why EIA is required:)

X Not necessary

Other (please explain)

Question 5:

In the case that steps were taken for an EIA, was the EIA approved by the relevant laws of the host country? If yes, please note the date of approval and the competent authority.

<input type="checkbox"/> Approved without a supplementary condition	<input type="checkbox"/> Approved with a supplementary condition	<input type="checkbox"/> Under appraisal
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(Date of approval: Competent authority:)

Under implementation

Appraisal process not yet started

Other()

Question 6:

If the project requires a certificate regarding the environment and society other than an EIA, please indicate the title of said certificate. Was it approved?

Already certified

Title of the certificate: ()

Requires a certificate but not yet approved

Not required

Other

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Question 7:

Are any of the following areas present either inside or surrounding the project site?

Yes X No

If yes, please mark the corresponding items.

- National parks, protection areas designated by the government (coastline, wetlands, reserved area for ethnic or indigenous people, cultural heritage)
- Primeval forests, tropical natural forests
- Ecologically important habitats (coral reefs, mangrove wetlands, tidal flats, etc.)
- Habitats of endangered species for which protection is required under local laws and/or international treaties
- Areas that run the risk of a large scale increase in soil salinity or soil erosion
- Remarkable desertification areas
- Areas with special values from an archaeological, historical, and/or cultural points of view
- Habitats of minorities, indigenous people, or nomadic people with a traditional lifestyle, or areas with special social value

Question 8:

Does the project include any of the following items?

Yes No

If yes, please mark the appropriate items.

- | | | | |
|-----------------------------------------------------------------------------------|---------|-----------------------|----------|
| <input type="checkbox"/> Involuntary resettlement | (scale: | households | persons) |
| <input type="checkbox"/> Groundwater pumping | (scale: | m ³ /year) | |
| <input type="checkbox"/> Land reclamation, land development, and/or land-clearing | (scale: | hectars) | |
| <input type="checkbox"/> Logging | (scale: | hectars) | |

Question 9:

Please mark related environmental and social impacts, and describe their outlines.

- | | |
|------------------------------------------------|-----------------------------------------|
| <input type="checkbox"/> Air pollution | <input type="checkbox"/> Accidents |
| <input type="checkbox"/> Water pollution | <input type="checkbox"/> Global warming |
| <input type="checkbox"/> Soil pollution | |
| <input type="checkbox"/> Waste | |
| <input type="checkbox"/> Noise and vibrations | |
| <input type="checkbox"/> Ground subsidence | |
| <input type="checkbox"/> Offensive odors | |
| <input type="checkbox"/> Geographical features | |
| <input type="checkbox"/> Bottom sediment | |
| <input type="checkbox"/> Biota and ecosystems | |
| <input type="checkbox"/> Water usage | |

- Involuntary resettlement
- Local economies, such as employment, livelihood, etc.
- Land use and utilization of local resources
- Social institutions such as social infrastructure and local decision-making institutions
- Existing social infrastructures and services
- Poor, indigenous, or ethnic people
- Misdistribution of benefits and damages
- Local conflicts of interest
- Gender
- Children's rights
- Cultural heritage
- Infectious diseases such as HIV/AIDS
- Other ()

Outline of related impact:



Question 10:

In the case of a loan project such as a two-step loan or a sector loan, can sub-projects be specified at the present time?

Yes No

Question 11:

Regarding information disclosure and meetings with stakeholders, if JICA's environmental and social considerations are required, does the proponent agree to information disclosure and meetings with stakeholders through these guidelines?

Yes No